No. 20-

In the Supreme Court of the United States

AMERICAN MEDICAL ASSOCIATION, *et al.*, *Petitioners*,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Respondents.*

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, *et al.*, *Petitioners*,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Respondents.*

ESSENTIAL ACCESS HEALTH, INC., *et al.*, *Petitioners*,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In 2019, the Department of Health and Human Services (HHS) issued a Rule imposing major changes on the Title X family planning program. *See* 84 Fed. Reg. 7,714 (Mar. 4, 2019). The Rule both prohibits and compels certain pregnancy-related speech between a Title X provider and her patient, proscribing abortion-related information but requiring information about non-abortion options—regardless of what the patient wants. The Rule also imposes burdensome physical-separation requirements on any Title X provider engaging in abortion-related activities outside the Title X program. All of the nation's major medical organizations opposed the Rule, explaining that it would violate fundamental medical ethics, force numerous providers out of the program, and leave patients with deficient health care. The en banc Ninth Circuit upheld the Rule against arbitrary-and-capricious and contrary-to-law challenges. The en banc Fourth Circuit invalidated the Rule on those same grounds.

The questions presented are:

1. Whether the Rule is arbitrary and capricious.

2. Whether the Rule violates the Title X appropriations act, which requires that "all pregnancy counseling" under Title X "shall be nondirective."

3. Whether the Rule violates Section 1554 of the Affordable Care Act, 42 U.S.C. § 18114, which requires that HHS "shall not promulgate any regulation" that harms patient care in any one of six ways, including by "interfer[ing] with communications" between a patient and her provider.

PARTIES TO THE PROCEEDING

Petitioners are:

- American Medical Association; Oregon Medical Association; Planned Parenthood Federation of America, Inc.; Planned Parenthood of Southwestern Oregon; Planned Parenthood Columbia Willamette; and Thomas N. Ewing, M.D.—all of which were plaintiffs in the proceeding below in the District of Oregon and appellees in the court of appeals;
- National Family Planning & Reproductive Health Association; Feminist Women's Health Center; and Deborah Oyer, M.D.—all of which were plaintiffs in the proceeding below in the Eastern District of Washington and appellees in the court of appeals;
- Essential Access Health, Inc. and Melissa Marshall, M.D.—both of which were plaintiffs in the proceeding below in the Northern District of California and appellees in the court of appeals.[*]

Respondents are:

- Alex M. Azar II, in his official capacity as the Secretary of Health and Human Services; U.S. Department of Health & Human Services; Diane Foley, M.D., in her official capacity as the Deputy Assistant Secretary, Office of Population Affairs; and the Office of Population Affairs—all

[*] Michele P. Megregian, C.N.M., a plaintiff in the District of Oregon proceeding, and Teresa Gall, a plaintiff in the Eastern District of Washington proceeding, have recently left their respective positions and are not petitioners here.

which were defendants in the proceedings below and appellants in the court of appeals.

The States of Oregon, New York, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Rhode Island, Vermont, and Wisconsin, the Commonwealths of Massachusetts, Pennsylvania, and Virginia, and the District of Columbia were also plaintiffs in the proceeding below in the District of Oregon and appellees in the court of appeals. They are separately represented and are not petitioners here.

The State of Washington was a plaintiff in the proceeding below in the Eastern District of Washington and an appellee in the court of appeals. It is separately represented and is not a petitioner here.

The State of California was a plaintiff in the proceeding below in the Northern District of California and an appellee in the court of appeals. It is separately represented and is not a petitioner here.

CORPORATE DISCLOSURE STATEMENT

The corporate petitioners—American Medical Association; Oregon Medical Association; Planned Parenthood Federation of America, Inc.; Planned Parenthood of Southwestern Oregon; Planned Parenthood Columbia Willamette; National Family Planning & Reproductive Health Association; Feminist Women's Health Center; and Essential Access Health, Inc.—all disclose that they have no parent corporation, nor is there any publicly held corporation that owns 10% or more of their stock.

DIRECTLY RELATED PROCEEDINGS

There are three directly related proceedings within the meaning of this Court's Rule 14.1(b)(iii):

1. *Oregon* v. *Azar*: D. Or. Nos. 19-317, 19-318; 9th Cir. No. 19-35386. The district court entered a preliminary injunction on April 29, 2019, which was vacated by the en banc Ninth Circuit decision challenged in this petition.

2. *Washington* v. *Azar*: E.D. Wash. Nos. 19-3040, 19-3045; 9th Cir. No. 19-35394. The district court entered a preliminary injunction on April 25, 2019, which was vacated by the en banc Ninth Circuit decision challenged in this petition.

3. *California* v. *Azar*: N.D. Cal. Nos. 19-1184, 19-1195; 9th Cir. Nos. 19-15974, 19-15979. The district court entered a preliminary injunction on April 26, 2019, which was vacated by the en banc Ninth Circuit decision challenged in this petition.

The Rule at issue was also challenged in two other district courts:

1. *Mayor & City Council of Baltimore* v. *Azar*: D. Md. No. 19-1103; 4th Cir. Nos. 19-1614, 20-1215. The district court issued a preliminary injunction on May 30, 2019, and a permanent injunction on February 14, 2020. The permanent injunction was affirmed by the en banc Fourth Circuit on September 3, 2020.

2. *Family Planning Ass'n of Maine* v. *Azar*: D. Me. No. 19-100; 1st Cir. No. 20-1781. The district court denied the plaintiffs' motion for a preliminary injunction on July 3, 2019, and then denied the plaintiffs' motion for summary judgment and dismissed the complaint on June 9, 2020. The plaintiffs filed a notice of

appeal to the First Circuit on August 7, 2020; briefing is set to begin on November 12, 2020, and argument is not yet scheduled.

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PETITION FOR A WRIT OF CERTIORARI

INTRODUCTION

This case concerns challenges to an HHS Rule that warps and decimates the Title X family planning program—a vital public health program that has provided critical care to millions of people each year. Two en banc circuits are split over the Rule's validity. The

Ninth Circuit upheld it against petitioners' arbitrary-and-capricious and contrary-to-law challenges. The Fourth Circuit found that decision flawed and reached opposite conclusions, holding the Rule both arbitrary and capricious and contrary to law. *See Mayor & City Council of Baltimore* v. *Azar*, __ F.3d __, 2020 WL 5240442, at *1 (4th Cir. 2020) (en banc). This Court's review is warranted to resolve that circuit conflict on important questions of federal law, and to correct the Ninth Circuit's erroneous decision.

For five decades, the Title X program has been an extraordinary success, serving to ensure that all individuals have access to family planning care—regardless of where they live or their economic means. The program provides vital health care services, like contraception, testing and treatment for sexually transmitted infections, breast and cervical cancer screening, and pregnancy testing and counseling. And, in accordance with the program's mission, these services must be provided free of charge to patients with incomes below the federal poverty level.

Since the program's inception, Section 1008 of Title X has provided that no program funds "shall be used in programs where abortion is a method of family planning." Title X projects have therefore never provided abortions, and this case is not about providing abortions. Rather, this case is about regulations that impose sweeping and harmful restrictions on a broad array of Title X services, including pregnancy counseling—none of which involves the provision of abortion.

Before the Rule, HHS had long recognized the importance of full, open communication to the patient-provider relationship and to medical ethics. Thus, for decades, HHS had consistently interpreted Section

1008 and administered the Title X program to require that providers offer pregnant patients the opportunity to receive nondirective counseling on all their medical options, including abortion. That position respects the integrity of the patient-provider relationship and is consistent with both medical ethics and HHS's own standards of care for all family planning professionals.

Moreover, through two other federal laws, Congress has constrained HHS's authority to issue regulations intruding on the patient-provider relationship. Beginning in 1996, Congress has repeatedly mandated in Title X appropriations acts that "all pregnancy counseling" under Title X "shall be nondirective" (the "Nondirective Mandate"). And in Section 1554 of the Affordable Care Act, Congress prohibited "any [HHS] regulation" that harms patient care in any one of six ways, including by interfering with patient-provider communications or violating the ethical standards of health care professionals.

In 2019, HHS issued a Rule imposing drastic changes on the Title X program. *See* 84 Fed. Reg. 7,714 (Mar. 4, 2019). The Rule requires that Title X providers *withhold* certain information about abortion from pregnant patients, contrary to a patient's stated request. And it requires providers to *force on* patients information about non-abortion options even if a patient does not want or need it. It also imposes cost-prohibitive physical-separation provisions requiring providers to establish separate facilities and to employ duplicative personnel and medical records if they engage in virtually any abortion-related activity *outside* the Title X program.

Every leading medical organization in the United States opposed the Rule. All were unequivocal that it

would violate fundamental principles of medical ethics. At the forefront was the American Medical Association, the author of the most comprehensive and authoritative medical ethical code in the country. The AMA emphasized in its comments that the patient-physician relationship is founded on candor—a point this Court itself recently underscored. *See National Inst. of Family & Life Advocates* v. *Becerra*, 138 S. Ct. 2361, 2374 (2018) ("'Doctors help patients make deeply personal decisions, and their candor is crucial.'"). The AMA thus warned that the Rule's restrictions would "dangerously interfere with the patient-physician relationship and conflict with physicians' ethical obligations." Moreover, long-serving Title X providers made clear they would be forced out of the program—resulting in a mass exodus of providers to the detriment of patients and public health. In its rulemaking, HHS said virtually nothing in response.

A divided Ninth Circuit upheld the Rule. That decision was incorrect, as the Fourth Circuit concluded. The Rule is arbitrary and capricious for several reasons, including that it "failed to recognize and address the ethical concerns of literally every major medical organization in the country." *Baltimore*, 2020 WL 5240442, at *1. The Rule is also contrary to law. It requires Title X projects to steer patients away from abortion and toward carrying a pregnancy to term, which presents a straightforward violation of the Nondirective Mandate. *Id.* at *16-20. The Rule further violates Section 1554 of the ACA, including because it "'interferes with communications' about medical options between a patient and her provider." *Id.* at *20. Finally, this Court's decision in *Rust* v. *Sullivan*, 500 U.S. 173 (1991), does not save the Rule. *Rust* held a similar 1988 rule permissible in light of *that* rulemaking's ad-

ministrative record and under federal law *as it stood at the time*. Things are different now. This Rule arises out of a different administrative record, created 30 years later, which does not support it. And this Rule is governed by two different federal laws, enacted after *Rust*, requiring that counseling be nondirective and that no HHS regulation interfere with patient-provider communications. The Rule violates both.

OPINIONS BELOW

The en banc court of appeals' opinion (App. 1a-94a) is reported at 950 F.3d 1067. A prior panel order on respondents' motion for stay pending appeal (App. 271a-289a) is reported at 927 F.3d 1068. The opinions of the district courts (App. 95a-134a, 135a-157a, 159a-269a) are reported at 389 F. Supp. 3d 898, 376 F. Supp. 3d 1119, 385 F. Supp. 3d 960.

JURISDICTION

The court of appeals entered judgment on February 24, 2020. A timely petition for rehearing was denied on May 8, 2020. App. 291a-293a. By order dated March 19, 2020, this Court extended the deadline to file any petition for a writ of certiorari to 150 days from, as relevant here, an order denying a timely petition for rehearing. This Court's jurisdiction rests on 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

The statutes and regulations involved are 5 U.S.C. § 706, 42 U.S.C. § 300a-6, 42 U.S.C. § 18114, Pub. L. No. 116-94, tit. II, 133 Stat. 2534, 2558, and 42 C.F.R. §§ 59.1-59.19. They are reproduced in the appendix to this brief. App. 295a-327a.

STATEMENT

A. Title X

The Title X program's central purpose is "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services." Pub. L. No. 91-572, § 2(1), 84 Stat. 1504, 1504 (1970). Congress created the program because modern family planning services were not then available throughout the country and often left out patients most in need. *See*, *e.g.*, S. Rep. No. 91-1004, at 9-12 (1970).

The Title X program has provided state-of-the-art, evidence-based family planning care to millions of people who could not otherwise afford it. Title X providers (funded through grants from HHS) have kept pace with advances in contraceptive care, and offer a broad range of essential services, including testing and counseling. As a result, the program has helped reduce rates of unintended pregnancy and abortion to historic lows.

Petitioners are leading national and state health care organizations with a deep dedication to the Title X program—including the American Medical Association, the National Family Planning & Reproductive Health Association (NFPRHA), Planned Parenthood, and Essential Access Health (Essential Access)—and individual health care professionals. The AMA is the largest professional association of physicians, residents, and medical students in the United States. It "literally wrote the book on medical ethics" (App. 124a)—the *Code of Medical Ethics*, which was the first national medical ethics code in the world and is widely recognized as the most comprehensive and authoritative ethical code for physicians.

NFPRHA, formed just after Title X was enacted, has represented the majority of the public entities and non-profit organizations in the Title X network through its history, supporting them in providing the highest levels of care on tight budgets. Essential Access has been a Title X grantee since the program's inception and for decades has administered the largest Title X provider network in the country, serving low-income patients throughout California. Before the Rule, California's Title X system served approximately one million patients annually; after just a few months under the Rule in 2019, the program's reach was reduced by more than 300,000 patients. *See* Office of Population Affairs, *Title X Family Planning Annual Report, 2019 National Summary*, at B-2 (Sept. 2020). As for Planned Parenthood, its affiliates collectively provided Title X services to an estimated 1.5 million individuals each year—approximately 40% of all patients who received care in the Title X program—until the Rule forced them out.

B. Statutory And Regulatory Background

Section 1008 of Title X provides that no program funds "shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. HHS's regulations have long prohibited Title X projects from providing abortions, and have required Title X grantees that provide abortions outside the Title X project to keep such activities "separate and distinct from Title X project activities." 65 Fed. Reg. 41,281, 41,282 (July 3, 2000). Since the program's inception, Title X care has been delivered by some providers who—*outside* the Title X program, with *non*-Title X funds—have also provided abortion services. And providers have long been authorized to share facilities, staff, and health records

systems with activities outside their Title X projects, including any "[n]on-Title X abortion activities." *Id.*

Moreover, for virtually the entire history of the program, HHS has made clear that Section 1008 does not prevent Title X providers from communicating with their patients about abortion in a nondirective way. *See* 65 Fed. Reg. 41,270, 41,271-41,272 (July 3, 2000). Thus, Title X regulations have long required that providers offer pregnant women the opportunity to receive nondirective counseling on all their medical options, including abortion. *See, e.g.*, *id.* at 41,270.

There was one brief exception. In 1988, HHS issued a rule that broadly prohibited Title X providers from discussing abortion with their pregnant patients. *See* 53 Fed. Reg. 2,922, 2,945 (Feb. 2, 1988). HHS also required Title X providers to "physically" separate their Title X services from abortion-related services. *Id.* at 2,940, 2,945.

Title X providers brought certain statutory and constitutional challenges to these changes, and this Court upheld the 1988 rule in *Rust* v. *Sullivan*, 500 U.S. 173 (1991). But HHS reversed itself just six months later. "[R]esponding to widespread concerns that [the 1988 rule] would interfere with the doctor-patient relationship," President George H.W. Bush issued a directive to HHS "cutting back significantly on [the rule's] scope and proscriptions." *National Family Planning & Reprod. Health Ass'n* v. *Sullivan*, 979 F.2d 227, 230, 235 (D.C. Cir. 1992). As President Bush declared: "'[P]atients and doctors can talk about absolutely anything they want, and they should be able to do that.'" *Id.* at 230. The 1988 rule was never fully implemented. When President Clinton took office, he di-

rected HHS to suspend the 1988 rule and promulgate new regulations. 58 Fed. Reg. 7,462 (Feb. 5, 1993).

Meanwhile, Congress acted to ensure that patients would have the right to receive vital medical information. In 1996, and every year since then, Congress has mandated in appropriations acts that "all pregnancy counseling" under Title X "shall be nondirective." *E.g.*, Pub. L. No. 116-94, tit. II, 133 Stat. 2534, 2558 (2019). As HHS acknowledged in the Rule here, the Nondirective Mandate requires the "meaningful presentation of options" without "'suggesting or advising one option over another.'" 84 Fed. Reg. at 7,716. That includes "present[ing] the options in a factual, objective, and unbiased manner" and ensuring that patients "take an active role in processing their experiences and identifying the direction of the interaction." *Id.* at 7,716, 7,747.

In 2000, consistent with the Nondirective Mandate, HHS issued a new rule formally repudiating the previously suspended 1988 rule. The 2000 rule required that patients be offered, and receive as requested, "nondirective counseling" on all pregnancy options, including abortion. 65 Fed. Reg. at 41,270. As HHS explained then, "[t]he policies reflected in, and interpretations reinstituted in conjunction with, the [2000 rule] … have been used by the program for virtually its entire history." *Id.* at 41,271.

HHS further recognized that the 2000 rule's requirements accord with "medical ethics and good medical care," and also implement Congress's "repeated[]" mandate "that pregnancy counseling in the Title X program be 'nondirective.'" 65 Fed. Reg. at 41,273. It found that the 1988 rule had "endanger[ed] women's lives and health by preventing them from receiving

complete and accurate medical information and interfere[d] with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients." *Id.* at 41,270.

In the 2000 rule, HHS also repudiated the 1988 rule's physical-separation requirement. Instead, the 2000 rule required Title X grantees to ensure that Title X funds were not used for any "[n]on-Title X abortion activities" and to keep such activities "separate and distinct from Title X project activities." 65 Fed. Reg. at 41,282. The 2000 rule expressly authorized "shared facilities," "common staff," and "single file system[s]." *Id.* As HHS explained, the physical separation contemplated by the 1988 rule was inconsistent "with the efficient and cost-effective delivery of family planning services." *Id.* at 41,276.

Ten years later, as part of the Affordable Care Act, Congress again acted to protect the integrity of the patient-provider relationship. Enacting a statutory prohibition on "any [HHS] regulation" that harms patient care in any one of six enumerated ways, Congress declared:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human services shall not promulgate any regulation that—
>
> > (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the pro-

> vider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

Pub. L. No. 111-148, § 1554, 124 Stat. 119, 259 (2010) (codified at 42 U.S.C. § 18114).

C. The Rule

Despite the success of Title X under a regulatory framework largely unchanged for decades, HHS proposed major changes in June 2018. As detailed below, the proposed rulemaking was opposed by every leading health care organization in the United States, which warned of its grave consequences. Yet HHS adopted the Rule without material changes. It consists of two primary, integrated provisions.

1. The Rule's first primary provision restricts information Title X providers may give their pregnant patients and forces other information on pregnant patients—regardless of their patients' requests.

The Rule *bans* providers from referring their pregnant patients to abortion providers—even when that is the patient's expressed wish; but it *mandates* referrals for prenatal care—even when the patient has no such interest. 42 C.F.R. §§ 59.5(a)(5), 59.14(a), 59.14(b)(1). Thus, Title X providers are prohibited from telling a pregnant patient how and where she can ob-

tain an abortion, but must provide that information for prenatal care.

Title X projects may furnish patients who want an abortion a "list" of certain health care providers. 42 C.F.R. § 59.14(b)(1)(ii). But the list is distorted by design—it must be skewed to ensure that the patient *not* learn which providers offer abortions. The list may include only "comprehensive primary health care providers (including providers of prenatal care)," *id.* § 59.14(b)-(c))—not reproductive health care specialists. And although some, but not the majority, of those providers may also provide abortion as part of their comprehensive health care services, "[n]either the list nor project staff may identify which providers on the list perform abortion." *Id.* § 59.14(c)(2). Thus, the list must conceal from the patient which providers, if any, would be willing to provide abortion services.

Moreover, even when a patient specifically requests information about abortion *only*, practitioners must disregard the patient's decision. If a practitioner provides any information about abortion, then the patient must *also* be counseled about other options she does not want and must be told about the "risks and side effects to … [the] unborn child." 84 Fed. Reg. at 7,747. But a practitioner need not even respond to the patient's request for information *at all*. Practitioners are authorized to counsel on only some, non-abortion options; they may rebuff questions about abortion and provide no information in response to patient queries. *Id.* at 7,789. In other words, "a patient may come in seeking an abortion, but the only counseling done is on prenatal care." *Baltimore*, 2020 WL 5240442, at *18.

The Rule's second primary provision imposes onerous physical-separation requirements on any Title X

grantee that engages in "prohibited activities," 84 Fed. Reg. at 7,789—virtually anything concerning abortion. The "prohibited activities" are defined by cross-reference to other sections of the Rule, including the speech-based restrictions. *Id.* Thus, Title X projects must not only use separate facilities, systems, and personnel from those involved in providing abortion care outside Title X, but also from any activities HHS might deem to "encourage, promote, or advocate" abortion. *Id.* at 7,788, 7,789.

The physical-separation requirements go substantially further than the 1988 rule and require a more extreme degree of physical distance and duplication: separate office entrances and exits, workstations, phone numbers, email addresses, and health records, for example. Notably, similar factors had been proposed in the 1988 rule, but were then removed when it was promulgated. *Compare* 52 Fed. Reg. 33,210, 33,214 (Sept. 1, 1987), *with* 53 Fed. Reg. at 2,945.

2. The comments in opposition to HHS's proposed rulemaking were extensive and unequivocal about its many flaws. Commenters explained that the proposed rule was contrary to medical ethics, would result in a mass exodus of providers from the Title X program, would leave many patients across the country without access to the program, and would result in deficient patient care and serious adverse health outcomes.

Concerning medical ethics, "'literally all of the nation's major medical organizations'" expressed "'grave … concerns.'" *Baltimore,* 2020 WL 5240442, at *10. At the forefront was the AMA. It warned in its comments that the proposal would "dangerously interfere with the patient-physician relationship and conflict with physicians' ethical obligations" to offer patients open

and frank information about their medical options—the lynchpin of proper medical care. *See* CA4 SJA187-189.[*] The American College of Obstetricians and Gynecologists, American Academy of Family Physicians, American Academy of Nursing, American Academy of Pediatrics, and American College of Physicians all raised similar concerns. *See, e.g.*, *Baltimore*, 2020 WL 5240442, at *10. HHS has since conceded that "no 'professional organization of any kind'" has taken the position that its rulemaking is in line with medical ethics. *Id.*

Long-serving Title X providers and grantees, some of which had participated in the program since its inception, further warned that the Rule would result in a mass exodus of providers from the Title X program and harm patient care. Planned Parenthood providers and four States "notified HHS that they would have to exit the Title X program because the restrictions are 'fundamentally at odds with the professional and ethical obligations of health care professionals.'" *Baltimore*, 2020 WL 5240442, at *10. Title X providers also documented the enormous costs of compliance with the Rule—in particular, the hundreds of thousands of dollars necessary to comply with the physical-separation requirements—which would "'lead to the shuttering of a number of invaluable clinics across the nation.'" *Id.* at *14.

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[*] This petition cites the Ninth Circuit and Fourth Circuit records on appeal. The excerpts of record appended to the Brief for Appellants (respondents here) before the Ninth Circuit (No. 19-35386, Dkt. No. 28-1) are cited as "CA9 ER." As for the Fourth Circuit, the supplemental joint appendix is cited as "CA4 SJA" (No. 19-1614, Dkt. 109).

Thus, as the comments made clear, the Rule imposed a destructive Hobson's choice on Title X providers, forcing them to "choose" between two bad options. They would have to exit Title X, lose federal funding, close clinics, reduce services, and lay off staff—disrupting and delaying care for patients, and especially those with low incomes, who would no longer be ensured free care. *See, e.g.*, CA4 SJA371-373. Or, if providers sought to hang on and continue providing at least some, diminished Title X care for their needy patients, they would have to offer care that no longer met the family planning standards HHS itself had established and conform to a Rule that undermined the functioning of this public health program in myriad ways. *See, e.g.*, CA4 SJA273-310.

HHS adopted the proposed rule in materially identical form, largely disregarding the comments described above. Thus, for example, HHS "merely stated—with no support—that it 'disagree[d]'" with the unanimous conclusion of medical authorities that the Rule violates medical ethics. *Baltimore*, 2020 WL 5240442, at *10. HHS also estimated that a Title X provider would face a cost of $30,000 to comply with the physical-separation requirements—less than 5% of the cost reflected in the administrative record—and provided "no justification … for [that] amount." *Id.* at *14-15. And again with no support, HHS stated that it believed the Rule would "contribute to more clients being served, gaps in service being closed, and improved client care." 84 Fed. Reg. at 7,723.

D. Procedural Background

1. Immediately after HHS issued the Rule, petitioners filed lawsuits in Oregon, Washington, and California, and then moved for preliminary injunctions. Pe-

titioners argued that the Rule was arbitrary and capricious and contrary to law—specifically, the Nondirective Mandate and Section 1554 of the ACA—and that the harms and equities favored an injunction. The basis for federal jurisdiction was 28 U.S.C. § 1331.

All three district courts agreed, preliminarily enjoining the Rule. App. 98a, 156a, 269a. Those courts all found every preliminary-injunction factor in petitioners' favor. Moreover, they rejected HHS's principal argument that the Rule should be upheld under this Court's decision in *Rust*. *See, e.g.*, App. 110a-112a. As the decisions made clear, this case concerns a different administrative record and different governing law, enacted after *Rust*—the Nondirective Mandate and Section 1554 of the ACA. *See, e.g.*, *id.* Finally, each court underscored the harms that would result from the Rule—most important, to patients and public health. As one court found, the Rule "will result in less contraceptive services, … less early breast cancer detection, less screening for cervical cancer, less HIV screening, … less testing for sexually transmitted disease," "more unintended pregnancies," and "more women suffering adverse reproductive health symptoms." App. 97a, 129a-130a.

2. HHS appealed and moved for a stay of all three injunctions pending appeal. A motions panel of the Ninth Circuit granted the stay. App. 289a.

Petitioners sought en banc reconsideration of the stay decision, which the court granted. CA9 Dkt. 85. HHS acknowledged that, because the motions panel's stay order had been "vacated," the preliminary injunctions remained in effect. *See* CA9 Dkt. 115 at 2; *see also* CA9 Dkt. 125 at 10, 14-16. But the en banc court then issued a divided order stating that the motions panel's

stay order "remain[ed] in effect," which allowed HHS to enforce the Rule. CA9 Dkt. 118 at 3.

As a result, while the appeal proceeded, "roughly one in every four Title X service sites … withdr[ew] from the Title X program … , which slashed the national patient capacity in half." *Baltimore*, 2020 WL 5240442, at *11 n.9. Those resulting withdrawals included Planned Parenthood providers, "which alone served roughly 40 percent of Title X patients." *Id.* Moreover, HHS recently reported that "[a]s a result of the … Rule, … the number of Title X service sites was reduced by 945 sites," and the "number of family planning users served in 2019 … was 21% lower than in 2018"—despite the Rule being in effect for only a few months. *See* Office of Population Affairs, *Title X Family Planning Annual Report, 2019 National Summary*, at ES-2 (Sept. 2020); *see also supra* p.7 (describing harm to the Essential Access Title X network in California). Six States now lack any Title X provider. *See* Office of Population Affairs, *Title X Family Planning Directory* (Aug. 2020).

3.a. The en banc Ninth Circuit, in a 7-4 decision, vacated the preliminary injunctions and, going further, upheld the Rule on the merits. App. 5a. The court did not have before it the full administrative record, as the majority acknowledged. App. 25a-27a & n.11. Nonetheless, the majority concluded that "[t]he record before [it] is sufficient to resolve plaintiffs' challenges" (App. 25a), and held that the Rule was valid.

In rejecting petitioners' contrary-to-law claims, the majority invoked this Court's decision in *Rust*, which upheld the 1988 rule under the law at that time, and explained that it would view those claims through an implied-repeal framework. Thus, the majority conclud-

ed, petitioners "must provide evidence" that Congress intended to overrule *Rust* in enacting the Nondirective Mandate or Section 1554. App. 27a-28a. According to the majority, petitioners failed to satisfy that standard. *Id.*

The majority acknowledged that the Nondirective Mandate "amended Title X by expressly requiring all pregnancy counseling to be nondirective." App. 29a n.13. The majority also acknowledged that the Rule prohibits abortion referrals but compels prenatal care referrals—regardless of what a patient requests. App. 29a, 36a. But the majority concluded that the term "counseling" does not include referrals, and, even if it did, nothing in the Nondirective Mandate "requires the provision of referrals for abortion on the same basis as referrals for prenatal care and adoption." App. 40a.

Turning to Section 1554, the majority again invoked *Rust*, relying heavily on the constitutional analysis in that decision. In *Rust*, this Court held that the 1988 rule did not unconstitutionally burden a woman's right to abortion because it concerned only a funding restriction, which, for constitutional purposes, "'places no governmental obstacle in the path of a woman who chooses to terminate her pregnancy.'" 500 U.S. at 201. According to the majority, the same reasoning should apply under Section 1554; thus, the majority saw a distinction between what it described as "§ 1554's prohibition on direct interference with certain health care activities and the … Rule's directives that ensure government funds are not spent for an unauthorized purpose." App. 46a. As a result, the majority concluded, the Rule "does not implicate" Section 1554. App. 48a.

Finally, the majority held that the Rule is not arbitrary and capricious, even though the administrative

record was not before the court. It broadly deferred to HHS's purported "'predictive judgments'" and "'expertise'" and concluded that HHS "properly examined the relevant considerations and gave reasonable explanations." App. 50a-51a, 68a.

b. Four judges dissented. App. 69a.

The dissent explained that the majority's reliance on *Rust* was misplaced because "Congress has … chosen to disburse public funds differently since the days of *Rust*" through the Nondirective Mandate and has also enacted Section 1554. App. 71a. And the Rule violates the Nondirective Mandate, the dissent concluded, because the Rule is "nothing but directive"; "patients are steered toward childbirth at every turn." App. 73a. The Rule also violates the plain terms of Section 1554 of the ACA by, among other things, interfering with communications between a patient and her provider, 42 U.S.C. § 18114(3), and violating the ethical standards of health professionals, *id.* § 18114(5). App. 79a-82a. *Rust*'s constitutional holding, the dissent reasoned, did not change that conclusion. "That a congressional decision not to subsidize abortion does not burden the abortion right in the *constitutional* sense … has no bearing whatsoever on whether an agency has overstepped its statutory authority." App. 82a.

Finally, the dissent concluded that the majority erred by deciding the merits of petitioners' APA claims without the administrative record. App. 83a-84a. The court should have addressed only the "*likelihood* of success on the merits," and under that standard, petitioners should have prevailed. App. 84a. The dissent focused on multiple problems with the Rule, including that it failed to offer a reasoned justification for its "dramatic shift in policy" (App. 86a); failed to respond

meaningfully to the record evidence that the Rule violates medical ethics (App. 87a n.13); and offered an explanation for its cost-benefit analysis that runs contrary to the evidence before the agency (App. 88a-94a).

REASONS FOR GRANTING THE PETITION

I. THE EN BANC FOURTH AND NINTH CIRCUITS ARE SPLIT OVER THE VALIDITY OF THE RULE

The en banc Ninth Circuit's decision is in irreconcilable conflict with the en banc Fourth Circuit's decision in *Mayor & City Council of Baltimore* v. *Azar*, __ F.3d __, 2020 WL 5240442 (4th Cir. 2020) (en banc). In *Baltimore*, the Fourth Circuit ruled for the challengers on the very same grounds that the Ninth Circuit rejected. Thus, as the dissent in *Baltimore* recognized, there is a clear "circuit split" over the validity of the Rule. *Id.* at *29, *53 (Richardson, J., dissenting). In Maryland, the Rule has been suspended; everywhere else, it continues to undermine this vital federal public health program. This conflict—between two en banc circuits on important questions of federal law affecting an essential federal health care program—warrants this Court's review.

A. The Ninth Circuit held that the Rule is "not arbitrary and capricious because," it concluded, "HHS properly examined the relevant considerations and gave reasonable explanations." App. 68a. The Fourth Circuit held the opposite—that the Rule "was promulgated in an arbitrary and capricious manner." *Baltimore*, 2020 WL 5240442, at *1, *9-15.

The Fourth Circuit's analysis focused on two core problems and explained why the Ninth Circuit's reasoning is flawed in both respects. First, the Fourth Circuit concluded, HHS "failed to recognize and ad-

dress the ethical concerns of literally every major medical organization in the country." *Baltimore*, 2020 WL 5240442, at *1. HHS "merely stated" that it "'disagrees'" and "'believes'" the Rule is "'not inconsistent' with medical ethics." *Id.* at *11. But that cursory and unexplained conclusion was insufficient under this Court's precedent. *See id.* at *10, *12 (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins.*, 463 U.S. 29, 56-57 (1983)). And the Fourth Circuit considered and rejected as "unpersuasive" the Ninth Circuit's decision. *Id.* at *13. Among other reasons, "the Ninth Circuit's discussion of medical ethics nowhere mentions the precise issue raised here: HHS's failure to justify or explain its conclusion that the … Rule is consistent with medical ethics in the face of overwhelming contrary evidence." *Id.* at *13.

Second, the Fourth Circuit concluded that HHS "arbitrarily estimated the cost of the physical separation of abortion services." *Baltimore*, 2020 WL 5240442, at *1. HHS claimed a cost of $30,000 per Title X project, and the Ninth Circuit found that sufficient. App. 60a n.32. The Fourth Circuit disagreed. As it explained, "there [were] multiple comments estimating the likely cost to comply … to be much higher than $30,000," and HHS, again, had "no response." *Baltimore*, 2020 WL 5240442, at *14-15. There was "no justification in the … Rule for the $30,000 amount," which appeared to have been "pulled from thin air." *Id.* at *15. Again relying on this Court's precedent, the Fourth Circuit concluded, "'[i]f judicial review is to be more than an empty ritual, it must demand something better than the explanation offered for the action taken in this case.'" *Id.* (quoting *Department of Commerce* v. *New York*, 139 S. Ct. 2551, 2576 (2019)).

B. The Ninth Circuit held that the Rule "do[es] not violate" the Nondirective Mandate. App. 40a. Again, the Fourth Circuit held the opposite, concluding that the Rule "violates the Nondirective Mandate." *Baltimore*, 2020 WL 5240442, at *20. Contrary to the Ninth Circuit's reasoning, the Fourth Circuit concluded that the Nondirective Mandate does apply to referrals, relying on the Rule itself, statutes, medical practice, and common sense. *Id.* at *16-18. Moreover, even apart from referrals, the Fourth Circuit found that "HHS's attempt to *appear* nondirective is deceptive and at odds with reality." *Id.* at *18. Contrary to a patient's wishes, the Rule requires counseling on non-abortion options and even authorizes a practitioner to counsel exclusively on non-abortion options. *Id.*

C. The Ninth Circuit held that the Rule does not violate Section 1554 of the ACA. App. 48a. Again, the Fourth Circuit held the opposite. *Baltimore,* 2020 WL 5240442, at *20-21. The Fourth Circuit catalogued the numerous ways in which the Rule violates Section 1554, including that it "quite clearly 'interferes with communications' about medical options between a patient and her provider." *Id.* at *20. And highlighting the AMA's strong opposition to the Rule "for its interference in the patient-physician relationship and violation of ethical standards," the court concluded that the "attempt to hoodwink patients" by providing a list of providers without identifying which ones perform abortions creates "'unreasonable barriers'" and "'impedes timely access'" to health care services. *Id.*

D. Finally, the Ninth Circuit relied heavily on *Rust* in upholding the Rule. Once again disagreeing, the Fourth Circuit held that *Rust* provided the Rule no cover. *Rust* addressed a different administrative record and "did not purport to speak to medical ethics re-

quirements." *Baltimore*, 2020 WL 5240442, at *11. *Rust* also did not speak to the statutory challenges to the Rule because both the Nondirective Mandate and Section 1554 of the ACA, enacted after *Rust*, changed the governing law. *Id.* at *19, *21.

II. THE NINTH CIRCUIT'S DECISION IS ERRONEOUS

A. The Rule Is Arbitrary And Capricious

This Court's precedents set forth two principles governing agency decisionmaking that HHS's rulemaking abandoned and that the Ninth Circuit failed to correct. First, an agency must base its decision "'on a consideration of the relevant factors'" and may not "'entirely fail[] to consider [an] important aspect of the problem.'" *Department of Homeland Sec.* v. *Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1905, 1913 (2020). Second, an agency may not "change[] course" from an existing policy without accounting for "'serious reliance interests,'" *id.* at 1913, and providing "a reasoned explanation for the change," *Encino Motorcars, LLC* v. *Navarro*, 136 S. Ct. 2117, 2125 (2016).

HHS failed to consider the extensive, unequivocal evidence before it that the Rule would force Title X providers to violate their medical ethics and, closely related, that the Rule would have devastating effects on patients and the public health. The AMA—the leading national association of physicians—warned that the Rule would put physicians in the position of "withhold[ing] information that their patients need to make decisions about their care" (CA4 SJA188), and would violate, among other things, their obligation to "[h]onor a patient's request not to receive certain medical information" (AMA, *Code of Medical Ethics* § 2.1.3 (2016)). Many long-serving Title X providers under-

scored this ethical problem and explained that providers would leave the program in droves as a result of the Rule. CA4 SJA371-373; CA4 SJA276.

In response, HHS was required to articulate a "genuine justification[]," *New York*, 139 S. Ct. at 2575-2576, and "offer a 'rational connection between the facts found and the choice made,'" *State Farm*, 463 U.S. at 52. HHS failed to do so—it stated simply that it "disagree[d]," and "believe[d] that the final rule adequately accommodates … ethical obligations while maintaining the integrity of the Title X program." 84 Fed. Reg. at 7,724. That conclusory assertion is insufficient under this Court's precedent. *See Baltimore*, 2020 WL 5240442, at *10-12.

Rust does not remedy that deficiency, and the Ninth Circuit was incorrect to find that it does (App. 64a-65a). All *Rust* said was that the 1988 regulations did not intrude upon the patient-physician relationship to the point of violating the First Amendment. 500 U.S. at 200. That statement says nothing about whether HHS's failure to consider medical ethics 30 years later in *this* rulemaking is arbitrary and capricious. *See Baltimore*, 2020 WL 5240442, at *11.

Also insufficient was HHS's consideration of the negative consequences the Rule would have for patients and public health, as detailed in the administrative record with evidence and based on past experiences. For example, one expert commenter detailed the harms to public health that have occurred when reproductive health care providers have lost public funding in the past—including HIV outbreaks and spikes in unintended pregnancies. *See* CA4 SJA461-462, 467. Commenters further catalogued the various ways that the Rule diminishes access to effective contraceptives,

thus undercutting the program's central purpose. *See, e.g.*, CA4 SJA274.

In response, HHS stated, contrary to the record, that it was "not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the … rulemaking and an increase in unintended pregnancies, births, or costs associated with either." 84 Fed. Reg. at 7,775. HHS cannot simply brush aside evidence of patient harm. *See State Farm*, 463 U.S. at 55-56.

HHS similarly failed to consider evidence that the Rule would cause Planned Parenthood providers, which served 40% of Title X patients, and other Title X providers to leave the program. *See State Farm*, 463 U.S. at 43. The administrative record established that other safety-net family-planning providers would be unable to absorb all the patients of those that leave the program, leaving many patients without access, or with diminished access, to vital, life-saving services. *See, e.g.*, CA4 SJA161-162; CA4 SJA372. HHS's response, again, was insufficient: It simply asserted, citing no evidence, that the Rule "will contribute to more clients being served, gaps in service being closed, and improved client care." 84 Fed. Reg. at 7,723.

The Ninth Circuit ignored or otherwise blessed these fundamental errors of agency decisionmaking. Thus, the court of appeals did not address HHS's failure to cite any evidence in the record—beyond its own unsupported assumptions—that the various harms commenters flagged would not take hold. The court stated that "HHS's predictive judgments about the Final Rule's effect on the availability of Title X services are entitled to deference." App. 58a. But agency predictions about the likely effects of a rule "'must be

based on some logic and evidence, not sheer speculation.'" *Sorenson Commc'ns Inc.* v. *FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014); *see also National Lifeline Ass'n* v. *FCC*, 921 F.3d 1102, 1113 (D.C. Cir. 2019). Here, there was nothing supporting HHS's reasoning; there was simply its "disagreement" with the evidence before it.

HHS also failed to consider the significant reliance interests of patients and providers in an established and trusted network of Title X projects, and did not adequately explain the need for its departure from the status quo. *See FCC* v. *Fox Tel. Stations, Inc.*, 556 U.S. 502, 515 (2009). Where, as here, an agency does "'not writ[e] on a blank slate,'" it must "weigh any such interests against competing policy considerations." *Regents of Univ. of Cal.*, 140 S. Ct. at 1915.

HHS undertook no such consideration. Nothing in the administrative record suggests, for example, that HHS considered that Title X providers, in reliance on HHS's longstanding regulations, had invested significant resources to build facilities that can accommodate both Title X projects and other programs to efficiently provide health care services to low-income people—and thus would not be able to bear the costs of compliance with the physical-separation requirements. Indeed, commenters explained, citing actual cost estimates and past experience, that those requirements were likely to cost approximately $625,000 per affected site. *E.g.*, CA4 SJA388. HHS ignored this and claimed, without evidence, that those requirements would cost $30,000 per site. 84 Fed. Reg. at 7,782; *see Baltimore*, 2020 WL 5240442, at *15. HHS further failed to account for any costs beyond the first year, which are likely to reach into the millions of dollars. *See* CA4 SJA388-389; *Baltimore*, 2020 WL 5240442, at *15 (requiring agency to

provide a "figure that makes at least some modicum of sense").

Yet HHS pressed forward with the physical-separation requirements, providing no "reasoned explanation" for this dramatic departure from its longstanding position. *See Encino Motorcars*, 136 S. Ct. at 2125-2126. HHS provided no evidence of misuse of Title X funds, nor any evidence that the budgeting, program review, and audit processes, with which Title X providers had long complied, were not an adequate safeguard. HHS thus resorted to speculation about the "risk[s]" of "appearance[s]," "perception[s]," and "potential" misuse of funds. 84 Fed. Reg. at 7,764-7,765. Such speculation cannot justify imposing extremely onerous costs on Title X grantees. *See National Lifeline*, 921 F.3d at 1114-1115; *Sorenson Commc'ns*, 755 F.3d at 708-709.

B. The Rule Violates The Nondirective Mandate

The Ninth Circuit acknowledged that the Nondirective Mandate "amended Title X by expressly requiring all pregnancy counseling to be nondirective," but then concluded that the Rule complies with that mandate. That conclusion was erroneous.

As the Fourth Circuit concluded, the Rule "'is nothing but directive,'" *Baltimore*, 2020 WL 5240442, at *16—skewing the counseling by a Title X project in favor of continuing a pregnancy to term and away from abortion. It is directive in at least three ways: (1) It bans referrals for abortion but mandates referrals for prenatal care—regardless of what a patient wants; (2) it requires Title X providers, when giving a pregnant patient a list of comprehensive care providers in the community, to conceal information about whether

any are abortion providers, even in response to a specific patient request; and (3) it requires the project to speak to a patient about options she does not want, even when she seeks information only about abortion.

Those requirements necessarily "suggest[] or advis[e] one option over another." 84 Fed. Reg. at 7,716. Under the Rule, if a patient tells her provider that she wants an abortion, the provider must refuse to provide her a referral and instead must provide a referral for care she neither needs nor requested—information about prenatal care. 42 C.F.R. §§ 59.5(a)(5), 59.14(a), 59.14(b)(1). This necessarily steers a patient toward carrying a pregnancy to term against the patient's wishes. Similarly, the Title X project can only provide a list containing comprehensive primary health care providers—reflecting either exclusively those who do *not* provide abortion or a majority of whom do not—and may *not* identify which, if any, of the providers on the list actually provide abortion. *Id.* §§ 59.14(b)-(c). As a result, a patient seeking an abortion will face delay and confusion if she attempts to use the list to find a provider that does provide abortion, if one exists. Finally, the Rule enlists providers in trying to override the patient's intent to obtain an abortion, by requiring counseling on non-abortion options the patient does not want. 84 Fed. Reg. at 7,747; *see Baltimore*, 2020 WL 5240442, at *17-18; CA9 ER19.

HHS has argued that a "failure" to refer a patient for abortion does not direct a patient to do anything. That argument fails. This case concerns HHS's requirements that projects *withhold* that information in response to patient requests and *force on* patients information about non-abortion options that they do not want or need. Those requirements are directive, for as HHS recognized, "[n]ondirective counseling is designed

to assist the patient in making a free and informed decision" and "involves presenting the options in a factual, objective, and unbiased manner." 84 Fed. Reg. at 7,747. Presenting information about how and where clients can obtain certain services, while suppressing that information about other services, is not "'objective'" or "'unbiased'" and steers a patient toward carrying a pregnancy to term. *Baltimore*, 2020 WL 5240442, at *17; *see also id.* at *18 ("Being required to refuse (not failing) to refer a patient to a physician who performs abortions when the patient has requested as much, and instead, referring her for prenatal care, is far from neutral.").

The Ninth Circuit's decision to the contrary rests on faulty conclusions. First, the court erroneously held that "'pregnancy counseling'" does not include "referrals." App. 34a. In so doing, the court deferred to HHS's "interpretation" of "'counseling' as a concept that is distinct from the term 'referrals,'" deeming it "reasonable and consistent with common usage." App. 30a. But "counseling" and "referrals" are not distinct concepts, as reflected in HHS's own Rule and clinical standards, the relevant statutes, medical practice, and common sense. As the Fourth Circuit concluded, HHS's purported interpretation, one that appears "*nowhere* in … the Rule" itself, is "nothing but a convenient litigation position which does not support" the Rule. *Baltimore,* 2020 WL 5240442, at *16-17.

In the Rule, HHS stated that "nondirective pregnancy counseling can include counseling on adoption, and *corresponding referrals* to adoption agencies." 84 Fed. Reg. at 7,730 (emphasis added). It also stated that "Title X providers may provide adoption counseling, information and referral … *as part of nondirective postconception counseling*." *Id.* at 7,733-7,734 (empha-

sis added). Even HHS's own evidence-based clinical standards for "Pregnancy Testing and Counseling" state that "[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals." CDC & OPA, *Providing Quality Family Planning Services* 13-14 (Apr. 24, 2014). HHS's argument that pregnancy counseling does not include referrals is not only incorrect but also at odds with its own positions.

In addition, Congress has made clear in a related statute that "referrals" are "included in nondirective counseling." 42 U.S.C. § 254c-6(a)(1) (instructing HHS to make grants to train health-center staff "in providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in nondirective counseling* to pregnant women." (emphasis added)); *see also Graham Cty. Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 559 U.S. 280, 290 (2010) ("'[A] legislative body generally uses a particular word with a consistent meaning in a given context.'"). Indeed, in describing that statute in the Rule here, HHS explained that "Congress … expressed its intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects." 84 Fed. Reg. at 7,733.

Thus, both Congress and HHS have recognized that pregnancy counseling includes referrals. So has the medical profession, which "'recognize[s] referrals as part of counseling.'" *Baltimore*, 2020 WL 5240442, at *18. "'As commonly understood by medical practitioners and in daily medical practice, counseling patients may include and, in some cases, must include, providing referrals.'" *Id.*

Second, the Ninth Circuit held that the term "non-directive" does not require providers to present all options on an "equal" basis. App. 31a. That conclusion missed the point, and incorrectly characterized petitioners' arguments. The Nondirective Mandate's operating principles are provider neutrality and patient-directed treatment—*i.e.*, where the patient "identif[ies] the direction of the interaction," 84 Fed. Reg. at 7,716. But the Rule requires Title X providers to steer patients who have stated they want an abortion away from that option and toward continuing a pregnancy to term. Such counseling—*against a patient's wishes*—is directive and thus violates Congress's mandate that "all pregnancy counseling" under Title X "shall be non-directive."

C. The Rule Violates Section 1554 Of The ACA

Section 1554 of the ACA is clear: HHS "*shall not* promulgate *any* regulation" that harms patient care in any one of six enumerated ways, including by interfering with communications between provider and patient or violating the ethical standards of health care professionals. 42 U.S.C. § 18114 (emphasis added). The Ninth Circuit decided that the Rule "does not implicate § 1554." App. 48a. That conclusion conflicts with the statute's plain terms.

First, the Ninth Circuit held that the Rule could not "impose burdens on health care providers and their clients" under Section 1554 because the Rule "merely reflect[ed] Congress's choice not to subsidize certain activities." App. 43a. In support, the Ninth Circuit invoked this Court's constitutional holding in *Rust*. App. 43a-46a. But that holding is inapposite, as the Fourth Circuit recognized. *Baltimore*, 2020 WL 5240442, at *21. On a constitutional challenge, the appropriate

comparator is the situation where Congress had not enacted Title X at all, because the constitutional question is whether the government, generally, has interfered with the right. That is not true of the statutory inquiry under Section 1554, where Congress has "enact[ed] statutory requirements and protections that exceed the constitutional floor." App. 81a (Paez, J., dissenting). "That a congressional decision not to subsidize abortion does not burden the abortion right in the *constitutional* sense … has no bearing whatsoever on whether an agency has overstepped its statutory authority." App. 82a.

Second, the Ninth Circuit concluded that Section 1554 was confined to provisions within the ACA and does not affect Title X, invoking the prefatory clause "[n]otwithstanding any other provision of this Act." App. 47a. That reading finds no home in the statute's text. The "notwithstanding" clause makes clear that Section 1554 may not be narrowed by *any* other provision—*including, but not limited to*, "other provisions *of the ACA*." *Baltimore*, 2020 WL 5240442, at *21 n.21. Section 1554 prohibits "*any* regulation" issued by HHS that harms patient care in any one of six ways. 42 U.S.C. § 18114 (emphasis added). Congress's choice of the word "any" without qualification demonstrates its broad sweep. *See Ali* v. *Federal Bureau of Prisons*, 552 U.S. 214, 219 (2008) ("'[T]he word 'any' has an expansive meaning[.]'").

The Ninth Circuit otherwise made no serious attempt to harmonize the Rule with Section 1554's plain terms. Nor is there any way to do so. The Rule dictates what a provider must and must not say to a patient about her pregnancy options, and thus "interferes with communications regarding a full range of treatment options between the patient and the provider."

42 U.S.C. § 18114(3). It further "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions." *Id.* § 18114(4). And it contravenes "the ethical standards of health care professionals" by prohibiting Title X projects from providing pregnant patients with information about all of their options. *Id.* § 18114(5). The AMA's *Code of Medical Ethics* states, for example, that medical professionals must "[p]resent relevant information accurately and sensitively, in keeping with the patient's preferences," and that "withholding information without the patient's knowledge or consent is ethically unacceptable." AMA, *Code of Medical Ethics*, §§ 2.1.1(b), 2.1.3; *see, e.g.*, CA4 SJA189; CA9 ER39-40; CA9 ER49-50; *see supra* pp.13-14, 23-24.

Section 1554 preserves providers' duty of candor with their patients, in accordance with the "ethical standards" that it invokes. Congress recognized that candor is fundamental to the patient-provider relationship and, thus, proper medical care. Indeed, as this Court recently underscored, "'[d]octors help patients make deeply personal decisions, and their candor is crucial.'" *National Inst. of Family & Life Advocates* v. *Becerra*, 138 S. Ct. 2361, 2374 (2018). That principle is especially important in the context of Title X, a program designed to reach patients with low incomes, many of whom have limited knowledge of and ability to navigate the health care system. Yet the Rule's restrictions contravene that principle and run afoul of Section 1554's protections, thereby "'undermin[ing] the trust that is necessary for facilitating healthy doctor-patient relationships and, through them, successful treatment outcomes.'" *Baltimore*, 2020 WL 5240442, at *20.

III. THE QUESTIONS PRESENTED ARE IMPORTANT

The Ninth Circuit's decision conflicts with the Fourth Circuit's decision and is erroneous. Those reasons alone warrant this Court's review. But it bears emphasis that the questions presented are important. They concern the integrity of the patient-provider relationship, founded on open and honest communications, the lynchpin of proper medical care. And they arise in the context of a vitally important federal health care program, with significant real-world consequences that undermine Congress's purpose and conflict with its mandates for the program.

Millions of people have depended on Title X since its inception, receiving critical family planning and sexual health care each year. And under a long-settled regulatory framework, the Title X program has been a resounding success. For 50 years, grants to reproductive health care providers have dramatically reduced unintended-pregnancy and abortion rates and have provided low-income individuals millions of screenings for cancer, sexually transmitted infections, and HIV. Title X's impact is hard to overstate; "[f]or six in 10 women who obtain contraceptive care at a Title X-funded site[], that provider was their only source of medical care over the past year." CA4 SJA151.

The Rule reverses that progress and hobbles the program. "[A]s of late February 2020," the Fourth Circuit recognized, "roughly one in every four Title X service sites ha[s] withdrawn from the Title X program in response to the … Rule, which slashed the national patient capacity in half, 'jeopardizing care for 1.6 million female patients nationwide.'" *Baltimore*, 2020 WL 5240442, at *11 n.9. Indeed, HHS just recently acknowledged that, as a result of the Rule, Title X ser-

vices sites decreased by 945 sites and the number of annual patients served in 2019 fell by 21%—despite the rule being in effect for only a few months. *See supra* p.17; *see also supra* p.7. These facts underscore how HHS's unsupported assumptions about supposed salutary benefits were and continue to be out of step with reality.

Thus, the consequences of the Rule are clear and stark—and already occurring. They "will be borne by the millions of women who turn to Title X-funded clinics for lifesaving care and the very contraceptive services that have caused rates of unintended pregnancy—and abortion—to plummet." App. 94a.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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OCTOBER 2020

APPENDICES

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 19-15974
D.C. No. 3:19-cv-01184-EMC

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,
Plaintiff-Appellee,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,
Defendants-Appellants.

No. 19-15979
D.C. No. 3:19-cv-01195-EMC

ESSENTIAL ACCESS HEALTH, INC.; MELISSA MARSHALL, M.D.,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; U+.S. DEPARTMENT OF HEALTH & HUMAN SERVICES,
Defendants-Appellants.

Appeal from the United States District Court for the Northern District of California
Edward M. Chen, District Judge, Presiding

No. 19-35386
D.C. Nos. 6:19-cv-00317-MC, 6:19-cv-00318-MC

STATE OF OREGON; STATE OF NEW YORK; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NORTH CAROLINA; COMMONWEALTH OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; STATE OF WISCONSIN; AMERICAN MEDICAL ASSOCIATION; OREGON MEDICAL ASSOCIATION; PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; PLANNED PARENTHOOD OF SOUTHWESTERN OREGON; PLANNED PARENTHOOD COLUMBIA WILLAMETTE; THOMAS N. EWING, M.D.; MICHELE P. MEGREGIAN, C.N.M.

Plaintiffs-Appellees,

v.

ALEX M. AZAR II; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; DIANE FOLEY; OFFICE OF POPULATION AFFAIRS,

Defendants-Appellants.

Appeal from the United States District Court for the District of Oregon
Michael J. McShane, District Judge, Presiding

No. 19-35394
D.C. Nos. 1:19-cv-03040-SAB, 1:19-cv-03045-SAB

STATE OF WASHINGTON; NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; FEMINIST WOMEN'S HEALTH CENTER; DEBORAH OYER, M.D.; TERESA GALL,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; DIANE FOLEY, M.D., IN HER OFFICIAL CAPACITY AS DEPUTY ASSISTANT SECRETARY FOR POPULATION AFFAIRS; OFFICE OF POPULATION AFFAIRS,
Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Washington
Stanley Allen Bastian, District Judge, Presiding

Argued and Submitted En Banc September 23, 2019
San Francisco, California
Filed February 24, 2020

OPINION

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* * *

Before: Sidney R. Thomas, Chief Judge, and Edward Leavy, Kim McLane Wardlaw, William A. Fletcher, Richard A. Paez, Jay S. Bybee, Consuelo M. Callahan,

Milan D. Smith, Jr., Sandra S. Ikuta, Eric D. Miller and Kenneth K. Lee, Circuit Judges.

Opinion by Judge Ikuta;
Dissent by Judge Paez

* * *

OPINION

IKUTA, Circuit Judge:

Title X of the Public Health Service Act gives the Department of Health and Human Services (HHS) authority to make grants to support "voluntary family planning projects" for the purpose of offering "a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a).[1] Section 1008 of Title X prohibits grant funds from "be[ing] used in programs where abortion is a method of family planning." *Id.* § 300a-6.

Since 1970, when Title X was first enacted, HHS has provided competing interpretations of this prohibition. Regulations issued in 1988, and upheld by the Supreme Court in 1991, completely prohibited the use of Title X funds in projects where clients received counseling or referrals for abortion as a method of family planning. *Rust v. Sullivan*, 500 U.S. 173, 177–79 (1991). Regulations issued in 2000 were more permissive.

In March 2019, HHS promulgated regulations that are similar to those adopted by HHS in 1988 and upheld by *Rust*. But the 2019 rule is less restrictive in at least

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[1] Congress did not design the Title X grant program to provide healthcare services beyond "family planning methods and services." 42 U.S.C. § 300(a); *cf*. Dissent at 81.

one important respect: a counselor providing nondirective pregnancy counseling "may discuss abortion" so long as "the counselor neither refers for, nor encourages, abortion." 42 C.F.R. § 59.14(e)(5). There is no "gag" on abortion counseling. *See id.*

Plaintiffs, including several states and private Title X grantees, brought various suits challenging the 2019 rule, and three district courts in three states entered preliminary injunctions against HHS's enforcement of the rule. In light of Supreme Court approval of the 1988 regulations and our broad deference to agencies' interpretations of the statutes they are charged with implementing, plaintiffs' legal challenges to the 2019 rule fail. Accordingly, we vacate the injunctions entered by the district courts and remand for further proceedings consistent with this opinion.

I

In 1970, Congress enacted Title X of the Public Health Service Act to give HHS authority to make grants to Title X projects that provide specified family planning services.[2] Family Planning Services and Population Research Act, Pub. L. No. 91-572, 84 Stat. 1504, 1508 (1970); 42 U.S.C. § 300a-4(c). The Act gives HHS broad authority to promulgate regulations to administer the grant program, as well as to impose conditions on the grants that HHS "may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made." § 1006(a)–(b), 84 Stat. at 1507; 42 U.S.C. § 300a-4(a)–(b).

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[2] Although Title X and its implementing regulations use both the terms "program" and "project," for consistency we refer to a program using Title X funds to provide services to clients as a "Title X project."

Congress placed only two limitations on HHS's discretion. First, an individual's acceptance of family planning services has to be "voluntary" and not "a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information." § 1007, 84 Stat. at 1508; 42 U.S.C. § 300a-5. Second, § 1008 of Title X provides:

> None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.

§ 1008, 84 Stat. at 1508; 42 U.S.C. § 300a-6.

Section 1008, which has never been amended, "was intended to ensure that Title X funds would 'be used only to support preventive family planning services, population research, infertility services, and other related medical, informational, and educational activities.'" *Rust*, 500 U.S. at 178–79 (quoting H.R. Conf. Rep. No. 91-1667, at 8 (1970)); *see also New York v. Sullivan*, 889 F.2d 401, 407 (2d Cir. 1989), *aff'd sub nom. Rust v. Sullivan*, 500 U.S. 173 (1991) (noting a legislator's statement that "[w]ith the 'prohibition of abortion' amendment—title X, section 1008—the [House] committee members clearly intend that abortion is not to be encouraged or promoted in any way through this legislation") (statement of Rep. Dingell). As *Rust* concluded, in enacting § 1008, Congress made a constitutionally permissible "value judgment favoring childbirth over abortion." 500 U.S. at 192 (quoting *Maher v. Roe*, 432 U.S. 464, 474 (1977)).

Although the purpose of § 1008 is clear, the Supreme Court has determined that its language is ambiguous because it does not expressly articulate how its prohibition applies to abortion counseling, referral, and

advocacy, or how to ensure that funds are not used "in programs where abortion is a method of family planning." *Id.* at 184. As a result of this ambiguity, HHS has provided a range of alternative interpretations of § 1008 over the years. We provide an overview of this history as context to our analysis of the issues raised by the government's appeals.

A

In 1971, HHS promulgated (without notice and comment) the first regulations designed to implement Title X. Project Grants for Family Planning Services, 36 Fed. Reg. 18,465, 18,465–66 (Sept. 15, 1971). The regulations did not address the scope of § 1008. Instead, HHS interpreted § 1008 through opinions from its Office of General Counsel. In the mid-1970s, HHS issued a legal opinion prohibiting directive counseling on abortion ("encouraging or promoting" abortion) in a Title X project, while permitting nondirective ("neutral") counseling on abortion. *Nat'l Family Planning & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992). Subsequent General Counsel opinions interpreted § 1008 as "prohibiting any abortion referrals beyond 'mere referral,' that is, providing a list of names and addresses without in any further way assisting the woman in obtaining an abortion." Statutory Prohibition on Use of Appropriated Funds Where Abortion is a Method of Family Planning, 53 Fed. Reg. 2922, 2923 (Feb. 2, 1988) (the 1988 Rule).

HHS revised its Title X regulations after notice and comment in 1980. *See* Grants for Family Planning Services, 45 Fed. Reg. 37,433 (June 3, 1980). But like the 1971 regulations, the 1980 regulations did not address the scope of § 1008. *Nat'l Family Planning*, 979 F.2d at 229 (citing 45 Fed. Reg. at 37,437). Instead, in

1981, HHS issued "Program Guidelines for Project Grants for Family Planning Services." *See* U.S. Dep't of Health & Human Servs., *Program Guidelines for Project Grants for Family Planning Services* (1981). For the first time, these guidelines required Title X projects to give Title X clients nondirective counseling on and referrals for abortion upon request. *Id.* § 8.6. The 1981 "guidelines were premised on a view that 'non-directive' counseling and referral for abortion were not inconsistent with [§ 1008] and were justified as a matter of policy in that such activities did not have the effect of promoting or encouraging abortion." 53 Fed. Reg. at 2923.

It was not until 1988 that HHS addressed the scope of § 1008 in notice-and-comment rulemaking. *See* 53 Fed. Reg. at 2922. The 1988 Rule recognized that "[f]ew issues facing our society today are more divisive than that of abortion." *Id.* Because § 1008 was intended to create "a wall of separation between Title X programs and abortion as a method of family planning," the 1988 Rule concluded that Congress intended Title X to circumscribe "family planning" to include "only activities related to facilitating or preventing pregnancy, not for terminating it." *Id.* at 2922–23. The 1988 Rule accordingly defined the term "family planning" as including "a broad range of acceptable and effective methods and services to limit or enhance fertility." *Id.* at 2944.

In light of these concerns, the 1988 Rule imposed specified limits on a Title X project. First, the project could not provide prenatal care. *Id.* at 2945. Therefore, "once a client served by a Title X project is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services by furnishing a list of avail-

able providers that promote the welfare of mother and unborn child." *Id.*

Further, a Title X project could not "provide counseling concerning the use of abortion as a method of family planning." *Id.* In the preamble to the 1988 Rule, HHS explained that counseling "which results in abortion as a method of family planning simply cannot be squared with the language of section 1008," and the 1988 Rule therefore rejected the 1981 program guidelines' requirement that Title X projects give nondirective counseling on abortion. *Id.* at 2923. In barring such nondirective counseling, HHS also relied on a General Accounting Office (GAO) report and Office of the Inspector General (OIG) audit of Title X projects indicating that some Title X projects were "promoting abortion" under the guise of providing nondirective counseling. *Id.* at 2924.[3]

Nor could a Title X project "provide referral for abortion as a method of family planning." *Id.* at 2945. Therefore, the list of available providers given to a pregnant client could not include "providers whose principal business is the provision of abortions." *Id.*

The 1988 Rule also required a Title X project to be organized "so that it is physically and financially separate" from activities prohibited by § 1008 and the regulations. *Id.* To meet this "program integrity" requirement, "a Title X project must have an objective integri-

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[3] For example, the audit found that some Title X projects were providing clients with brochures prepared by abortion clinics, providing and witnessing the signing of consent forms required by abortion clinics, making appointments for clients at abortion clinics, and using Title X funds to pay the administrative costs for loans provided to clients to pay for abortions. 53 Fed. Reg. at 2924 n.7.

ty and independence from prohibited activities. Mere bookkeeping separation of Title X funds from other monies is not sufficient." *Id.*

HHS explained that its rules requiring physical and financial separation were supported by OIG-audit and GAO-report findings that Title X projects were arguably violating § 1008 and that the lack of separation led to confusion as to whether federal funds were being used for abortion services. *Id.* Both OIG and GAO "urged [HHS] to give more specific, formalized direction to programs about the extent of prohibition on abortion as a method of family planning." *Id.* at 2923–24.

After HHS promulgated the 1988 Rule, Title X grantees challenged the facial validity of the regulations on the grounds that the regulations were not authorized by Title X, were arbitrary and capricious under the Administrative Procedure Act (APA), and violated the First and Fifth Amendment rights of Title X clients and the First Amendment rights of Title X health care providers. The Supreme Court addressed these challenges in *Rust.*

Rust first rejected the plaintiffs' claim "that the regulations exceed [HHS]'s authority under Title X and are arbitrary and capricious." *Id.* at 183. Because the language of § 1008 was "ambiguous" as to "the issues of counseling, referral, advocacy, or program integrity," the Court gave "substantial deference" to HHS's interpretation under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984), and concluded that "[t]he broad language of Title X plainly allows [HHS]'s construction of the statute." *Rust*, 500 U.S. at 184. "By its own terms, § 1008 prohibits the use of Title X funds 'in programs where

abortion is a method of family planning'" but "does not define the term 'method of family planning,' nor does it enumerate what types of medical and counseling services are entitled to Title X funding." *Id.* In light of the "broad directives provided by Congress in Title X in general and § 1008 in particular," *Rust* concluded that HHS's "construction of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy within the Title X project" was permissible. *Id.*

Rust likewise upheld the program integrity requirements, which mandated separate facilities, personnel, and records. The Court concluded that the requirements were "based on a permissible construction of the statute" and were "not inconsistent with congressional intent." *Id.* at 188. *Rust* noted that "if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities." *Id.* at 190. As such, *Rust* declined to upset HHS's "reasoned determination that the program integrity requirements are necessary to implement the prohibition" in § 1008. *Id.*

Rust also rejected the plaintiffs' argument that the regulations were arbitrary and capricious because "they 'reverse a longstanding agency policy that permitted nondirective counseling and referral for abortion'" and constitute "a sharp break from [HHS]'s prior construction of the statute." *Id.* at 186. According to the Court, HHS's revised interpretation was entitled to deference because "the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.* (quoting *Chevron*, 467 U.S. at 863–64). HHS gave a reasoned basis for its change of interpretation, includ-

ing that the new regulations were "more in keeping with the original intent of the statute." *Id.* at 187.

Rust then turned to the constitutional arguments. The Court rejected the argument that the restrictions violated the First Amendment speech rights of grantees, their staff, and clients, holding that the regulations permissibly implemented Congress's decision to allocate public funds "to subsidize family planning services which will lead to conception and childbirth, and declin[e] to promote or encourage abortion." *Id.* at 193 (internal quotation marks omitted). "Congress' power to allocate funds for public purposes includes an ancillary power to ensure that those funds are properly applied to the prescribed use," and "the regulations are narrowly tailored to fit Congress' intent in Title X that federal funds not be used to 'promote or advocate' abortion as a 'method of family planning.'" *Id.* at 195 n.4. Doctors were "always free to make clear that advice regarding abortion is simply beyond the scope of the [Title X] program." *Id.* at 200. *Rust* also rejected arguments that the restrictions violated a woman's Fifth Amendment right to choose whether to obtain an abortion because "[the] decision to fund childbirth but not abortion 'places no governmental obstacle in the path of a woman who chooses to terminate her pregnancy, but rather, by means of unequal subsidization of abortion and other medical services, encourages alternative activity deemed in the public interest.'" *Id.* at 201 (quoting *Harris v. McRae*, 448 U.S. 297, 315 (1980)). The regulations did not infringe the doctor-patient relationship, the Court held, because the doctor and patient remained free to discuss abortion and abortion-related services "outside the context of the Title X project." *Id.* at 203. Accordingly, *Rust* upheld the 1988 Rule.

Within months after *Rust* was decided, legislators introduced the Family Planning Amendments Act of 1992, H.R. 3090, 102d Cong. (1991), which sought to undo the 1988 Rule and to codify the 1981 program guidelines, *see* S. Rep. No. 102-86 (1991). Under the proposed legislation, every applicant for a Title X grant had to agree to offer "nondirective counseling and referrals regarding—(i) prenatal care and delivery; (ii) infant care, foster care, and adoption; and (iii) termination of pregnancy." H.R. 3090, 102d Cong. § 2 (1991); S. 323, 102d Cong. § 2 (1991); H.R. Rep. No. 102-767, at 2 (1992). The bill failed to obtain the necessary votes. *See* S. 323, 102d Cong., Roll No. 452 (Oct. 2, 1992).

After this legislative effort to overturn *Rust* failed, President Clinton issued a memorandum directing HHS to suspend the 1988 Rule. *See* The Title X "Gag Rule," 58 Fed. Reg. 7455 (Jan. 22, 1993). Two weeks later (without notice or comment) HHS issued an interim rule suspending the 1988 Rule and announcing that the nonregulatory interpretations that existed prior to the 1988 Rule, including those in the 1981 program guidelines, would apply. *See* Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7462 (Feb. 5, 1993). Legislators introduced another bill, the Family Planning Amendments Act of 1995, H.R. 833, 104th Cong. (1995), which included the same language as the amendments proposed in 1991, and would have required nondirective counseling on and referral for the "termination of pregnancy." H.R. 833, 104th Cong. § 2(b)(3) (1995). As before, these efforts were unsuccessful.

Around this same time, Congress was debating whether to appropriate funds for Title X projects. *See* 141 Cong. Rec. H8194-02, at 8249–62 (Aug. 2, 1995). In response to concerns that Title X clinics were pressing

teenagers to obtain abortions, *see id.* at H8260 (Rep. Waldholtz), legislators proposed a compromise bill that would ensure no federal funds were used to support abortion services. As ultimately enacted, the 1996 appropriations rider provided (among other things) "[t]hat amounts provided to [Title X] projects … shall not be expended for abortions, [and] that all pregnancy counseling shall be nondirective." Pub. L. No. 115-245, 132 Stat. 2981, 3070–71. A version of this rider has been reenacted each year since 1996.

In the wake of the defeat of the Family Planning Amendments Acts of 1992 and 1995, HHS issued a new regulation adopting the language of the failed legislation. *See* Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 65 Fed. Reg. 41,270 (July 3, 2000) (the 2000 Rule). The 2000 Rule provided that a Title X project was required to offer a pregnant woman "neutral, factual information and nondirective counseling" on "each of the following options: (A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination." *Id.* at 41,279. Each Title X project also had to provide referral for each option "upon request." *Id.*

The 2000 Rule eliminated several of the 1988 Rule's provisions. For instance, the 2000 Rule dropped the 1988 Rule's definition of "family planning" but did not provide a replacement definition. *See id.* at 41,278. Instead, the 2000 Rule simply stated that a family planning project must "[p]rovide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)." *Id.* at 41,278–79. The 2000 Rule also

eliminated the physical and financial separation requirement. *See id.* at 41,276.[4]

While HHS's oscillations in interpreting § 1008 were playing out, Congress enacted various laws (referred to as federal conscience laws) prohibiting discrimination against individuals and entities who objected to performing or promoting abortion on religious or moral grounds. Beginning in 1973, Congress enacted four statutes (collectively referred to as the Church Amendments) that prevent the government from conditioning grant funds on assistance with abortion-related activities, 42 U.S.C. § 300a-7(b), and prohibit grant recipients from discriminating against individuals who refused to assist with abortion because of their "religious beliefs or moral convictions," *id.* § 300a-7(c). In 1996, Congress enacted the Coats-Snowe Amendment to the Public Health Service Act, which prohibits the federal government from discriminating against any health care entity because it refuses to engage in certain abortion-related activities, including providing referrals for abortions. Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, tit. V, § 515, 110 Stat. 1321, 1321-245 (1996) (codified at 42 U.S.C. § 238n(a)). Finally, in 2004 Congress began including a rider in health care appropriations bills to prohibit discrimination by recipients of federal grants against health care entities that refused to make referrals for abortion, among other things. Consolidat-

[4] In promulgating the 2000 Rule, HHS did not go as far as some commenters urged. In rejecting comments that it should read § 1008 narrowly as prohibiting only "the provision of, or payment for, abortions" and nothing else, HHS stated that this was *not* "the better reading of the statutory language." 65 Fed. Reg. at 41,272. HHS also acknowledged that the 1988 Rule was "a permissible interpretation" of § 1008. *Id.* at 41,277.

ed Appropriations Act, 2005, Pub. L. No. 108-447, 118 Stat. 2890, 3163 (2004) (referred to as the Weldon Amendment).[5]

In 2008, HHS concluded that the 2000 Rule's requirement that Title X projects *must* provide counseling and referrals for abortion upon request was inconsistent with these federal conscience laws. Therefore, HHS promulgated regulations to clarify it "would not enforce this Title X regulatory requirement on objecting grantees or applicants." Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,087 (Dec. 19, 2008) (the 2008 nondiscrimination regulations). After a new administration took office, HHS decided these regulations were "unclear and potentially overbroad in scope" and rescinded them. Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011).

Thus, before the 2018 rulemaking, HHS's interpretations of § 1008 had seesawed through multiple formulations: from permitting—then requiring—nondirective counseling on abortion as a method of family planning (in 1971 and 1981 guidance documents); to prohibiting counseling and referrals for abortion as a method of family planning (in the 1988 Rule, upheld by the Supreme Court in 1991); and then to once again requiring nondirective counseling and referrals for abortion on request (in the 2000 Rule). HHS also vacillated

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[5] The Weldon Amendment has been continuously enacted since 2004. *See, e.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, Pub. L. 115-245, 132 Stat. 2981, 3118.

in its interpretation of the federal conscience laws. This uncertain history was the backdrop for HHS's reconsideration of this controversial area in 2018.

B

In 2018, HHS returned to the task of interpreting § 1008 and issued a notice of proposed rulemaking "to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning." Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502, 25,502 (June 1, 2018). After receiving over 500,000 comments reflecting a "sharp diversity of opinion," HHS issued a final rule in March 2019. Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714, 7723 (Mar. 9, 2019) (the Final Rule). The Final Rule largely represents a return to the 1988 Rule that the Supreme Court upheld in *Rust*.

The Final Rule's definition of the statutory term "family planning" is substantially similar to the 1988 Rule's definition. It "means the voluntary process of identifying goals and developing a plan for the number and spacing of children," including by means of "a broad range of acceptable and effective family planning methods and services." 84 Fed. Reg. at 7787; 42 C.F.R. § 59.2 (2019). Like the 1988 Rule, the Final Rule states that family planning services "include preconception counseling" but not "postconception care (including obstetric or prenatal care) or abortion as a method of family planning." 84 Fed. Reg. at 7787; 42 C.F.R. § 59.2.

In the preamble to the Final Rule, HHS explained that it adopted this definition of "family planning" to

"address in part its concern that the requirement for abortion referrals, as provided in the 2000 [Rule], violates or leads to violations of section 1008's prohibition on funding Title X projects where abortion is a method of family planning." 84 Fed. Reg. at 7729. HHS also explained it was reestablishing the 1988 Rule's requirement that family planning methods and services be "acceptable and effective," omitting the 2000 Rule's requirement that they also be "medically approved," because the term "medically approved" lacked clear meaning in this context and does not appear in the statute. *Id.* at 7740–41.

Repeating the language of Title X, *see* 42 U.S.C. § 300(a), the Final Rule provides that a family planning project must "[e]ncourage family participation in the decision to seek family planning services," 42 C.F.R. § 9.5(a)(14). In the preamble, HHS noted that this language was required by the Title X statute itself and that Congress had enacted an appropriations rider that "specifically emphasizes that grantees encourage family participation 'in the decision of minors to seek family planning services.'" 84 Fed. Reg. at 7718 (quoting Pub. L. No. 115-245, div. B, sec. 207, 132 Stat. 2981, 3070 (2018)).

The Final Rule also sets forth requirements and limitations for post-conception services. *See* 42 C.F.R. § 59.14. Under the Rule, once a client is verified as being pregnant, the client "shall be referred to a health care provider for medically necessary prenatal health care." *Id.* § 59.14(b)(1). The regulations explain that "[p]rovision of a referral for prenatal health care is consistent with [Title X] because prenatal care is a medically necessary service." *Id.* § 59.14(e)(1).

The Final Rule differs from the 1988 Rule with respect to pregnancy counseling. HHS noted that the 1996 appropriations rider, as reenacted annually, required "that all pregnancy counseling shall be nondirective."[6] 84 Fed. Reg. at 7725 n.36, 7729. Interpreting the rider's language as permitting such counseling, *id*. at 7725, the Final Rule states that a Title X project can give a pregnant client nondirective pregnancy counseling "when provided by physicians or advanced practice providers." 42 C.F.R. § 59.14(b)(1)(i).[7]

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[6] The appropriations rider for 2018 provides:

> For carrying out the program under title X of the [Public Health Service] Act to provide for voluntary family planning projects, $286,479,000: *Provided*, That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

Pub. L. No. 115-245, div. B, tit. II, 132 Stat. 2981, 3070–71 (2018).

[7] The Final Rule defines "Advanced Practice Provider" as:

> [A] medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM).

42 C.F.R. § 59.2.

Unlike the 1988 Rule, the Final Rule establishes that a counselor providing nondirective pregnancy counseling "may discuss abortion" so long as "the counselor neither refers for, nor encourages, abortion." *Id.* § 59.14(e)(5). To ensure compliance with federal conscience laws, however, a Title X provider is not required to discuss abortion upon request. *See* 84 Fed. Reg. at 7716, 7746–47. In short, the Final Rule does not impose a "gag" on abortion counseling: a counselor "may discuss abortion" but is not required to do so. 42 C.F.R. § 59.14(e)(5).[8]

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[8] The dissent relies heavily on its mistaken view that the Final Rule is a "Gag Rule" that "gags health care providers from fully counseling women about their options while pregnant." Dissent at 81. The dissent conjures up a "Kafkaesque" situation where counselors have to "walk on eggshells to avoid a potential transgression" of the Final Rule and in response to questions about terminating a pregnancy can merely say: "I can't help you with that or discuss it. Here is a list of doctors who can assist you with your pre-natal care despite the fact that you are not seeking such care." Dissent at 85–86 (citation omitted). But this "Kafkaesque" scenario is belied by the Final Rule itself, which expressly authorizes counseling on abortion while prohibiting referrals for abortion. Indeed, the Final Rule provides its own example of a straightforward conversation with a client who asks about abortion:

> [When a] pregnant woman requests information on abortion and asks the Title X project to refer her for an abortion[, then] [t]he counselor tells her that the project does not consider abortion a method of family planning and, therefore, does not refer for abortion. The counselor offers her nondirective pregnancy counseling, *which may discuss abortion*, but the counselor neither refers for, nor encourages, abortion.

42 U.S.C. § 59.14(e)(5) (emphasis added). The dissent's arguments that the Final Rule is a "Gag Rule" is merely a restatement of its disagreement with the Final Rule's interpretation of § 1008 as precluding "referral for abortion as a method of family planning." 84 Fed. Reg. at 7717.

Although the Final Rule permits a Title X project to provide nondirective counseling that includes information about abortion, it expressly prohibits referrals for abortion as a method of family planning. HHS explained its understanding that "referral for abortion as a method of family planning, and such abortion procedure itself, are so linked that such a referral makes the Title X project or clinic a program one where abortion is a method of family planning." 84 Fed. Reg. at 7717. Accordingly, "[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." 42 C.F.R. § 59.14(a). Further, "[a] Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning." *Id.* § 59.14(c)(1).

While referrals for abortion as a method of family planning are not allowed, the Title X project may give a pregnant client a "list of licensed, qualified, comprehensive primary health care providers," which may include "providers of prenatal care[], some, but not the majority, of which also provide abortion as part of their comprehensive health care services." *Id.* § 59.14(c)(2). "Neither the list nor project staff may identify which providers on the list perform abortion." *Id.* The Title X project may also provide referrals for abortion when such a procedure is medically necessary. 84 Fed. Reg. at 7748.

Finally, the Final Rule, like the 1988 Rule, requires that a Title X project be organized "so that it is physically and financially separate … from activities that are prohibited under section 1008 of the Public Health Ser-

vice Act and §§ 59.13, 59.14, and 59.16 of these regulations." 42 C.F.R. § 59.15. HHS explained that the physical and financial separation requirements were necessary to avoid the risk "of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities, and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics." 84 Fed. Reg. at 7764.

The effective date of the Final Rule was set for May 3, 2019, but the compliance deadline for the physical separation requirements is March 4, 2020. *Id.* at 7714.

C

Before the Final Rule's effective date, several states and private Title X grantees (collectively, plaintiffs) filed lawsuits against HHS in three different district courts seeking preliminary injunctive relief. The lawsuits challenged the Final Rule under the APA as arbitrary and capricious, contrary to law, and in excess of statutory authority. 5 U.S.C. § 706(2)(A), (C).[9] All three district courts granted plaintiffs' preliminary injunction motions on similar grounds. *See Washington v. Azar*, 376 F. Supp. 3d 1119 (E.D. Wash. 2019); *California v. Azar*, 385 F. Supp. 3d 960 (N.D. Cal. 2019); *Or-*

[9] Plaintiffs also brought various constitutional claims, but the district courts did not base their preliminary injunctions on these claims. Plaintiffs do not raise these claims as alternative grounds for affirming the district courts' grants of injunctive relief, so any such argument was waived. *See United States v. Gamboa-Cardenas*, 508 F.3d 491, 502 (2007).

egon v. Azar, 389 F. Supp. 3d 898 (D. Or. 2019). HHS timely appealed each of the preliminary injunction orders.[10]

We review a district court's grant of a preliminary injunction "for an abuse of discretion." *Gorbach v. Reno*, 219 F.3d 1087, 1091 (9th Cir. 2000) (en banc). But "legal issues underlying the injunction are reviewed de novo because a district court would necessarily abuse its discretion if it based its ruling on an erroneous view of law." *adidas Am., Inc. v. Skechers USA, Inc.*, 890 F.3d 747, 753 (9th Cir. 2018) (citation omitted).

II

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *accord Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015). The first factor—likelihood of success on the merits—"is the most important" factor. *Id.* If a movant fails to establish likelihood of success on the merits, we need not consider the other factors. *Id.*

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[10] HHS also moved to stay the injunctions pending a decision on the merits of its appeals. We granted the stay motion in a published order. *See California v. Azar*, 927 F.3d 1068 (9th Cir. 2019) (per curiam). Upon the vote of a majority of nonrecused active judges, we ordered reconsideration en banc of the stay motion, *California v. Azar*, 927 F.3d 1045, 1046 (9th Cir. 2019) (mem.), but we did not vacate the stay order itself, so it remained in effect, *California v. Azar*, 928 F.3d 1153, 1155 (9th Cir. 2019) (mem.). The stay motion is now denied as moot.

The Supreme Court has recognized that when an issue of law is key to resolving a motion for injunctive relief, the reviewing court has the power "to examine the merits of the case" and resolve the legal issue. *Munaf v.Geren*, 553 U.S. 674, 691 (2008) (internal quotation marks omitted) (quoting *N.C. R. Co. v. Story*, 268 U.S. 288, 292 (1925)). "Adjudication of the merits is most appropriate if the injunction rests on a question of law and it is plain that the plaintiff cannot prevail." *Id.*; *accord Blockbuster Videos, Inc. v. City of Tempe*, 141 F.3d 1295, 1297 (9th Cir. 1998). The Supreme Court reaffirmed this conclusion in *Winter*, noting that it could "address the underlying merits of plaintiffs' [legal] claims" in the preliminary injunction appeal and proceed to a decision. 555 U.S. at 31; *see also Blockbuster Videos*, 141 F.3d at 1297; *Friends of the Earth v. U.S. Navy*, 841 F.2d 927, 931 (9th Cir. 1988).

This approach applies in appropriate APA cases. *See Beno v. Shalala*, 30 F.3d 1057, 1063–64 (9th Cir. 1994). In *Beno*, we considered plaintiffs' claim that an agency's action was "'arbitrary and capricious' within the meaning of the APA." *Id.* at 1063. The APA claim required only review of the administrative record and interpretation of relevant statutes; "additional fact-finding [was] not necessary to resolve th[e] claim." *Id.* at 1064 n.11. Because "the district court's denial of injunctive relief rested primarily on interpretations of law, not on the resolution of factual issues," we reviewed de novo the district court's legal conclusions and addressed plaintiffs' claims on the merits. *Id.* at 1063–64 (internal quotation marks omitted). We held this was appropriate because "in APA cases, a district court decision is generally accorded no particular deference, and is reviewed de novo because the district court is in no better position than this court to review

the administrative record." *Id.* at 1063 n.9 (internal quotation marks and citations omitted). This approach is consistent with the Supreme Court's ruling that district courts' "factfinding capacity" is "typically unnecessary to judicial review of agency decisionmaking" because both the district court and the court of appeals "are to decide, on the basis of the record the agency provides, whether the action passes muster under the appropriate APA standard of review." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

Here, the only significant issues raised are legal. Plaintiffs argue that the Final Rule is invalid on its face because it conflicts with other statutes and the agency acted in an arbitrary and capricious manner in promulgating it. An agency's action violates the APA when it is "in excess of statutory jurisdiction [or] authority," 5 U.S.C. § 706(2)(C), or when it is "not in accordance with law," *id.* § 706(2)(A), for instance, when it violates another statute, *see FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003). The record before us is sufficient to resolve plaintiffs' challenges, and no additional factual development is required.[11] The district

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[11] Although the parties did not submit the full administrative record (which includes over 500,000 public comments) to the district courts, all public comments made during the rulemaking process are available online and were available to the parties in raising arguments to the district courts. *See Compliance with Statutory Program Integrity Requirements*, regulations.gov (last visited Oct. 29, 2019), https://www.regulations.gov/document?D=HHS-OS-2018-0008-0001; 84 Fed. Reg. at 7722 & n.26. Indeed, the parties used selected public comments to support their arguments in their briefs both to the district courts and to us. Despite this, the dissent asserts that "[d]eciding the merits of [p]laintiffs' arbitrary and capricious claim is … premature" because "[w]e do not have the complete administrative record." Dissent at 95–96. But neither plaintiffs nor the dissent identify additional arguments that

courts issued preliminary injunctions based on their view that plaintiffs were likely to prevail on the merits of these legal claims, and thus the district courts were not in any better position to decide these issues than we are. *See Beno*, 30 F.3d at 1063 n.9.[12] We have received extensive briefing and heard argument on the issues presented. Because we can decide, based on the record provided, "whether the action passes muster

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could be made after submission of the full record, *see* Dissent at 95–96; at most, plaintiffs stated at oral argument (but not in their briefing) that they might delve deeper into the approximately 500,000 public comments to provide additional support for their existing arguments. Because HHS did not omit or withhold material information from the administrative record, the cases on which the dissent relies are inapposite. *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 793 (D.C. Cir. 1984) (holding that review could not go forward on a partial record where doing so "would be fundamentally unfair" because agency had withheld significant information); *Nat. Res. Def. Council, Inc. v. Train*, 519 F.2d 287, 292 (D.C. Cir. 1975) (remanding to district court for further review where agency omitted a key document that "throws light on the factors and considerations relied upon" by the agency from the administrative record). Accordingly, we conclude that the record before us is sufficient to resolve plaintiffs' arguments that aspects of the Final Rule are arbitrary and capricious. *See McChesney v. FEC*, 900 F.3d 578, 583 (8th Cir. 2018); 5 U.S.C. § 706 ("[T]he court shall review the whole record or those parts of it cited by a party.").

[12] In considering plaintiffs' claims that HHS's action was arbitrary and capricious, the district courts properly limited their review to the record before them. *See California*, 385 F. Supp. 3d at 1000–18; *Washington*, 376 F. Supp. 3d at 1131; *Oregon*, 389 F. Supp. 3d at 914–19. While the district courts made factual findings and predictions to support their conclusion that plaintiffs showed a likelihood of irreparable harm, *see, e.g.*, *California*, 385 F. Supp. 3d at 978–85, *see also* Fed. R. Civ. P. 52(a), these findings are not relevant to the resolution of the arbitrary and capricious challenge, *see Fla. Power & Light Co.*, 470 U.S. at 744.

under the appropriate APA standard of review," *Fla. Power & Light Co.*, 470 U.S. at 744, we may resolve the legal issues on their merits, *Beno*, 30 F.3d at 1064.

III

We first consider plaintiffs' argument that the Final Rule is facially invalid. Plaintiffs wisely do not press the argument that the Final Rule is an impermissible interpretation of the text of § 1008. *Rust* held that "[t]he broad language of Title X plainly allows [the 1988 Rule's] construction of the statute," 500 U.S. at 184, and the Final Rule is substantially the same as the 1988 Rule with respect to the provisions at issue here.

Rather, plaintiffs mainly argue that two intervening congressional enactments altered the legal landscape so that *Rust*'s holding is no longer valid. First, plaintiffs point to the 1996 appropriations rider enacted to ensure no federal funds were used to support abortion services. *See* Pub. L. No. 115-245, div. B, tit. II, 132 Stat. 2981, 3070–71 (2018). Second, plaintiffs rely on a section of the Patient Protection and Affordable Care Act (ACA) that limits HHS's ability to promulgate regulations. *See* Pub. L. No. 111-148, § 1554, 124 Stat. 119, 259 (2010) (codified at 42 U.S.C. § 18114).

In considering these arguments, we are mindful that the Supreme Court's "interpretive decisions, in whatever way reasoned, effectively become part of the statutory scheme." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409 (2015). Therefore, *Rust*'s conclusion that § 1008 could be interpreted to bar abortion counseling, referral, and advocacy within a Title X project became a part of Title X's scheme, and we may not lightly infer that Congress intended to overrule that holding in enacting the appropriations rider or § 1554 of

the ACA. Because "[t]he modification by implication of [a] settled construction of an earlier and different section" by a later enactment "is not favored," *United States v. Madigan*, 300 U.S. 500, 506 (1937), plaintiffs must provide evidence that Congress intended to alter *Rust*'s conclusion that the 1988 Rule was a permissible interpretation of Title X and § 1008. They fail to do so.

A

We first turn to plaintiffs' argument that the Final Rule violates the 1996 appropriations rider. At the time HHS promulgated the Final Rule, the appropriations rider provided that "amounts provided to [the Title X project] shall not be expended for abortions, [and] that all pregnancy counseling shall be nondirective." Pub. L. No. 115-245, div. B, tit. II, 132 Stat. 2981, 3070–71 (2018). HHS interpreted this appropriations rider as permitting Title X projects to provide counseling on abortion, and incorporated this interpretation in the Final Rule. *See* 84 Fed. Reg. at 7725; 42 C.F.R. § 59.14(e)(5).

Plaintiffs' argument about the correct interpretation of this provision proceeds in three steps. First, according to plaintiffs, the term "pregnancy counseling" must be interpreted as including referrals. Second, plaintiffs contend that the term "nondirective" means the presentation of all options on an equal basis. Third, putting these two definitions together, plaintiffs argue that the term "nondirective pregnancy counseling" requires the provision of referrals for abortion on the same basis as referrals for prenatal care and adoption. Because the Final Rule requires referrals for medically necessary prenatal health care and permits referrals for adoption but precludes referrals for abortion, *see* 42 C.F.R. § 59.14, plaintiffs contend that the Final Rule

does not provide nondirective pregnancy counseling, and thus violates the appropriations rider. We consider each of these steps in turn.

1

At the first step, plaintiffs and the dissent argue that the statutory term "pregnancy counseling" must be interpreted as including referrals.[13] Congress has not provided a definition of the term "pregnancy counseling," or otherwise "directly addressed the precise question at issue." *Chevron*, 467 U.S. at 843. In the face of Congressional silence, we give "substantial deference" to the interpretations provided by HHS. *Rust*, 500 U.S. at 184.[14]

In the Final Rule, HHS provided its interpretation by treating the terms "counseling" and "referral" as referring to distinct legal concepts. *See* 84 Fed. Reg. at 7716–17. While a counselor may "provide *nondirective pregnancy counseling* to pregnant Title X clients on the patient's pregnancy options, *including abortion*," *id*. at 7724 (emphasis added), the Final Rule prohibits any "referral for abortion as a method of family planning," *id*. at 7717.

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[13] As HHS recognized, the appropriations rider amended Title X by expressly requiring all pregnancy counseling to be nondirective. 84 Fed. Reg. at 7725, 7729. Congress "may amend substantive law in an appropriations statute, as long as it does so clearly." *Robertson v. Seattle Audubon Soc'y*, 503 U.S. 429, 440 (1992).

[14] HHS is the agency authorized to promulgate regulations to implement Title X, *see* 42 U.S.C. § 300a-4(a).

In its brief on appeal, HHS made explicit the Final Rule's implicit interpretation of "counseling."[15] According to HHS, under the Final Rule and as a matter of common usage, "counseling and referrals are distinct" because "'[p]regnancy counseling' involves providing information about medical options, which is different from referring a patient to a specific doctor for a specific form of medical care."

HHS's interpretation of the phrase "pregnancy counseling" as a concept that is distinct from the term "referrals" is reasonable and consistent with common usage. The dictionary indicates that counseling does not include referrals. The dictionary definition of the term "counseling" is "a practice or professional service designed to guide an individual to a better understanding of [her] problems and potentialities … ." *Counseling*, Webster's Third New International Dictionary 518 (2002); *see also Counseling*, The American Medical Association Encyclopedia of Medicine 317 (1989) (defining

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[15] We may defer to an interpretation made in a legal brief so long as it is not a post hoc rationalization "advanced by an agency seeking to defend past agency action against attack." *Auer v. Robbins*, 519 U.S. 452, 462 (1997). As in *Auer*, there is no reason here to think that HHS's position is a "post hoc rationalization." *Id.* Indeed, HHS has long treated "counseling" and "referral" as distinct concepts. The 1981 guidelines and the 2000 Rule both provided that Title X projects were required to provide "nondirective counseling on each of the options [including pregnancy termination], *and referral upon request*." 65 Fed. Reg. at 41,279; *Program Guidelines for Project Grants for Family Planning Services*, § 8.6 (1981) (emphasis added); *see also* 53 Fed. Reg. at 2923 (explaining that the 1981 guidelines required providers to furnish "nondirective 'options couns[e]ling"—including "on pregnancy termination (abortion)"—"followed by referral for these services if [the patient] so requests"). And the 2000 Rule treated "non-directive counseling," *see* 65 Fed. Reg. at 41,272–74, as distinct from "[r]eferral[s] for abortion, *see id.* at 41,274.

"counseling" as "[a]dvice and psychological support given by a health professional and usually aimed at helping a person cope with a particular problem"). By contrast, "referral" is defined as "the process of directing or redirecting (as a medical case, a patient) to an appropriate specialist or agency for definitive treatment." *Referral*, Webster's Third New International Dictionary 1908 (2002). As in *Rust*, "[t]he broad language of Title X," as amended by the 1996 appropriations rider, "plainly allows [HHS]'s construction of the statute." 500 U.S. at 184.

Plaintiffs' and the dissent's argument that the term "pregnancy counseling" must be interpreted as including referrals is primarily based on their reading of a separate statute enacted by Congress, the Children's Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000); *see* Dissent at 90–91. A provision of that Act, the "Infant Adoption Awareness" section, 42 U.S.C. § 254c-6, requires HHS to make grants to adoption organizations "for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women." 42 U.S.C. § 254c-6(a)(1). According to plaintiffs and the dissent, this language shows Congress intended that referrals be "included in nondirective counseling" and that all options, including abortion, should be presented on an equal basis. *See* Dissent at 90–91.

This argument fails. The Infant Adoption Awareness section neither provides a definition of "nondirective counseling" nor "expressly states" that nondirective counseling "encompasses referrals." *Cf*. Dis-

sent at 87 n.4.[16] Simply put, the section does not show that referrals are a type of nondirective counseling. Indeed, it does not impose any requirements or limitations on nondirective pregnancy counseling at all; rather, it provides funds to adoption organizations to enable them to offer training to the staff of health centers regarding the provision of adoption information and referrals to clients. HHS could reasonably conclude that this section does not indicate that it considers referrals to be a type of counseling, as opposed to something that may occur at the same time as counseling. 84 Fed. Reg. at 7733. Given that the Infant Adoption Awareness section is not part of Title X, does not use language similar to that in the 1996 appropriations rider, and was enacted for a substantially different purpose, it sheds no light on Congress's intent in enacting the appropriations rider or on the interpretation of its statutory language. *Cf. Northcross v. Bd. of Educ. of Memphis City Sch.*, 412 U.S. 427, 428 (1973) (per curiam) (providing that it is appropriate to interpret the language of two separate statutes pari passu where two statutes use similar language and were enacted for the same purpose).[17]

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[16] Although the dissent claims that Congress "clarified the meaning of the term 'nondirective'" and that Congress's "intent is clear," in fact, the dissent merely offers its own interpretation of what the term means in context. Dissent at 90.

[17] In addition to discussing the Infant Adoption Awareness section, 42 U.S.C. § 254c-6(a)(1), both the plaintiffs and HHS point to other statutes that reference counseling and referrals. HHS notes that Congress has frequently referred to counseling and referrals separately, showing that the two are legally distinct concepts. *See*, *e.g.*, 42 U.S.C. § 300z-10(a) ("Grants or payments may be made only to … projects which do not provide abortions or abortion counseling or referral … ."); *id.* § 300z-3(b) (referring to "counseling and referral services"); 18 U.S.C. § 248(e)(5) ("repro-

Plaintiffs' and the dissent's second argument, that industry practice requires interpreting "counseling" as including referrals, also fails, because the sources on which plaintiffs rely shed no light on the proper interpretation of the term "nondirective pregnancy counseling." Dissent at 87 n.4. Plaintiffs first point to HHS's guidelines in *Providing Quality Family Planning Services* (the QFP), which state that during a "visit [to] a provider of family planning services," pregnancy-test results "should be presented to the client, followed by a discussion of options and appropriate referrals." U.S. Dep't of Health & Human Servs., *Providing Quality Family Planning Services*, Morbidity & Mortality Wkly. Rep., Apr. 25, 2014, at 13–14. Rather than requiring an interpretation of counseling as including referrals, this language suggests that counseling (i.e., "discussion of options") and referrals are distinct. Plaintiffs also point to a letter submitted by the American Medical Association (AMA) during the notice-and-comment period on the Final Rule. In this letter, the AMA listed several provisions in its *Code of Medical Ethics* which it claimed made it unethical for a practi-

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ductive health services" includes "counseling or referral services relating to the human reproductive system, including services relating to pregnancy or the termination of a pregnancy"). Plaintiffs identify other statutes that suggest referrals can occur during the course of counseling. *See*, *e.g.*, 42 U.S.C. § 300ff-33 ("post-test counseling (including referrals for care)" provided to individuals with positive HIV/AIDS test); *id.* § 3020e-1(b) (referring to "pension counseling and information programs" that "provide outreach, information, counseling, referral, and other assistance"); 20 U.S.C. § 1161k(c)(4)(A) (requiring college counselors to provide "referrals to and follow-up with other student services staff"). Because these statutes do not use the same language as the appropriations rider and were not enacted for the same purpose, they do not assist us in interpreting Congress's direction "that all pregnancy counseling shall be nondirective." *See* 84 Fed. Reg. at 7745.

tioner to refrain from providing "all appropriate referrals, including for abortion services." But the provisions of the code cited in the letter do not even discuss referrals, let alone define the term; rather, they state that patients have a right "to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives" and "to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment." These sources do not show that the term "referrals" is included in the phrase "nondirective pregnancy counseling."[18]

Because HHS can reasonably interpret "nondirective pregnancy counseling" as not including referrals, *see* 84 Fed. Reg. at 7716, plaintiffs fail at the first step of their arguments, that "pregnancy counseling" must be deemed to include referrals.

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Plaintiffs also fail at the second step of their argument: that the term "nondirective" means the presentation of all options on an equal basis. Neither Title X nor the appropriations rider defines "nondirective." Again, because Congress has "not directly addressed the precise question at issue," *Chevron*, 467 U.S. at 843, we must give substantial deference to HHS's interpretation. *Rust*, 500 U.S. at 184. In the Final Rule, HHS filled the Congressional silence by interpreting "nondirective pregnancy counseling" to mean "the meaning-

[18] The dissent does not address these sources and merely asserts, without explanation, that "industry understanding recognizes that counseling includes referrals." Dissent at 87 n.4 (citing *California*, 385 F. Supp. 3d at 989).

ful presentation of options where the physician or advanced practice provider (APP) is 'not suggesting or advising one option over another.'" 84 Fed. Reg. at 7716 (quoting 138 Cong. Rec. H2822-02, 2826 (statement of Rep. Lloyd)).

Under this definition, "nondirective" does not mean the presentation of all possible medical options. Rather, "nondirective" means that options must be provided in a neutral manner, without suggesting or advising one option over another. Thus, a physician or APP providing nondirective counseling to a client does not have to discuss every possible option available to that client, but must present options in a neutral manner and refrain from encouraging the client to select a particular option. In other words, HHS interpreted "nondirective" to refer to the neutral manner in which counseling is provided rather than to the scope of topics that must be covered in counseling. 84 Fed. Reg. at 7716.

This is a reasonable interpretation of "nondirective." It is consistent with HHS's longstanding distinction between "nondirective" counseling that is "neutral" and "directive" counseling that encourages or promotes abortion. *Nat'l Family Planning*, 979 F.2d at 229. And it is consistent with the dictionary definition of the term "nondirective" as a type of counseling where "the counselor refrains from interpretive or associative comment but usually by repeating phrases used by the client encourages [the client] to express, clarify, and restructure [the client's] problems." *Nondirective*, Webster's Third New International Dictionary 1536 (2002); *see also* 84 Fed. Reg. at 7716 (nondirective counseling involves "clients tak[ing] an active role in processing their experiences and identifying the direction of the interaction"). Because HHS's interpretation of "nondirective" is reasonable, we defer to that

interpretation. *See Chevron*, 467 U.S. at 843–44; *Nw. Envtl. Advocates v. EPA*, 537 F.3d 1006, 1014 (9th Cir. 2008).

We also reject plaintiffs' and the dissent's argument that the Final Rule is directive because it requires referrals for medically necessary prenatal health care. Dissent at 85. HHS could reasonably conclude that referrals for prenatal care are nondirective, as HHS defines this term, because a referral for prenatal care does not steer the client toward any particular option and does not discourage a client from seeking an abortion outside of the Title X program. As HHS points out, "seeking prenatal care is not the same as choosing the option of childbirth." 84 Fed. Reg. at 7748. Further, HHS could reasonably conclude that providing a referral for prenatal care is not directive because it is "medically necessary" for the health of the client during pregnancy, *id.* at 7748, 7761–62, regardless of whether the client later chooses an abortion outside of a Title X project.[19] "Where care is medically necessary,

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[19] Plaintiffs and the dissent point to declarations from doctors and nurse practitioners conclusorily stating that prenatal care "is *not* medically necessary for someone who wishes to terminate her pregnancy." Dissent at 88 n.5. But HHS reasonably concluded otherwise, 84 Fed. Reg. at 7748, 7761–62, based on its determination that "pregnancy may stress and affect extant [i.e., existing] health conditions [of the client]," such that "primary health care may be critical to ensure that pregnancy does not negatively impact such conditions," *id.* at 7750.

The dissent's argument that HHS did not justify the referral requirement on the ground that prenatal care is medically necessary for the health of the client, Dissent at 88 n.5, is refuted by the record; indeed, the sentence of the Final Rule on which the dissent relies for this argument makes clear that prenatal care is "important for … *the health of the women*," 84 Fed. Reg. at 7722 (emphasis added); *see also id.* at 7748, 7761–62.

as prenatal care is for pregnancy, referral for that care is not directive because the need for the care preexists the direction of the counselor, and is, instead, the result of the woman's pregnancy diagnosis or the diagnosis of a health condition for which treatment is warranted." *Id.* at 7748. Because prenatal care is medically necessary for a pregnant client, *see id.* at 7748, 7761–62, referrals for such care are distinguishable from referrals for abortions for the purpose of family planning, which are not medically necessary. Indeed, the Supreme Court has long recognized that abortion need not be treated the same as other medical procedures: "Abortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325 (1980); *see also Maher*, 432 U.S. at 480 ("The simple answer to the argument" that a law imposes different requirements on abortion than other medical procedures is that other "procedures do not involve the termination of a potential human life.").[20] Given these distinctions, requiring referrals

[20] Given the "inherent[] differen[ces]" between abortion and other medical procedures, *McRae*, 448 U.S. at 325, the dissent's attempt to liken nontherapeutic abortion to treatment options for prostate cancer is meritless, Dissent at 87. Prostate cancer is a disease, and "chemotherapy, radiation, [and] hospice" are treatment options. Dissent at 87. Pregnancy is not a disease, and a nontherapeutic abortion is not a treatment option.

By contrast, abortion is *not* used as a "method of family planning" under § 1008 or the Final Rule when abortion is medically necessary (i.e., therapeutic). *See Abortion, elective*, The American Medical Association Encyclopedia of Medicine 57 (1989) (defining a "therapeutic abortion" as an abortion "carried out to save the life or health of the mother"). Referrals for and counseling on therapeutic abortions are not subject to the same restrictions as those imposed on nontherapeutic ones; rather, in situations where "emergency care is required," the Final Rule *requires* that clients

for medically necessary prenatal health care but not for nontherapeutic abortions does not make pregnancy counseling directive.[21]

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be referred "immediately to an appropriate provider of medical services needed to address the emergency." 42 C.F.R. § 59.14(b)(2); *see also id.* § 59.14(e)(2) (requiring referral for emergency medical care upon the discovery of an ectopic pregnancy).

[21] The dissent's argument that clients who receive counseling on prenatal care and abortion (but not referrals for abortion providers) are "coerced," "demeaned," and prevented from taking "an active role in identifying the direction" of their lives is absurd. Dissent at 88 (cleaned up). Nothing in the Final Rule prevents clients from procuring abortions. *See* 42 C.F.R. § 59.14. Similarly, the dissent's reliance on the 2000 Rule to argue that failing to provide abortion referrals is coercive, Dissent at 88 n.5, is misplaced because the 2000 Rule merely suggested that a referral for "prenatal care *and delivery*" might be coercive if the client has rejected that option, 65 Fed. Reg. at 41,275 (emphasis added); the 2000 Rule said nothing about whether it is coercive to require a referral for prenatal care to safeguard the health of the client, *see* 84 Fed. Reg. at 7722.

The dissent's suggestion that clients relying on Title X services cannot locate abortion providers without a referral from a Title X counselor, Dissent at 89 n.6, is contrary to the reality—recognized in the Final Rule—that "[i]nformation about abortion and abortion providers is widely available and easily accessible, including on the internet," 84 Fed. Reg. at 7746. We decline to second-guess HHS's determination based on plaintiffs' unsupported declarations. *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2571 (2019); *cf.* Dissent at 89 n.6. In any event, Title X was not designed to be a source of assistance for procuring abortions, *cf.* Dissent at 87–89; rather, Congress's purpose in enacting Title X was to "fund and, thereby, encourage preconception services, a focus that "generally excludes payment for postconception care and services," including abortion. 84 Fed. Reg. at 7723. Congress's restriction on Title X projects leaves clients with "at least the same range of choice in deciding whether to obtain" an abortion as they would have had if Congress provided no Title X funding. *Harris*, 448 U.S. at 317. As *Rust* recognized, "a doctor's abil-

Nor is the Final Rule directive because it allows referrals for adoption. *See* 42 C.F.R. § 59.5(a)(1). The Infant Adoption Awareness section, 42 U.S.C. § 254c-6(a)(1), does not require Title X projects to urge or encourage adoptions; rather, it provides funds for training staff of eligible health centers (which may include Title X projects) to provide adoption information and referrals on an equal basis with other courses of action included in nondirective counseling. Based on this legislation, HHS reasonably concluded that referrals for adoption are "appropriate under Title X, since Congress specified that Title X clinics and providers were eligible health centers to whom adoption related training should be offered," 84 Fed. Reg. at 7730. Further, the language of the Infant Adoption Awareness section suggests that Congress did not interpret the phrase "nondirective counseling" as necessarily requiring a presentation of all options on an equal basis. To the contrary, if Congress had defined "nondirective counseling" to require the presentation of all options on an equal basis, it would have been unnecessary to encourage health center staff to present information about adoption "on an equal basis with all other courses of action" as part of nondirective counseling, because the staff would have already been required to do so. 42 U.S.C. § 254c-6(a)(1).

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ity to provide, and a woman's right to receive, abortion-related information remains unfettered outside the context of the Title X project." 500 U.S. at 203. That some Title X clients "may be effectively precluded by indigency" or other circumstances from procuring "abortion-related services" is a product of those circumstances, "not of governmental restrictions." *Id.*; *cf.* Dissent at 89 n.6. Thus, the dissent, and the amici on which it relies, mistakenly fault the Final Rule for not helping clients "access[] abortion." Dissent at 87–89.

Finally, the Final Rule's restrictions on referral lists do not render pregnancy counseling directive because a referral list does not present information in a way that encourages or promotes a specific option—it is merely "[a] list of licensed, qualified, comprehensive primary health care providers." 42 C.F.R. § 59.14(b)(1)(ii). As *Rust* recognized, doctors are "free to make clear that advice regarding abortion is simply beyond the scope of the program." 500 U.S. at 200.[22]

Because HHS has reasonably interpreted the phrase "pregnancy counseling" as not including referrals, and has interpreted the word "nondirective" to mean a neutral presentation of options as opposed to the presentation of all possible options, we reject plaintiffs' argument that the term "nondirective pregnancy counseling" requires the provision of referrals for abortion on the same basis as referrals for prenatal care and adoption. Accordingly, the challenged provisions of the Final Rule do not violate the 1996 appropriations rider.

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[22] Plaintiffs briefly argue that the Final Rule's general prohibition on promoting or providing support for abortion as a method of family planning, *see* 42 C.F.R. § 59.14(a), may "chill discussions of abortion and thus inhibit[] neutral and unbiased counseling." We reject this argument. If a provider promoted or supported abortion as a method of family planning, the counseling would be directive and therefore violate the appropriations rider. *See* 84 Fed. Reg. at 7747. By contrast, the Final Rule's prohibition on promoting or supporting abortion as a method of family planning both reinforces the rider's nondirective-counseling requirement and implements § 1008's prohibition on using Title X funds in programs "where abortion is a method of family planning." § 1008, 42 U.S.C. § 300a-6.

B

Plaintiffs next argue that the Final Rule is inconsistent with § 1554 of the ACA. *See* § 1554, 124 Stat. at 259 (codified at 42 U.S.C. § 18114). In March 2010, Congress passed the ACA "to expand coverage in the individual health insurance market," *King v. Burwell*, 135 S. Ct. 2480, 2485 (2015), and to decrease the cost of health care, *Nat'l Fed. of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538 (2012). The ACA adopted "a series of interlocking reforms" primarily involving insurance reform, including barring insurers from considering an individual's health when deciding whether to offer coverage, requiring individuals to maintain health insurance coverage or face a penalty, and offering certain tax credits to make health insurance more affordable. *King*, 135 S. Ct. at 2485.

While Title I of the ACA focuses on health insurance issues, Subtitle G of that title, entitled "Miscellaneous Provisions," does not address insurance directly. Instead, it sets forth a series of measures aimed at protecting the interests of entities and individuals that might be affected by the ACA's sweeping program. Among other things, it requires HHS to promote transparency by providing a "list of all of the authorities provided to the Secretary under th[e] Act." 42 U.S.C. § 18112. It also precludes discrimination against health care providers for failing to offer assisted suicide, *see id.* § 18113, ensures that individuals and entities have the freedom not to participate in federal health insurance programs, *see id.* § 18115, and prohibits health care programs and employers from engaging in various discriminatory acts, *see id.* § 18116. Section 1554, part of Subtitle G's "Miscellaneous Provisions," is titled "Access to therapies" and provides:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
>
> (6) limits the availability of health care treatment for the full durations of a patient's medical needs.

§ 1554, 124 Stat. at 259; 42 U.S.C. § 18114.

Plaintiffs and the dissent contend that three provisions of the Final Rule conflict with this provision of the ACA: the Final Rule's restrictions on promoting or supporting abortion as a method of family planning and making referrals for abortion; its physical and financial separation requirement; and its requirement that pro-

viders encourage family participation in family planning decisions. Dissent at 92–93.[23]

We disagree. The Supreme Court has long made a distinction between regulations that impose burdens on health care providers and their clients and those that merely reflect Congress's choice not to subsidize certain activities. *See Rust*, 500 U.S. at 192; *cf. United States v. Am. Library Ass'n*, 539 U.S. 194, 211–12 (2003); *Regan v. Taxation With Representation of Wash.*, 461 U.S. 540, 549–50 (1983). Under the Supreme Court's jurisprudence, a state's decision not to subsi-

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[23] The government argues that plaintiffs' ACA-based challenge is waived because § 1554 was not raised during the notice-and-comment period, and so HHS did not have an opportunity to provide analysis and reasoning regarding whether the Final Rule was consistent with § 1554 or to make any conforming changes to the Final Rule. Plaintiffs contend that many comments used terminology similar to that used in § 1554, and the similarity in terminology was enough to give HHS notice that the Final Rule could violate § 1554. For instance, plaintiffs claim that commenters' objections to the Final Rule on the grounds that it would "ban Title X providers from giving women full information about their health care options" gave HHS notice that the Final Rule would violate § 1554's ban on promulgating a regulation that "interferes with communications regarding a full range of treatment options." 42 U.S.C. § 18114(3). The district courts agreed. *See California*, 385 F. Supp. 3d at 994–95; *Oregon*, 389 F. Supp. 3d at 914; *Washington*, 376 F. Supp. 3d at 1130. Because there is an obvious difference between arguing that a regulation violates best medical practices and arguing that a regulation violates a statute, we are doubtful that plaintiffs preserved their argument that the Final Rule violated § 1554. *See Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam) (holding that a proponent must raise a "specific argument," as opposed to a "general legal issue" to preserve a legal argument for review) (citing *Nuclear Energy Inst., Inc. v. Envtl. Prot. Agency*, 373 F.3d 1251, 1291 (D.C. Cir. 2004)). Nevertheless, because the Final Rule does not conflict with § 1554, we need not address this question of waiver.

dize abortion on the same basis as other procedures does not impose a burden on women, even when indigence "may make it difficult and in some cases, perhaps, impossible for some women to have abortions," because the law "neither created nor in any way affected" her indigent status. *Maher*, 432 U.S. at 474; *see also Webster v. Reprod. Health Servs.*, 492 U.S. 490, 509–10 (1989) (holding that a state law prohibiting abortions in public hospitals was permissible because it "leaves a pregnant woman with the same choices as if the State had chosen not to operate any public hospitals at all"); *Harris*, 448 U.S. at 317 ("[T]he Hyde Amendment [prohibiting the use of federal funds to pay for abortion services except under specified circumstances] leaves an indigent woman with at least the same range of choice in deciding whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all.").

Rust applied this well-established principle to the Title X context, rejecting arguments that the 1988 Rule's limitations on counseling and referrals for abortion impermissibly burdened the doctor-patient relationship, interfered with a woman's right to make "an informed and voluntary choice by placing restrictions on the patient-doctor dialogue," and impeded a woman's access to abortion services. 500 U.S. at 202. The Court recognized "[t]here is a basic difference between direct state interference with a protected activity and state encouragement of an alternative activity consonant with legislative policy." *Id.* at 193 (quoting *Maher*, 432 U.S. at 475). A government restriction on funding certain activities "is not denying a benefit to anyone, but is instead simply insisting that public funds be spent for the purposes for which they were authorized." *Id.* at 196. Nor do restrictions on funding interfere

with appropriate medical care. In the context of Title X funding, restrictive regulations "leave the [Title X] grantee unfettered" in the services it can perform outside of the Title X project, *id.*, because the regulations "govern solely the scope of the Title X project's activities" and "do not in any way restrict the activities of those persons acting as private individuals," *id.* at 198–99. Further, "the Title X program regulations do not significantly impinge upon the doctor-patient relationship" because the doctor and patient may "pursue abortion-related activities when they are not acting under the auspices of the Title X project," *id.* at 200, and "[a] doctor's ability to provide, and a woman's right to receive, information concerning abortion and abortion-related services outside the context of the Title X project remains unfettered," *id.* at 203. The Court distinguished the sorts of limitations imposed by the 1988 Rule from a regime "in which the Government has placed a condition on the recipient of the subsidy rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally funded program." *Id.* at 197 (emphasis omitted).[24]

Rust's logic applies equally to statutory and constitutional claims. If, as the Supreme Court has concluded, a rule implementing the government's policy decision to encourage childbirth rather than abortion does

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[24] The Supreme Court has repeatedly reaffirmed *Rust*'s ruling that the government may constitutionally preclude recipients of federal funds from addressing specified subjects so long as the limitation does not interfere with a recipient's conduct outside the scope of the federally funded program. *See Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013) (citing *Rust*, 500 U.S. at 195 n.4); *accord Walker v. Tex. Div., Sons of Confederate Veterans, Inc.*, 135 S. Ct. 2239, 2246 (2015).

not burden or interfere with a client's health care at all, *see Harris*, 448 U.S. at 317, then it does not matter whether the client's heath care rights were created by the Constitution or a statute.

The same reasoning applies here and requires us to distinguish between § 1554's prohibition on direct interference with certain health care activities and the Final Rule's directives that ensure government funds are not spent for an unauthorized purpose. As in *Rust*, the Final Rule's restrictions on funding certain activities do not create unreasonable barriers, impede access to health services, restrict communications, or otherwise involve "denying a benefit to anyone." *Id.* at 196. Nor, as *Rust* explained, do they interfere with appropriate medical care or "significantly impinge upon the doctor-patient relationship." *Id.* at 200. Rather, the Final Rule leaves a grantee "unfettered in its other activities" because it governs solely the scope of the services funded by Title X grants, *id.* at 196, and doctors and their clients remain free to exchange abortion-related information outside the context of the Title X project, *id.* at 203.[25] Therefore, the Final Rule's measures to ensure that government funds are spent for the purposes for which they were authorized does not violate

[25] Plaintiffs and the *California* district court speculate (without any support in the record) that the Final Rule's referral-list restrictions will delay clients from locating abortion providers and thus leave them worse off. *See California*, 385 F. Supp. 3d at 998. This is merely another version of the argument that Congress cannot prohibit Title X projects from assisting clients seeking abortion referrals. But such an argument has been rejected by the Supreme Court. *See Rust*, 500 U.S. at 193–94 (recognizing that restrictions of this type are permissible to ensure that "the limits of [Title X] are observed" so that project grantees and their employees do not "engag[e] in activities outside of the project's scope").

§ 1554's restrictions on direct regulation of certain aspects of care.

The ACA itself makes clear that § 1554 is meant to prevent direct government interference with health care, not to affect Title X funding decisions. The most natural reading of § 1554 is that Congress intended to ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients. Indeed, by introducing § 1554 with language focusing on the ACA—that "[n]otwithstanding any other provision of this Act," HHS may not take certain steps, 42 U.S.C. § 18114—Congress showed its intent to ensure that certain interests of individuals and entities would be protected notwithstanding the broad scope of the ACA, and that such protections would supersede any other provision of the ACA "in the event of a clash." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 939 (2017) (citations omitted).

By contrast, the ACA did not seek to alter the relationship between federally funded grant programs and abortion in a fundamental way. *See*, *e.g.*, Pub. L. No. 111-148, title X, § 10104(c)(2), 124 Stat. at 897 (codified at 42 U.S.C. § 18023(c)(2)). Section 10104(c)(2)(A) of the Act provides that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." 42 U.S.C. § 18023(c)(2)(A). An Executive Order issued shortly after the ACA was passed emphasized the ACA's neutrality regarding abortion issues, stating that "[u]nder the Act, longstanding Federal laws to protect conscience … re-

main intact and new protections prohibit discrimination against health care facilities and health care providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions." Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act, Exec. Order No. 13,535, 75 Fed. Reg. 15,599 (Mar. 24, 2010). Nor did the ACA single out Title X for any changes. The ACA mentions Title X only to clarify that Title X providers may qualify as "teaching health centers" eligible for funds under a different grant program. *See* Pub. L. No. 111-148, tit. V, § 5508, 124 Stat. at 669–70 (codified at 42 U.S.C. § 293*l*-1).

In short, the ACA did not address the implementation of Congress's choice not to subsidize certain activities. The Final Rule places no substantive barrier on individuals' ability to obtain appropriate medical care or on doctors' ability to communicate with clients or engage in activity when not acting within a Title X project, and therefore the Final Rule does not implicate § 1554.[26]

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[26] The plaintiffs raise several other arguments that the Final Rule violates Title X, but they do not merit much discussion. First, Washington argues that the Final Rule violates § 1008's requirement that "acceptance by any individual of family planning services … shall be voluntary" because the Final Rule requires doctors to provide referrals for prenatal care regardless whether a client asks for abortion information. We disagree. The Final Rule preserves the requirement that "[a]cceptance of services must be solely on a voluntary basis," 42 C.F.R. § 59.5(a)(2), and nothing in the Final Rule makes acceptance of family planning services a "prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program." 42 U.S.C. § 300a-5.

Second, some plaintiffs argue, and the *Washington* district court held, 376 F. Supp. 3d at 1130, that the central purpose of Ti-

In sum, the Final Rule is not contrary to the appropriations rider, § 1554 of the ACA, or Title X. Plaintiffs' claims based on these provisions will not succeed. Accordingly, plaintiffs have not demonstrated likelihood of success on the merits based on these grounds. *See Winter*, 555 U.S. at 20.

IV

We now turn to plaintiffs' arguments that the Final Rule is arbitrary and capricious under the APA.[27] The APA requires a reviewing court to "hold unlawful and

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tle X is "to equalize access to comprehensive, evidence-based, and voluntary family planning" and that the Final Rule is inconsistent with this purpose. We disagree. The Supreme Court determined that provisions substantially identical with those in the Final Rule were consistent with Title X. *Rust*, 500 U.S. at 178–79.

Finally, Washington argues in passing that 42 C.F.R. § 59.18 is invalid because it allows Title X funds to be used "to offer family planing methods and services" but not "to build infrastructure for *purposes prohibited with these funds*, such as support for the abortion business of a Title X grantee or subrecipient." 42 C.F.R. § 59.18(a) (emphasis added). According to Washington, this provision "limits the use of Title X funds for core functions" and therefore violates a provision of Title X authorizing the use of funds "to assist in the establishment and operation of voluntary family planning projects," § 1001; 42 U.S.C. § 300. This argument is meritless, because § 59.18 merely harmonizes § 1001 with § 1008's prohibition on the use of Title X funds "in programs where abortion is a method of family planning." § 1008; 42 U.S.C. § 300a-6.

[27] While the district court in *Oregon* found only "serious questions going to the merits of [the] claims that the Final Rule is arbitrary and capricious," 389 F. Supp. 3d at 903, the *California* district court went further and concluded that the promulgation of the Final Rule was, in fact, arbitrary and capricious, 385 F. Supp. 3d at 1000. Rather than review these determinations separately, we consolidate our analysis given that the Final Rule is not arbitrary and capricious as a matter of law.

set aside agency action, findings, and conclusions found to be … arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). Our review under this directive is narrow and deferential. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019). We "must uphold a rule if the agency has examined the relevant considerations and articulated a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *FERC v. Elec. Power Supply Ass'n*, 136 S. Ct. 760, 782 (2016) (cleaned up). "Th[is] requirement is satisfied when the agency's explanation is clear enough that its path may reasonably be discerned," *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (internal quotation marks omitted), even where an agency's decision is "of less than ideal clarity," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009).

We defer to the agency's expertise in interpreting the record and to "the agency's predictive judgment" on relevant questions. *Id.* at 521; *see also Trout Unlimited v. Lohn*, 559 F.3d 946, 959 (9th Cir. 2009). "It is well established that an agency's predictive judgments about areas that are within the agency's field of discretion and expertise are entitled to particularly deferential review, so long as they are reasonable." *BNSF Ry. Co. v. Surface Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir. 2008) (quoting *Wis. Pub. Power, Inc. v. FERC*, 493 F.3d 239, 260 (D.C. Cir. 2007)). Agency predictions of how regulated parties will respond to its regulations do not require "complete factual support in the record" and "necessarily involve[] deductions based on the expert knowledge of the agency." *FCC v. Nat'l Citizens*

Comm. for Broad., 436 U.S. 775, 814 (1978) (internal quotation marks omitted).[28]

We also defer to the agency's expertise in identifying the appropriate course of action. With respect to the agency's final decision, we cannot "ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives." *Elec. Power Supply Ass'n*, 136 S. Ct. at 782. Nor may we "substitute our judgment for that of the [agency]." *Dep't of Commerce*, 139 S. Ct. at 2569. We are also prohibited from "second-guessing the [agency]'s weighing of risks and benefits and penalizing [it] for departing from the … inferences and assumptions" of others. *Id.* at 2571.

Nor do we give heightened review to agency action that "changes prior policy." *Fox*, 556 U.S. at 514. The APA "makes no distinction … between initial agency action and subsequent agency action undoing or revising that action." *Id.* at 514–15. Initial agency determinations are "not instantly carved in stone." *Chevron*, 467 U.S. at 863. Of course, the "requirement that an agency provide reasoned explanation for its action would ordinarily demand that [the agency] display awareness that it *is* changing position" and "that there are good reasons for the new policy." *Fox*, 556 U.S. at 515. For example, an agency may not "depart from a prior policy *sub silentio* or simply disregard rules that

[28] The district courts relied on the predictions and opinions of experts provided by plaintiffs. *See, e.g.*, *California*, 385 F. Supp. 3d at 1015–19; *Oregon*, 389 F. Supp. 3d at 918; *Washington*, 376 F. Supp. 3d at 1131. But it is not our job to weigh evidence or pick the more persuasive opinions and predictions. Rather, the agency has discretion to rely on its own expertise "even if, as an original matter, a court might find contrary views more persuasive." *Lands Council v. McNair*, 629 F.3d 1070, 1074 (9th Cir. 2010) (internal quotations marks omitted).

are still on the books." *Id.* Likewise, "[i]t would be arbitrary or capricious to ignore," where applicable, that "its new policy rests upon factual findings that contradict those which underlay its prior policy," or that "its prior policy has engendered serious reliance interests that must be taken into account." *Id.* But under our narrow review, an agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *Id.* In sum, we "must confine ourselves to ensuring that [the agency] remained within the bounds of reasoned decisionmaking." *Dep't of Commerce*, 139 S. Ct. at 2569 (internal quotation marks omitted).

Plaintiffs argue that several aspects of the Final Rule are arbitrary and capricious: (1) the physical and financial separation requirement; (2) HHS's overall cost-benefit analysis; (3) the counseling and referral restrictions; (4) the requirement that pregnancy counseling be provided only by medical doctors or advanced practice providers; and (5) the requirement that family planning options be "acceptable and effective," rather than also "medically approved." We consider these arguments in turn.

A

Plaintiffs first argue that HHS's promulgation of the physical and financial separation requirement in 42 C.F.R. § 59.15 was arbitrary and capricious because HHS failed to substantiate an adequate need for the requirement and ignored the predictions of some commenters that the requirement would have a significant

adverse impact on the Title X network and client health.

We disagree. HHS examined the relevant considerations and provided a reasoned analysis for adopting this provision. *See Elec. Power Supply Ass'n*, 136 S. Ct. at 782. It stated its primary reason for reestablishing the requirement was that physical separation would more effectively implement § 1008. 84 Fed. Reg. at 7764. While the financial separation required by the 2000 Rule was a necessary component of § 1008's implementation, HHS explained, physical separation was equally required given Congress's mandate that Title X funds not support programs in any location "'*where*' abortion is offered as a method of family planning." *Id.* at 7765 (emphasis added). HHS also expressly adopted the 1988 Rule's rationale for physical and financial separation upheld in *Rust*, *id.*, and gave ample additional reasons supporting this conclusion.

First, HHS pointed to the public confusion caused when physical separation was lacking. *Id.* According to HHS, the performance of abortion services and Title X-funded services in the same location engendered confusion and rendered it "often difficult for patients, or the public, to know when or where Title X services end and non-Title X services involving abortion begin." *Id.* at 7764. This confusion was evidenced by comments HHS had received on the Final Rule; according to HHS, many commenters seemed wholly unaware of the fact that Title X explicitly excludes funding for projects where abortion is a method of family planning. *Id.* at 7729. HHS could reasonably conclude that the physical separation requirements could help minimize the appearance that the government is funding abortion as a method of family planning. *See* Brief of Amici Curiae Ohio and 12 Other States in Support of Defendants-

Appellants and Reversal at 16–19, *California v. Azar*, Nos. 19-15974 & 19-15979 (9th Cir. June 7, 2019) (emphasizing the importance to many citizens of putting "a greater distance between public funding and abortion-performing entities," and noting that at least 18 states have enacted laws designed to avoid even the appearance that state healthcare funds are being used to support entities involved in abortion services).

Second, HHS concluded that performing all services in the same facility "create[s] a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, … and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics." 84 Fed. Reg. at 7764. This risk is not speculative. As HHS explained, economies of scale and shared overhead achieved through collocation of a Title X clinic and an abortion-providing clinic effectively support the provision of abortion. *See id.* at 7766. HHS relied in part on recent studies that show abortions are increasingly being performed at facilities that had historically focused on providing contraceptive and family planning services (the typical profile of facilities that receive Title X funds), which supports the inference that a growing number of Title X recipients may perform abortions at facilities that also offer Title X-funded services. *Id.* at 7765.

In reaching its conclusion, HHS responded to commenters' concerns in detail. HHS first noted the concern that requiring physical and financial separation "would increase the cost for doing business." *Id.* at 7766. HHS explained that such comments confirmed its concern that Title X funds were directly or indirectly supporting abortion as a method of family planning. *Id.* "Money is fungible," *Holder v. Humanitarian Law Pro-*

ject, 561 U.S. 1, 31 (2010), and HHS reasonably concluded that "flexibility in the use of Title X funds under the 2000 [Rule]" allowed grantees to use Title X funds to "build infrastructure that can be used for [prohibited] purposes … such as support for the abortion business of a Title X grantee," 84 Fed. Reg. at 7773, 7774.

Next, with respect to those Title X projects that would need to make changes to comply with the separation requirements, HHS predicted that the costs of compliance would not be as significant as some commenters predicted. *Id.* at 7781 (noting such commenters "did not provide sufficient data to estimate these [predicted] effects across the Title X program"). HHS discounted the predictions, which relied on "assumptions that [providers] would have to build new facilities in order to comply with the requirements." *Id.* Rather, HHS predicted that most entities would likely choose lower cost methods of compliance. *Id.* For example, "Title X providers which operate multiple physically separated facilities and perform abortions may shift their abortion services, and potentially other services not financed by Title X, to distinct facilities, a change which likely entails only minor costs." *Id.* HHS explained that the Final Rule permitted "case-by-case determinations on whether physical separation is sufficiently achieved to take the unique circumstances of each program into consideration," and that "[p]roject officers are available to help grantees successfully implement the Title X program" and to come up with "a workable plan" for compliance. *Id.* at 7766.

Finally, HHS addressed the "contention of some commenters that the physical and financial separation requirements will destabilize the network of Title X providers," upset the reliance interests of providers who have incurred costs relying on HHS's previous

regulations, and "exacerbate health inequalities or harm patient care." *Id.* HHS disagreed with the commenters' predictions that the separation requirements would result in a significant departure of Title X providers from the program, explaining that the Final Rule "continues to allow organizations to receive Title X funds even if they also provide abortion as a method of family planning, as long as they comply with" the separation requirements. *Id.* HHS further noted that a Congressional Research Service report estimated that only 10 percent of clinics that receive Title X funding offer abortion as a method of family planning. *Id.* at 7781. And while some Title X providers "may share resources with unaffiliated entities that offer abortion as a method of family planning," HHS estimated that only around 20 percent of all Title X service sites had "their Title X services and abortion services … currently collocated" such that they would be materially impacted by the separation requirements. *Id.* Accordingly, HHS concluded that the separation requirements would have only "minimal effect on the majority of current Title X providers." *Id.*

At the same time, HHS predicted that providers who were willing to comply with the new requirements would expand their services and that other provisions of the Final Rule would encourage new "individuals and institutions to participate in the Title X program." *Id.* at 7766. For example, HHS expected "that honoring statutory protections of conscience in Title X may increase the number of providers in the program," because providers or entities would now "know they will be protected from discrimination on the basis of conscience with respect to counseling on, or referring for, abortion." *Id.* at 7780. HHS cited a poll by the Christian Medical Association showing that faith-based med-

ical professionals would limit the scope of their practice without conscience protections; HHS reasoned the Final Rule's prohibition on abortion referral and removal of the 2000 Rule's abortion counseling requirement would allow such professionals to enter the Title X program. *Id.* at 7780 n.138.[29] And while HHS acknowledged that it "cannot calculate or anticipate future turnover in grantees," under HHS's "best estimates," it did "not anticipate that there will be a decrease in the overall number of facilities offering services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." *Id.* at 7782.[30]

Plaintiffs, in effect, argue that HHS's determination was arbitrary and capricious because the agency

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[29] HHS's inferences regarding the data's implication for Title X applications is within HHS's core area of expertise and therefore entitled to deference. *See Trout Unlimited*, 559 F.3d at 959; *BNSF Ry. Co.*, 526 F.3d at 781. The dissent's de novo evaluation of the study is not entitled to such deference. *See* Dissent at 103–104.

[30] In supporting its argument that HHS's cost-benefit analysis is arbitrary and capricious, the dissent looks outside the record to argue that some grantees, such as Planned Parenthood, have voluntarily terminated their participation in Title X. *See* Dissent at 101 & n.15. Of course, such post hoc, extra-record evidence cannot be a basis for determining whether HHS's promulgation of the Final Rule was arbitrary and capricious. In any event, the dissent's extra-record observation is misleading: HHS has issued supplemental grant awards to other Title X recipients that, in HHS's estimation, "will enable grantees to come close to—if not [in excess of]—prior Title X patient coverage," Press Release, Dep't Health & Human Servs., HHS Issues Supplemental Grant Awards to Title X Recipients (Sept. 30, 2019), https://www.hhs.gov/about/news/2019/09/30/hhs-issues-supplemental-grant-awards-to-title-x-recipients.html.

relied on its own predictions and rejected those submitted by commenters opposing the Final Rule. We reject this argument because HHS's predictive judgments about the Final Rule's effect on the availability of Title X services are entitled to deference. *See Trout Unlimited*, 559 F.3d at 959. Here, the predictions concern matters squarely within HHS's "field of discretion and expertise." *BNSF Ry. Co.*, 526 F.3d at 781 (quoting *Wis. Pub. Power*, 493 F.3d at 260). As the agency tasked with implementing the grant program, HHS is in the best position to anticipate the behavior of grantees and prospective grantees. HHS reasonably considered the evidence before it, where "complete factual support" for any prediction was "not possible or required," *Nat'l Citizens Comm. for Broad.*, 436 U.S. at 814, such that its decision "remained 'within the bounds of reasoned decisionmaking,'" *Dep't of Commerce*, 139 S. Ct. at 2569 (quoting *Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 105 (1983)). Although the commenters opposing the Final Rule provided numerous expert declarations elaborating their gloomy assumptions about the future behavior and activities of current and future Title X grantees, at bottom such future-looking "pessimistic" predictions and assumptions are "simply evidence for the [agency] to consider," *Dep't of Commerce*, 139 S. Ct. at 2571, and are not entitled to controlling weight.[31] HHS need not

[31] *Department of Commerce* held that it was not arbitrary and capricious for the Secretary of Commerce to decline to rely on the conclusions of the "technocratic" experts in the Census Bureau. 139 S. Ct. at 2571. So too here: HHS may reasonably decide not to rely on the opinions of outside commenters, even where they claim expertise. The dissent insinuates that reliance on *Department of Commerce* is misplaced because "the Court *struck down* the Secretary of Commerce's attempt to reinstate the citizenship question on the census." Dissent at 101 n.15. But the

produce "some special justification for drawing [its] own inferences and adopting [its] own assumptions." *Id.* Although plaintiffs and the dissent have reached a different conclusion, we consider only whether the agency examined the relevant considerations and laid a reasonably discernable path.

In light of HHS's reasoned explanation of its decisions and its consideration of the comments raised, we reject plaintiffs' arguments that HHS failed to base its decision on evidence, failed to consider potential harms in its cost-benefit analysis, failed to explain its reasons for departing from the 2000 Rule's provisions, and failed to consider the reliance interest of providers who have incurred costs relying on HHS's previous regulation. The Final Rule's separation requirements are not arbitrary and capricious.

B

Plaintiffs and the dissent make a similar argument that HHS's cost-benefit analysis of the Final Rule was arbitrary and capricious. Dissent at 100–106. They argue that HHS ignored the commenters who predicted the Final Rule would cause an exodus of Title X providers and have a deleterious effect on client care, and instead relied on its own predictions about the Final Rule's benefits.

Court "d[id] not hold that the agency decision … was substantively invalid"; it merely affirmed the district court's decision to remand to the agency due to a perceived "mismatch between the decision the Secretary made and the rationale provided." *Dep't of Commerce*, 139 S. Ct. at 2575–76. Here, there is no "disconnect between the decision [HHS] made and the explanation given," *id.* at 2575, so the grounds on which *Department of Commerce* ultimately affirmed the decision to remand are irrelevant.

Like plaintiffs' challenge to the physical and financial separation requirements, the challenge to HHS's cost-benefit analysis fails. HHS considered and addressed "the concern expressed by some commenters regarding the effect of this rule on quality and accessibility of Title X services," and explained its reasons for relying on its own predictions regarding the likely behavior of current and future Title X grantees. 84 Fed. Reg. at 7780. HHS likewise rejected the "extremely high cost estimates" for compliance with the separation requirements, reasoning that providers would tend to seek out lower cost options, such as shifting abortion services to distinct facilities rather than constructing new ones. *Id.* at 7781–82.[32] HHS was not required to accept the commenters' "pessimistic" cost predictions,

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[32] The dissent asserts that HHS "calculated [the] costs of compliance with the physical separation requirement in a 'mystifying' way." Dissent at 102 n.16 (quoting *California*, 385 F. Supp. 3d at 1008). But there is nothing "mystifying" about HHS's cost estimates. HHS estimated that between 10 and 30 percent of all Title X projects would need to be evaluated to determine compliance with the physical separation requirements. 84 Fed. Reg. at 7781. It then predicted that such evaluations would determine that between 10 to 20 percent of the evaluated sites do not comply with the physical separation requirements. *Id.* "At each of these service sites, [HHS] estimates that an average of between $20,000 and $40,000, with a central estimate of $30,000, would be incurred to come into compliance with physical separation requirements in the first year following publication of a final rule in this rulemaking." *Id.* at 7781–82. HHS then added together the costs of conducting the evaluations and bringing non-compliant facilities into compliance, and concluded its estimates "would imply costs of $36.08 million in the first year following publication of a final rule." *Id.* at 7782. Based solely on statements made by plaintiffs' lawyers during oral argument, the dissent speculates that HHS's cost estimates were too optimistic. Dissent at 102 n.16. But we need not favor plaintiffs' pessimistic cost estimates over those provided by HHS. *See Dep't of Commerce*, 139 S. Ct. at 2571.

Dep't of Commerce, 139 S. Ct. at 2571, and the agency adequately explained why it did not expect grantees to participate in a mass rejection of Title X funds, *see* 84 Fed. Reg. at 7766. In light of HHS's conclusion that an ample number of Title X projects would continue to provide family planning services, HHS reasonably concluded that the harms flowing from a gap in care would not develop. *See id*. at 7775, 7782. We give substantial deference to such predictive judgments within the scope of HHS's expertise. *Trout Unlimited*, 559 F.3d at 959. On this record, we will not second-guess HHS's consideration of the risks and benefits of its action. *See Dep't of Commerce*, 139 S. Ct. at 2571.

C

Plaintiffs next assert that the referral restrictions are arbitrary and capricious. They first argue that HHS failed to justify the need for this provision adequately. We disagree. HHS stated it was reestablishing the 1988 Rule for referrals because it concluded that the 2000 Rule was inconsistent with § 1008. Under HHS's interpretation of § 1008, "in most instances when a referral is provided for abortion, that referral necessarily treats abortion as a method of family planning." 84 Fed. Reg. at 7717. Further, HHS concluded that the 2000 Rule's requirement that Title X projects provide abortion referrals and nondirective counseling on abortion was inconsistent with federal conscience laws. *Id*. at 7716. HHS referenced its 2008 nondiscrimination regulations, which had reached the same conclusion. *Id*. (quoting 73 Fed. Reg. at 78,087). HHS also explained that eliminating the 2000 Rule's counseling and referral requirements would "reduce the regulatory burden [on HHS] associated with monitoring and regulating Title X providers for compliance," *id*. at

7719, "add clarity to extant conscience protections, [and make] it easier for entities to participate who may have felt unable to do so in the past," *id.* at 7778. In sum, HHS engaged in "reasoned decisionmaking." *Dep't of Commerce*, 139 S. Ct. at 2569.[33]

Plaintiffs next argue that HHS did not justify the need for the counseling and referral restrictions because non-objecting health care staff could provide counseling and referrals for abortion without violating the federal conscience laws. Therefore, plaintiffs urge, HHS's reliance on federal conscience laws as justification was arbitrary and capricious. We reject this argument, because it amounts to little more than the claim that HHS should have adopted plaintiffs' preferred regulatory approach. But HHS acted well within its authority in deciding how best to avoid conflict with the federal conscience laws. We do not "ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives." *Elec. Power Supply Ass'n*, 136 S. Ct. at 782. Rather, we defer to the agency's reasoned conclusion.

Plaintiffs also argue that HHS failed to consider claims by some commenters that the restrictions would require "providers to violate their ethical obligations to stay in the program" because they require "providers to withhold information about abortion (including referral) that the patient needs," and to provide "a biased

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[33] The plaintiffs' argument that the referral restrictions are arbitrary and capricious because they conflict with guidelines in the QFP is meritless, because these guidelines were based on the 2000 Rule, and are superseded by the Final Rule. *See* Dep't Health & Human Servs., *Announcement of Availability of Funds for Title X Family Planning Services Grants*, at 14–15 (2019).

and misleading list of primary health care providers."[34] But HHS specifically addressed those concerns. It stated that the counseling and referral restrictions would not result in ethical violations because the Final Rule permitted providers to give "nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options, including abortion." 84 Fed. Reg. at 7724.[35] HHS reasoned that the Final Rule al-

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[34] The dissent repeatedly echoes the plaintiffs' claims that the Final Rule contradicts or violates medical ethics because it limits Title X projects from encouraging and supporting abortion and from referring clients to abortion providers. *See* Dissent at 92–93, 98–99 & n.13. Despite the dissent's and plaintiffs' ethical claims, neither cites an opinion from the AMA's *Code of Medical Ethics* directly addressing abortion. *See, e.g.*, Dissent at 99 n.13. Rather, the dissent and plaintiffs cite more general guidance regarding a physician's obligation to inform the patient regarding "treatment alternatives" for medical conditions; because a nontherapeutic abortion is not a "treatment" option for a medical condition but rather a procedure for terminating a healthy pregnancy, such guidance does not directly relate to this issue.

It is not surprising that medical ethical rules are not as absolute as the dissent claims; as noted in *Roe v. Wade*, the AMA's views of medical ethics and abortion changed from a condemnation of the "unwarrantable destruction of human life" to the conclusion that abortions could properly be performed in some circumstances. 410 U.S. 113, 142 (1973). Despite greater public acceptance of abortion today, the issue raises controversial ethical questions, as demonstrated by (among other things) the continued enactment of federal conscience laws and public comments urging HHS to protect physicians' ability to decline to counsel on or refer for abortion. *See* 84 Fed. Reg. at 7746–47; *see also* Brief of Amici Curiae Ohio, *supra* at 16 (many citizens "believe that permitting abortion providers or advocates to participate in providing a government-funded service implies a public imprimatur on abortion—an imprimatur that citizens legitimately seek to withhold").

[35] The dissent argues that in reaching this conclusion, HHS contradicted its prior conclusion in the 2000 Rule as to "what medical ethics demand." Dissent at 99. But HHS did not provide an

lows physicians "to discuss the risks and side effects of each option, [including abortion,] so long as this counsel in no way promotes or refers for abortion as a method of family planning." *Id.* A client may "ask questions and … have those questions answered by a medical professional." *Id.* HHS also noted that where care is medically necessary, referral for that care is required, notwithstanding the Final Rule's other requirements. *Id.* Consistent with *Rust*, HHS concluded that "it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers." *Id.* at 7746.[36] These statements show HHS examined the relevant considerations arising from commenters citing medical ethics and rationally articulated an ex-

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opinion on this issue when it overruled its prior 1988 Rule; it merely referenced the views of commenters, without adopting those views as its own. *See* 65 Fed. Reg. at 41,273. Thus, the dissent's argument that HHS "changed its position on what medical ethics demand" is meritless.

[36] *Rust* rejected ethical arguments similar to those raised here. *See* 500 U.S. at 213–14 (Blackmun, J. dissenting) (arguing that "the ethical responsibilities of the medical profession demand" that a physician be free to inform patients about abortion). According to the Court, "the Title X program regulations do not significantly impinge upon the doctor-patient relationship" because, among other reasons, "the doctor-patient relationship established by the Title X program [is not] sufficiently all encompassing so as to justify an expectation on the part of the patient of comprehensive medical advice," and "a doctor's silence with regard to abortion cannot reasonably be thought to mislead a client into thinking that the doctor does not consider abortion an appropriate option for her," given that "[t]he program does not provide post conception medical care." *Id.* at 200. And under the Final Rule, as under the 1988 Rule, "[t]he doctor is always free to make clear that advice regarding abortion is simply beyond the scope of the program." *Id.*

planation for its conclusion. *See Elec. Power Supply Ass'n*, 136 S. Ct. at 782.

Because HHS's decisionmaking path "may reasonably be discerned," *Dep't of Commerce*, 139 S. Ct. at 2578, we reject plaintiffs' claims that the counseling and referral restrictions are arbitrary and capricious.

D

We next consider plaintiffs' claim that the Final Rule's requirement that all pregnancy counseling be provided by medical doctors or advanced practice providers is arbitrary and capricious. Plaintiffs argue that because HHS defined the term "advanced practice providers" too narrowly, and did not have a reasoned basis for drawing the line at which medical professionals may provide pregnancy counseling, the provision is arbitrary and capricious.

We disagree. HHS explained that, in its judgment, "medical professionals who receive at least a graduate level degree in the relevant medical field and maintain a federal or State-level certification and licensure to diagnose, treat, and counsel patients … are qualified, due to their advanced education, licensing, and certification to diagnose and treat patients while advancing medical education and clinical research." 84 Fed. Reg. at 7728.[37] We have no basis to conclude that this line-

[37] Although the dissent asserts that this requirement will "reduce the number of people who can provide pregnancy counseling and … require significant changes in Title X providers' staffing," Dissent at 102, HHS's definition covers a wide range of licensed medical professionals that HHS reasonably deemed qualified to provide health care advice, including physician assistants, certified nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwifes, *see* 42 C.F.R. § 59.2.

drawing determination, an inherently discretionary task, "is so implausible" that a difference with plaintiffs' views "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). Accordingly, we reject plaintiffs' arguments that HHS's technical determination of which medical professionals may provide pregnancy counseling is arbitrary and capricious.

E

Finally, we reject plaintiffs' argument that HHS was arbitrary and capricious in reestablishing the language of the 1988 Rule's requirement that all family planning methods and services be "acceptable and effective," instead of retaining the 2000 Rule's revision requiring that such methods and services also be "medically approved." 84 Fed. Reg. at 7732.

HHS adequately explained its reasons for reestablishing the 1988 Rule. HHS explained that the change was intended to "ensure that the regulatory language is consistent with the statutory language," *id.* at 7740, which requires Title X projects to "offer a broad range of acceptable and effective family planning methods and services," 42 U.S.C. § 300(a). HHS also explained that the meaning of "medically approved" was unclear. 84 Fed. Reg. at 7741. "For example, would approval by one medical doctor suffice, or would some larger number need to approve, and if so, how many; would certain medical organizations, or governmental organizations, or both, need to approve, and if so, which ones; would a certain level of medical consensus need to exist concerning a particular method or service, and if so, how would the Department measure that consensus; and when doctors and medical organizations disagree either

about a family planning method or service, how would that requirement apply?" *Id.* at 7732.

HHS also explained its rejection of the comment suggesting the phrase "medically approved" means "FDA approved." HHS stated that "[s]ome family planning methods cannot be medically approved by … the [FDA], because they do not fall within its jurisdiction," and provided examples, such as fertility-awareness based methods of family planning. *Id.* at 7741 & n.69. In HHS's judgment, "[t]his did not mean that such methods of family planning are unacceptable or ineffective in the view of medical sources." *Id.* at 7741. Accordingly, HHS determined that "[t]he statutory language of 'acceptable and effective family methods or services,' without the phrase 'medically approved[,]' provides sufficient guidance to Title X projects in considering the types of family planning methods and services that they provide." *Id.*

HHS likewise sufficiently addressed comments that its decision to omit the phrase "medically approved" would promote political ideology over science, lead to negative health consequences for clients, and undermine recommendations from other agencies. *See id.* at 7740–41. We defer to HHS's reasonable conclusion that Title X's statutory requirement that family planning methods and services must be "acceptable and effective" sufficiently prohibits Title X projects from engaging in health fraud or quackery. *Id.* at 7741.

Because HHS "examined the relevant considerations and articulated a satisfactory explanation for its action," *Elec. Power Supply Ass'n*, 136 S. Ct. at 782 (cleaned up), we reject plaintiffs' argument that this change was arbitrary and capricious.

In sum, we hold that the Final Rule is not arbitrary and capricious.

* * *

Because plaintiffs' claims will not succeed given our resolution of the underlying legal questions, we end our analysis here. *See Munaf*, 553 U.S. at 691; *Garcia*, 786 F.3d at 740. We hold that the Final Rule is a reasonable interpretation of § 1008, it does not conflict with the 1996 appropriations rider or other aspects of Title X, and its implementation of the limits on what Title X funds can support does not implicate the restrictions found in § 1554 of the ACA. Moreover, the Final Rule is not arbitrary and capricious because HHS properly examined the relevant considerations and gave reasonable explanations. *See Elec. Power Supply Ass'n*, 136 S. Ct. at 782. Plaintiffs will not prevail on the merits of their legal claims, so they are not entitled to the "extraordinary remedy" of a preliminary injunction. *See Winter*, 555 U.S. at 22. Accordingly, the district courts' preliminary injunction orders are vacated and the cases are remanded for further proceedings consistent with this opinion. The government's motion for a stay pending appeal is denied as moot.

VACATED AND REMANDED.[38]

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[38] Costs on appeal shall be taxed against plaintiffs.

PAEZ, Circuit Judge, joined by THOMAS, Chief Judge, WARDLAW and FLETCHER, Circuit Judges, dissenting:

Millions of Americans depend on Title X for their health care, including lifesaving breast and cervical cancer screenings, HIV testing, and infertility and contraceptive services. Congress created the Title X program in 1970 to ensure that family planning services would be "readily available to all persons desiring such services," Pub. L. No. 91-572 § 2, 84 Stat. 1504 (1970), and entrusted the United States Department of Health and Human Services ("HHS") with the responsibility of disbursing Title X funds to health care providers serving low-income Americans.

Since then, Congress has twice circumscribed HHS's authority in administering the Title X program. First, Congress directed that the health care providers who receive Title X funds inform pregnant patients of their options without advocating one choice over another. Second, Congress barred HHS from promulgating regulations that burden patients' access to health care, interfere with communications between patients and their health care providers, or delay patients' access to care.

In 2019, HHS promulgated the regulations at issue in this litigation ("the Rule"). *See* Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019). Among other things, the Rule gags health care providers from fully counseling women about their options while pregnant and requires them to steer women toward childbirth (the "Gag Rule"). It also requires providers to physically and financially separate any abortion services they provide (through

non-Title X funding sources) from all other health care services they deliver (the "Separation Requirement").

Three separate district courts in well-reasoned opinions recognized that the Rule breaches Congress's limitations on the scope of HHS's authority and enjoined enforcement of the Rule.[1] In vacating the district courts' preliminary injunctions, the majority sanctions the agency's gross overreach and puts its own policy preferences before the law. Women[2] and their families will suffer for it. I strongly dissent.

* * *

The majority would return us to an older world, one in which a government bureaucrat could restrict a medical professional from informing a patient of the full range of health care options available to her. Fortunately, Congress has ensured such federal intrusion is no longer the law of the land.

The majority heavily relies, mistakenly, on *Rust v. Sullivan* and *Harris v. McRae*, decisions that held the Constitution confers no affirmative entitlement to state

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[1] *See Oregon v. Azar* (*Oregon*), 389 F. Supp. 3d 898 (D. Or. 2019); *State of California v. Azar* (*California*), 385 F. Supp. 3d 960 (N.D. Cal. 2019); *Washington v. Azar* (*Washington*), 376 F. Supp. 3d 1119 (E.D. Wash. 2019).

[2] While the Rule disproportionately impacts women, people of all genders rely on Title X services, can become pregnant, and will suffer the consequences of the Rule. *See*, *e.g.*, Cal. Code Regs., tit. 2, § 11035(g) (defining individuals eligible for pregnancy accommodation as including "transgender employee[s] who [are] disabled by pregnancy"); Jessica A. Clarke, *They Them, and Theirs*, 132 Harv. L. Rev. 894, 954 (2019) ("People of all gender identities can be pregnant[.]"); *see also* Juno Obedin-Maliver & Harvey J. Makadon, *Transgender Men and Pregnancy*, 9 Obstetric Med., 4, 5 (2016).

subsidization of abortion. Maj. Op. 22–24, 50 n.21, 55–59; *Rust*, 500 U.S. 173, 201 (1991); *McRae*, 448 U.S. 297, 318 (1980); *see also Webster v. Reproductive Health Services*, 492 U.S. 490, 509 (1989); *Maher v. Roe*, 432 U.S. 464, 474 (1977). "Whether freedom of choice that is constitutionally protected warrants federal subsidization," the Court reasoned in *McRae*, "is a question for Congress to answer, not a matter of constitutional entitlement." 448 U.S. at 318. It is constitutionally permissible to "leave[] an indigent woman with at least the same range of choice in deciding whether to obtain a medically necessary abortion as she would have had if Congress had chosen to subsidize no health care costs at all." *Id.* at 317. In other words, Congress can choose to disburse its funds however it likes. I do not take issue with that principle.

The problem for the majority's position is that Congress has in fact chosen to disburse public funds differently since the days of *Rust*. Perhaps recognizing that medical ethics and gender norms have evolved, Congress in 1996 and again in 2010 enacted statutory protections that exceed the constitutional floor set decades ago. In 1996 (and every year since) Congress clarified that its decision not to subsidize abortion does not prohibit pregnancy counseling on the range of women's options; to the contrary, Congress explicitly required that "all pregnancy counseling shall be nondirective." Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321 (1996) ("the nondirective mandate"). And, in 2010, Congress prohibited HHS from promulgating regulations that frustrate patients' ability to access health care. 42 U.S.C. § 18114.

The majority disregards twenty years of progress, insistent on hauling the paternalism of the past into the

present. Because Congress has clarified the scope of HHS's authority, the *Rust* line of cases has little bearing on the matter before us. Our only task is to determine whether HHS has exceeded the authority Congress granted it. And as the district courts concluded, it has.

I. THE RULE VIOLATES CONGRESS'S NONDIRECTIVE MANDATE

Since 1996, Congress has provided a clear limitation on Title X funding, specifying "that all pregnancy counseling *shall be nondirective*." Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, and Continuing Appropriations Act, Pub. L. No. 115-245, 132 Stat. 2981, 3070–71 (2018) (emphasis added). The district courts separately determined that the Rule conflicts with Congress's nondirective mandate. 5 U.S.C. § 706(2)(A); *see Oregon*, 389 F. Supp. 3d at 909–13; *California*, 385 F. Supp. 3d at 986–92; *Washington*, 376 F. Supp. 3d at 1130. I agree.[3]

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[3] We review for abuse of discretion the district courts' grant of the preliminary injunctions. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). "The district court's interpretation of the underlying legal principles, however, is subject to de novo review and a district court abuses its discretion when it makes an error of law." *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003). Because Plaintiffs' first two claims, namely whether the Rule violates Congress's nondirective mandate or the Affordable Care Act, turn on the merits of several legal issues, I agree with the majority that we may address the merits of those issues directly. The majority goes too far, however, in adjudicating the merits of the third claim, namely whether the promulgation of the Rule was arbitrary and capricious, for the reasons discussed in Section III, *infra*.

The Rule is nothing but directive. By its very terms, it requires a doctor to refer a pregnant patient for prenatal care, even if she does not want to continue the pregnancy, while gagging her doctor from referring her for abortion, even if she has requested specifically such a referral. 42 C.F.R. §§ 59.14(a), (b). The Rule does not stop there. If a doctor provides a patient a referral list of primary health care providers, no more than half of those providers may offer abortion services. 42 C.F.R. § 59.14(c)(2). And if the patient asks who on the list might actually provide her an abortion? The Rule muzzles her doctor from telling her. *Id.* The result is that patients are steered toward childbirth at every turn.

What can a doctor even say when confronted with her patient's questions about abortion? The Rule bars doctors from "promot[ing] … or support[ing] abortion as a method of family planning, []or tak[ing] any other affirmative action to assist a patient" in exercising her right to abortion. 42 C.F.R. § 59.14(a); *see also* 42 C.F.R. § 59.5(a)(5). Imagine a patient visits her Title X provider and asks whether she can get an abortion at the local hospital. Would it qualify as "promoting" abortion to answer the question? The Gag Rule makes doctors who desire to provide their patients with accurate information "walk on eggshells to avoid a potential transgression of the … Rule, whereas those describing the option of continuing the pregnancy face no comparable risk." *California*, 385 F. Supp. 3d at 992.

The result is Kafkaesque. *Oregon*, 389 F. Supp. 3d at 912. As Judge McShane of the District of Oregon observed:

> The Gag Rule is remarkable in striving to make professional health care providers deaf and

> dumb when counseling a client who wishes to have a legal abortion or is even considering the possibility. The rule handcuffs providers by restricting their responses in such situations to providing their patient with a list of primary care physicians who can assist with their pregnancy without identifying the ones who might perform an abortion. Again, the response is required to be, "I can't help you with that or discuss it. Here is a list of doctors who can assist you with your pre-natal care despite the fact that you are not seeking such care. Some of the providers on this list—but in no case more than half—may provide abortion services, but I can't tell you which ones might. Have a nice day." This is madness.

Id. at 913 (footnote omitted).

The majority purports to see no problem here. Although HHS itself defines "nondirective counseling" as "the meaningful presentation of options where the [medical professional] is 'not suggesting or advising one option over another,'" 84 Fed. Reg. at 7716 (citation omitted), the majority insists such counseling does not require the meaningful presentation of "all" options. Maj. Op. 47. Rather, in the majority's tortured telling, "nondirective" requires only the "neutral" presentation of *some* options.[4] Maj. Op. 47.

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[4] The majority sanctions HHS's post hoc interpretation that "counseling" does not include "referrals." Maj. Op. 41–46. Judge Chen of the Northern District of California readily dismissed this argument. *California*, 385 F. Supp. 3d at 988–91. As Judge Chen explained, nondirective counseling encompasses referrals for three reasons. First, Congress expressly stated so, a point HHS recognized when it promulgated the Rule. *See* 42 U.S.C. § 254c-6(a)(1)

Excluding an entire category of options is neither meaningful nor neutral. If a man were diagnosed with prostate cancer, and his doctor concluded that chemotherapy, radiation, or hospice were equally viable responses, each with different consequences for his quality of life, he would be upset, to say the least, to discover that he had been referred only for hospice care. Such a sham "presentation" of options would in no sense be nondirective.

So too here. Indeed, HHS itself has recognized that there can be no meaningful choice when a whole category of options is hidden from a patient: "In nondirective counseling, abortion must not be the only option presented by [medical professionals]; otherwise the counseling would violate … the Congressional directive that all pregnancy counseling be nondirective[.]" 84 Fed. Reg. at 7747. The Gag Rule does exactly that. For all pregnancy counseling not involving abortion, women can take an "active" and "informed" role in their pregnancy and family planning process; but once a

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(requiring HHS to make training grants on "providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in* nondirective counseling to pregnant women") (emphasis added); 84 Fed. Reg. at 7733 ("Congress has expressed its intent that postconception adoption information and *referrals be included as part of any nondirective counseling* in Title X projects when it passed … 42 U.S.C. 254c-6[.]") (emphasis added). Second, HHS itself describes referrals as part of counseling throughout the Rule and has done so across administrations. *See, e.g.*, 84 Fed. Reg. at 7730, 7733–34; U.S. Dep't Health & Human Services, *Program Guidelines for Project Grants for Family Planning Services* § 8.2 (1981) ("Post-examination counseling should be provided to assure that the client … receives appropriate referral for additional services as needed."). Third, industry understanding recognizes that counseling includes referrals. *See California*, 385 F. Supp. 3d at 989.

woman asks for abortion information, she can no longer be provided all the information she seeks about her own medical care. *See* 84 Fed. Reg. at 7716–17. "[E]mpower[ed]" so long as she does what the agency and the majority want; "coerc[ed]" and demeaned if she tries to "take an active role in … identifying the direction" of her life's course. 84 Fed. Reg. at 7716; 65 Fed. Reg. at 41275.[5] The consequences will be profound, de-

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[5] Indeed, in 2000, the agency concluded 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." 65 Fed. Reg. at 41275 (emphasis added).

The majority attempts to salvage the prenatal care referral requirement by claiming that prenatal care is medically necessary for *all* patients' health, regardless of their intent to end a pregnancy. Maj. Op. 48 & n.19. That's not true, as the American College of Obstetricians and Gynecologists ("ACOG") and other professional medical associations, as well as numerous physicians and other health care providers have attested. *See, e.g.*, Br. of Amici Curiae Am. Coll. of Obstetricians & Gynecologists, et al., at 14–15 ("Prenatal care is not medically indicated when a pregnant patient plans to terminate her pregnancy—it is recommended only when a patient plans to continue her pregnancy."); Decl. of J. Elisabeth Kruse, Nat'l Family Planning & Reprod. Health Ass'n Supplemental Excerpts of Record ("SER") at 256 (*Washington*) ("[O]f course, such care is *not* medically necessary for someone who wishes to terminate her pregnancy."); Decl. of Dr. Melissa Marshall, California SER 579 (*California*) ("[P]renatal health care is not medically necessary when a patient is terminating her pregnancy."); Decl. of Dr. Judy Zerzan-Thul, Washington SER 161 (*Washington*) ("[I]f a patient determined to be pregnant elects to terminate the pregnancy, pre-natal care would not be medically necessary."). And, regardless, that's not how HHS justified the requirement. Rather, HHS required the prenatal care referral because "such care is important" not only for women's health but also "for healthy *pregnancy and birth*." 84 Fed. Reg. at 7722 (emphasis added).

laying some women's access to time-sensitive care and preventing others from accessing abortion altogether.[6]

Congress has prohibited such a result. Contrary to the majority's contention that HHS is owed *Chevron* deference because Congress has not clarified the meaning of the term "nondirective", Maj. Op. 46, Congress

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[6] As health care providers and amici make clear, the notion that "information about abortion is readily available 'on the internet' betrays a complete lack of understanding of the realities of our Title X patient population" who, "because of language, literacy (including health literacy and electronic literacy), or economic barriers[,]" depend on referrals from Title X providers in order to access care. Kruse, Nat'l Family Planning & Reprod. Health Ass'n SER 262 (*Washington*); *see also* Decl. of Dr. Sarah Prager, *id.* at 298–99 ("Because many Title X patients have linguistic, educational, informational, and financial barriers to accessing healthcare, the impediments introduced by the New Rule may prevent such patients from accessing abortion altogether."); Decl. of Dr. Blair Darney, Oregon SER 41 (*Oregon*) ("Researchers have studied the reasons women delay entry to care for abortion; logistics such as knowing where to go is among the reasons."); *cf.* Maj. Op. 50 n.21.

The barriers created by the Gag Rule are particularly substantial for young people, LGBTQ people, those with limited English proficiency, and patients in rural areas. *See, e.g.*, Br. of Amici Curiae Nat'l Ctr. for Youth Law, et al., at 16–17 ("Adolescents without easy access to transportation, a phone, and the Internet might be unable to research the providers on the list they are given. They also might not immediately comprehend that a medical professional, whom they trust, has referred them for care that they do not need or want … Particularly for adolescents who are homeless or in foster care, navigating a maze of providers that might or might not offer abortion services could prove impossible."); Br. of Amici Curiae Nat'l Ctr. for Lesbian Rights, et al., at 13; Decl. of Kathryn Kost, California SER 156 (*California*). As one health care provider concluded, "The New Rule's coercive requirements would force me to disrespect, contradict, and patronize my patient, and violate her trust[.]" Kruse, Nat'l Family Planning & Reprod. Health Ass'n SER 262 (*Washington*).

has in fact done so. And where Congress's intent is clear, we "must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

Congress has used "nondirective counseling" in only two instances: the annual HHS Appropriations Act at issue here and section 254c-6(a)(1) of the Public Health Service Act ("PHSA"). The latter provides that HHS shall make training grants "providing adoption information and referrals to pregnant women *on an equal basis with all other courses of action included in nondirective counseling* to pregnant women." 42 U.S.C. § 254c-6(a)(1) (emphasis added).

In response, the majority asserts that because § 254c-6(a)(1) is not part of Title X and was enacted for a different purpose, "it sheds no light on Congress's intent in enacting the appropriations rider or on the interpretation of its statutory language." Maj. Op. 44. If § 254c-b(a)(1) sheds no light, HHS certainly didn't think so: it *relied* on the PHSA definition in formulating the Rule. *See* 84 Fed. Reg. at 7733 ("Congress has expressed its intent that … referrals be included as part of any nondirective counseling in Title X projects when it passed the … Public Health Service Act[.]"); 84 Fed. Reg. at 7745. As HHS apparently recognized, Congress's use of the term "nondirective counseling" should be read consistently between the PHSA and the nondirective appropriations rider to include providing referrals on an equal basis with all other options. *See Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972) ("[A] legislative body generally uses a particular word with a consistent meaning in a given context."); *see also Dir., Office of Workers' Comp. Prog., Dep't of Labor v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995) (instructing that in interpreting an ambigu-

ous statutory phrase, "[i]t is particularly illuminating to compare" two different statutes employing the "virtually identical" phrase).

Because the Gag Rule requires doctors to push patients toward one option over another, it violates Congress's mandate that patients receive counseling on their pregnancy options in a nondirective manner.

II. THE RULE VIOLATES SECTION 1554 OF THE AFFORDABLE CARE ACT

In 2010, as part of the Affordable Care Act's ("ACA") sweeping reforms, Congress imposed limits on the scope of HHS's regulatory authority:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates principles of informed consent and the ethical standards of health care professionals; or

(6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114 ("section 1554"). The three district courts separately determined that the Rule violates section 1554 of the ACA. *See Oregon*, 389 F. Supp. 3d at 914–15; *California*, 385 F. Supp. 3d at 992–1000; *Washington*, 376 F. Supp. 3d at 1130. I agree.

First, the Gag Rule—which restricts communications between health care providers and patients, 42 C.F.R. §§ 59.14(a)–(c)—will "obfuscate and obstruct patients from receiving information and treatment for their pressing medical needs." *California*, 385 F. Supp. 3d at 998; *see also Washington*, 376 F. Supp. 3d at 1130. In so doing, the Rule exceeds HHS's statutory authority: it "impedes timely access to health care services[,]" "interferes with communications regarding a full range of treatment options[,]" "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions[,]" and "violates … the ethical standards of health care professionals[.]" 42 U.S.C. § 18114.

Second, the Separation Requirement—which requires Title X recipients to physically and financially separate abortion provision from all other medical services, through the use of separate entrances and exits as well as separate accounting, personnel, and medical records, 42 C.F.R. § 59.15—plainly will impinge on the ability of providers to offer care. *See Oregon*, 389 F. Supp. 3d at 915; *Washington*, 376 F. Supp. 3d at 1130. By its own terms, HHS's Separation Requirement creates unreasonable barriers to health care; it also frustrates "timely access" to care, contrary to Congress's

plain directive that HHS may not do so. 42 U.S.C. § 18114.

Finally, the Rule's requirement that doctors encourage family participation in reproductive decisions will "force [doctors] to breach their ethical obligations" in certain circumstances. *California*, 385 F. Supp. 3d at 1000; *see also Washington*, 376 F. Supp. 3d at 1130. This requirement directly contravenes Congress's prohibition on promulgating regulations that "violate[] … the ethical standards of health care professionals[.]" 42 U.S.C. § 18114.

Tellingly, the majority does not even attempt to argue that the Rule complies with the ACA. Instead, it characterizes the Rule as falling conveniently outside the scope of the limitations Congress imposed on HHS in the ACA. It relies on the *Rust* and *McRae* line of cases for the proposition that, as a constitutional matter, Congress need not subsidize abortion. It then asserts that the constitutional minima identified in those cases "applies equally" to statutory claims. Maj. Op. 55–59. The majority offers no support for this bold proposition.

How could it? Congress may, and regularly does, enact statutory requirements and protections that exceed the constitutional floor. *Aetna Life Ins. Co. v. Lavoie*, 475 U.S. 813, 828 (1986) ("The Due Process Clause demarks only the outer boundaries … Congress and the states, of course, remain free to impose more rigorous standards[.]"); *Am. Legion v. Am. Humanist Assoc.*, 139 S. Ct. 2067, 2094 (2019) (Kavanaugh, J., concurring) ("The constitutional floor is sturdy and often high, but it is a floor."). That is exactly what Congress has done

here.[7] That a congressional decision not to subsidize abortion does not burden the abortion right in the *constitutional* sense, *see e.g.*, *McRae*, 448 U.S. at 316, has no bearing whatsoever on whether an agency has overstepped its statutory authority. And, here, the agency has.[8]

III. THE RULE IS LIKELY ARBITRARY AND CAPRICIOUS

Finally, I turn to Plaintiffs' claim that the promulgation of the Rule was arbitrary and capricious under the Administrative Procedure Act ("APA"). As an initial matter, the majority contends that it is appropriate, on review of the district courts' preliminary injunctions, to adjudicate the merits of the arbitrary and capricious claim. Maj. Op. 35–39. It is not. Unlike our

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[7] The majority's assertion that the ACA does not impact Title X is contradicted by the terms of the ACA. Maj. Op. 59–60. Section 1554 governs "*any* regulation," 42 U.S.C. § 18114 (emphasis added). If Congress had meant to restrict its scope to the ACA, it would have said "any regulation *pursuant to this Act*." *Cf. St. Paul Fire & Marine Ins. Co. v. Barry*, 438 U.S. 531, 550 (1978) (discussing the breadth of the word "any" and concluding that if Congress intends to limit the scope of statutory language, it will make that explicit). As Judge Chen reasoned, the clause "[n]otwithstanding any other provision of this Act" is most naturally read to mean that the Secretary "cannot engage in the type of rulemaking proscribed by [s]ection 1554 even if another provision … could be construed to permit it." *California*, 385 F. Supp. 3d at 995. In other words, "the directive of [s]ection 1554 is to be given primacy" over other parts of the ACA.

[8] The majority makes much of the fact that the Rule is purportedly "less restrictive in at least one important respect" than the 1988 regulation upheld in *Rust*. Maj. Op. 16. That is immaterial. The *Rust* decision predated the passage of the nondirective mandate by half a decade and the ACA by two decades, so whether the Rule or its 1988 predecessor violated those laws was not and could not possibly have been before the Court.

consideration of Plaintiffs' first two claims, which required us to address the underlying legal question to determine whether the district courts abused their discretion, review of the arbitrary and capricious claim requires examination of the administrative record. We do not have the complete administrative record before us, and neither did the district courts when they issued the preliminary injunctions. Deciding the merits of Plaintiffs' arbitrary and capricious claim is therefore premature. *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more *nor less* information than did the agency when it made its decision.") (emphasis added); *Nat. Res. Def. Council, Inc. v. Train*, 519 F.2d 287, 291 (D.C. Cir. 1975) ("The Administrative Procedure Act and the cases require that the complete administrative record be placed before a reviewing court."); *see also Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) ("[G]iven the haste that is often necessary … a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits. A party thus is not required to prove his case in full at a preliminary-injunction hearing[.]").[9] Indeed, "[t]o review less than the full administrative record might allow a party to withhold evidence unfavorable to its case, and so the

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[9] Indeed, while Defendants pursued their appeals of the preliminary injunctions, briefing advanced to the merits in the Eastern District of Washington. There, Defendants produced to Plaintiffs the full administrative record (two months after the preliminary injunction issued), *see* Case No. 1:19-cv-03040-SAB, Dkt. No. 88 (June 24, 2019) and, with the benefit of the complete record, Plaintiffs further developed their arbitrary and capricious claim. *See* Case No. 1:19-cv-03040-SAB, Dkt. No. 121 (Nov. 20, 2019).

APA requires review of 'the whole record.'" *Boswell Mem'l Hosp.*, 749 F.2d at 792. Accordingly, I address only Plaintiffs' *likelihood* of success on the merits. The majority should have done the same.[10]

Under the APA, a court "shall … hold unlawful and set side agency action … found to be … arbitrary [and] capricious." 5 U.S.C. § 706(2)(A). An agency action is arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs' Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (internal quotation marks omitted).

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[10] The cases on which the majority relies to proceed to the merits are inapt. First, unlike the cases the majority cites, Maj. Op. 35–39, we do not have the full administrative record before us. *Cf. Beno v. Shalala*, 30 F.3d 1057, 1064 n.11 (9th Cir. 1994) (reaching the merits because "Plaintiffs' … claim requires a review of the administrative record, which is *complete*, and interpretation of relevant statutes; additional fact-finding is not necessary to resolve this claim") (emphasis added); *Blockbuster Videos, Inc. v. City of Tempe*, 141 F.3d 1295, 1297 (9th Cir. 1998) (same, because "[t]he record … is fully developed"); *see also Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("The APA specifically contemplates judicial review *on the basis of the agency record compiled in the course of … [the] agency action*[.]") (emphasis added). Nor is this a case that implicates sensitive foreign policy concerns. *Munaf v. Geren*, 553 U.S. 674, 692 (2008) (reasoning that reaching the merits was "the wisest course" because the case "implicate[d] sensitive foreign policy issues in the context of ongoing military operations").

When an agency changes its policy, the agency must provide a "reasoned explanation for its action." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). The new policy need not be better than the old one, but it must be permissible and based on "good reasons." *Id.* When the reasons the agency relies on for changing its position are "not new," the agency fails to provide a "reasoned explanation." *Org. Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 967 (9th Cir. 2015) (en banc). "In explaining its changed position, an agency must also be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (internal quotation marks omitted). Here, the Rule replaced the regulation adopted in 2000, not the 1988 regulation addressed in *Rust*; thus the 2000 Rule is the one to which we must look to assess HHS's changed positions. *See* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41270 (Jul. 3, 2000). Plaintiffs are likely to prevail on their claim that the promulgation of the Rule was arbitrary and capricious for at least two reasons.[11]

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[11] None of the district courts needed to address Plaintiffs' arbitrary and capricious arguments because they had independently found Plaintiffs were likely to succeed on their other merits arguments. Nevertheless, each district court recognized the strength of Plaintiffs' APA challenge. *California*, 385 F. Supp. 3d at 1000–19 (addressing—with painstakingly detailed analysis—the shortcomings of HHS's justifications for the physical separation requirement, the counseling and referral restrictions, the "physicians or advanced practice providers" requirement, and the removal of the "medically approved" requirement, as well as HHS's inadequate cost-benefit analysis); *Oregon*, 389 F. Supp. 3d at 917–18 (noting that HHS "nowhere squares" particular medical ethics requirements with the requirements of the Rule and that HHS "ap-

A. HHS Failed to Provide a Reasoned Justification for Its Policy Change

First, the Rule represents a dramatic shift in policy, yet HHS failed to provide the required "reasoned explanation for its action." *Fox Television*, 556 U.S. at 515. Take the Gag Rule and Separation Requirement, for example. In 2000, when it adopted regulations rescinding the 1988 version of the Gag Rule, HHS explicitly considered Congress's recently enacted nondirective mandate as well as comments emphasizing that "medical ethics and good medical care … requir[e] that patients receive full and complete information to enable them to make informed decisions"; "[c]onsequently," the agency "decided to reflect [the nondirective requirement] … in the regulatory text." 65 Fed. Reg. at 41273. By contrast, here HHS has changed its position on what medical ethics demand without providing a reasoned explanation for or acknowledgment of the change, as is required by the APA.[12] *See Org. Vill. of Kake*, 795 F.3d at 966 ("Unexplained inconsistency between agency actions is a reason for holding an interpretation to be an arbitrary and

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pears to have failed to seriously consider persuasive evidence"); *Washington*, 376 F. Supp. 3d at 1131 (recognizing that Plaintiffs and amici had "presented facts and argument that the … Rule is arbitrary and capricious because it reverses long-standing positions of [HHS]" without considering relevant medical opinions and likely consequences).

[12] That abortion remains controversial, as the majority contends, Maj. Op. 75 n.34, does not explain why HHS may shift its understanding of medical ethics from 2000 without a reasoned explanation.

capricious change.") (internal quotation marks and citation omitted).[13]

Similarly, in 2000, HHS recognized that "Title X grantees are subject to rigorous financial audits" and ultimately concluded that a physical separation requirement "is *not* likely ever to result in an enforceable compliance policy that is consistent with the efficient

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[13] I also agree with Judge McShane of the District of Oregon that HHS's "failure to respond meaningfully to the evidence" that the Gag Rule contradicts medical ethics "renders its decision[] arbitrary and capricious." *Oregon*, 389 F. Supp. 3d at 918 (quoting *Tesoro Alaska Petroleum Co. v. FERC*, 234 F.3d 1286, 1294 (D.C. Cir. 2000)). A doctor and leader of the American Medical Association—the organization that "literally wrote the book on medical ethics"—stated that the American Medical Association's *Code of Medical Ethics* prohibits withholding information from a patient, except in emergency situations, and requires decisions or recommendations to be based on the patient's medical needs. *Id.* at 916. He concluded that the Gag Rule "is an instruction to physicians to intentionally mislead patients, which, if followed, is an instruction for physicians to directly violate the *Code of Medical Ethics*[.]" *Id.* at 917.

In its cursory response, HHS merely announced that it "believes" the Rule presents no ethical problems because patients are permitted to ask questions "and to have those questions answered by a medical professional." 84 Fed. Reg. at 7724. That assertion is contradicted by the plain text of the Rule, which specifically prohibits medical professionals from answering certain questions, such as, "who on this list is an abortion provider?" 42 C.F.R. § 59.14(c)(2). HHS's insistence that the Gag Rule is "nondirective" does not salvage the Rule either, as it is both conclusory and, for the reasons explained in Section I, *supra*, false. Because the Gag Rule "contradicts … persuasive evidence from the leading expert on medical ethics," and HHS has failed to present even a "plausible explanation outlining its rationale for rejecting the evidence and reaching a different conclusion," *Oregon*, 389 F. Supp. 3d at 917 (citing *State Farm Mut.*, 463 U.S. at 43), it is arbitrary and capricious. The majority is wrong to conclude otherwise.

and cost-effective delivery of family planning services." 65 Fed. Reg. at 41275–76 (2000) (emphasis added). As justification for its about-face in the new Rule, HHS speculated about a "risk" of Title X funds being used for impermissible purposes.[14] 84 Fed. Reg. at 7765 (discussing the risk of "potential co-mingling" without citing *any* evidence of co-mingled funds). A speculative risk is not a reasoned explanation. *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1244 (9th Cir. 2001); *see also Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006).

B. HHS's Cost-Benefit Analysis Is Contrary to the Evidence

Second, the Rule is likely arbitrary and capricious because HHS offered an explanation for its cost-benefit analysis that runs contrary to the evidence before the agency. *See State Farm Mut.*, 463 U.S. at 43. As the district courts explained, there are at least three provisions of the Rule that will cause providers to leave the Title X program, leading to decreased access to Title X-funded care, which will in turn create costs that HHS did not account for.

First, the Gag Rule. Because it "require[s] doctors to violate … fundamental ethical and professional norms[,]" *Oregon*, 389 F. Supp. 3d at 916, the Gag Rule will trigger providers to leave the Title X program, "drastically reduc[ing] access to Title X services, and lead[ing] to serious disruptions in care for Title X pa-

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[14] To be clear: the "recent studies" that the majority notes HHS relied on do not demonstrate any actual misuse of Title X funds. Maj. Op. 66. Rather, they reflect facilities that comply with Title X but likely will be forced out of the program by the Separation Requirement. 84 Fed. Reg. at 7765.

tients." *California*, 385 F. Supp. 3d at 1008. For example, the provider serving approximately 40% of all Title X patients—1.6 million people—which is also the only family planning provider in ten percent of rural counties, declared that if the Gag Rule is implemented, it will leave the Title X program in order to maintain its ethical obligations to patients.[15] *Oregon*, 389 F. Supp. 3d at 918; *California*, 385 F. Supp. 3d at 979.

Second, the Separation Requirement. Compliance with the Separation Requirement will be so cost-prohibitive for many providers that they will have to leave the Title X program.[16] *California*, 385 F. Supp. 3d at 1008–11.

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[15] Indeed, this exodus has come to pass. Plaintiffs informed us that all Planned Parenthood Title X direct grantees would withdraw from Title X beginning August 19, 2019, as a result of enforcement actions by HHS, and they have done so. *See* Sarah McCammon, *Planned Parenthood Withdraws From Title X Program Over Trump Abortion Rule*, Nat'l Pub. Radio (Aug. 19, 2019), https://www.npr.org/2019/08/19/752438119/planned-parenthood-out-of-title-x-over-trump-rule. Planned Parenthood is not alone. *See* Nicole Acevedo, *Nearly 900 Women's Health Clinics Have Lost Federal Funding Over Gag Rule*, NBC News (Oct. 22, 2019) https://www.nbcnews.com/news/latino/nearly-900-women-s-healthclinics-have-lost-federal-funding-n1069591; Anna North, *How A Beloved Clinic for Low-Income Women Is Fighting to Stay Alive in the Trump Era*, Vox (Nov. 22, 2019), https://www.vox.com/identities/2019/11/22/20952297/title-x-funding-abortion-birth-control-trump.

[16] HHS also calculated costs of compliance with the physical separation requirement in a "mystifying" way. *California*, 385 F. Supp. 3d at 1008. HHS's internal guidelines—and common sense—suggest that compliance costs for making physically separate facilities would include expenses related to equipment, leasing space, utilities, and personnel. Yet, HHS estimated that an average of only $30,000 per affected Title X site would be incurred to comply with the physical separation requirement. 84 Fed. Reg. at 7782.

Third, the requirement that only "physicians or advanced practice providers" may provide counseling. *See* 84 Fed. Reg. at 7727–28 (defining "advanced practice providers"). This limitation will significantly reduce the number of people who can provide pregnancy counseling and will require significant changes in Title X providers' staffing, or else devastate their capacity to serve patients. *Id*. at 7778 (noting that for "1.7 million Title X family planning encounters in 2016," services were delivered by providers who are not "physicians or advanced practice providers"); *California*, 385 F. Supp. 3d at 1013 (recognizing that "65% of Title X sites rel[ied] on trained health educators, registered nurses, and other qualified providers (excluding physicians and advanced practice clinicians) to counsel patients in selecting contraceptive methods") (internal quotation marks and citation omitted).

HHS dismissed the loss of access by speculating that there would not "be a decrease in the overall number of facilities offering [Title X] services, since [HHS] anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." 84 Fed. Reg. at 7782. HHS simultaneously contradicted that very prediction, by stating, "[HHS] *cannot* calculate or anticipate future turnover in grantees." *Id*. (emphasis added). Nonetheless, HHS stated, "[b]ased on [HHS's] best estimates, it anticipates that the net impact on those seeking services from current grantees will be zero[.]" *Id*. HHS provided *no expla-*

As Plaintiffs' counsel indicated at oral argument, even just hiring a *single* front desk staff member to staff a new entrance to a facility would exceed that estimate, not to mention all the other costs that would accompanying creating and maintaining such a facility. *See, e.g.*, Washington SER 355–56 (*Washington*); California SER 396–97 (*California*).

nation of how it arrived at its "best estimates." *See also California*, 385 F. Supp. 3d at 983 ("[A]t oral argument [before the district court], when pressed for any record evidence substantiating this (highly consequential) assertion, Defendants' counsel could offer none."). Nor did HHS provide any specifics about its estimates, such as the locations or geographic distribution of any "new" clinics, their number or size, or how long it would take them to become operational grantees. Thus, HHS failed to offer "an explanation for its decision that runs counter to the evidence before" it. *State Farm Mut.*, 463 U.S. at 43. Proceeding in this manner is the hallmark of arbitrary and capricious administrative action.

The majority disagrees, citing readily distinguishable case law and a poll that did not conclude what the majority purports it does.[17] Maj. Op. 68–69. The "poll" that HHS cited is a summary showing both that a ma-

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[17] The majority relies extensively on the Supreme Court's recent opinion, *Dep't of Commerce v. New York*, 139 S. Ct. 2551 (2019). Maj. Op. 62, 63–64, 70–77. That case raised the issue of whether the Secretary of Commerce was required to accept the Census Bureau's predictions about accurate gathering of citizenship data. *Dep't of Commerce*, 139 S. Ct. at 2569. The Court held that the Secretary was not beholden to the Bureau's analysis because "the Census Act authorizes the Secretary, *not the Bureau*, to make policy choices within the range of reasonable options[,]" *id.* at 2571 (emphasis added), *and* there was support for the Secretary's decision, *id.* at 2569. Conversely, here, we are reviewing HHS's own administrative decisions in the face of contravening evidence, and there is no support for HHS's decisions.

Moreover, the Court *struck down* the Secretary of Commerce's attempt to reinstate the citizenship question on the census. *See* 139 S. Ct. at 2575–76 ("Our review is deferential, but we are 'not required to exhibit a naiveté from which ordinary citizens are free.'"). Similarly, here, deference to HHS does not mean turning a blind eye to the agency's actions, as the majority does.

jority of "faith-based healthcare professionals" would prefer not to violate their conscience *and* that a *majority* of them *never* experienced pressure to refer a patient for a procedure to which the professional had moral, ethical, or religious objections. 84 Fed. Reg. at 7780 n.138; Freedom2Care & The Christian Med. Ass'n, *National Poll Shows Majority Support Healthcare Conscience Rights*, *Conscience Law* (May 3, 2011), https://perma.cc/3AU4-ACGA. Nothing suggests that the poll asked medical professionals about expanding into Title X. It is baffling how HHS made the leap from the poll data—the quality and veracity of which is unclear from the summary the agency cited—to its conclusion that there would be no decrease in facilities. *Id.* And a predicate to giving deference to an agency is that the agency's inferences must not *contradict* the findings of the study. *State Farm Mut.*, 463 U.S. at 43. That is by no means *de novo* review, contrary to the majority's contention. Maj. Op. 69 n.29.

Moreover, the cases on which the majority relies to endorse HHS's guesswork arose in different circumstances. Maj. Op. 68–71. When the Supreme Court in *FCC v. National Citizens Committee for Broadcasting* condoned an agency's "forecast" for future behaviors without "complete factual support," the underlying agency decision was "to 'grandfather'" existing policies into a new rule. 436 U.S. 775, 813–14 (1978). There, the agency's predictions concerned maintenance of the status quo, rather than the change in policy HHS made here. And in other cases cited by the majority, the regulations at issue "reflect[ed] reasoned predictions about technical issues." *BNSF Ry. Co. v. Surface Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir. 2008) (citation omitted); *see also Trout Unlimited v. Lohn*, 559 F.3d 946, 959 (9th Cir. 2009) (noting that the record showed

that the agency relied on "scientific data, and not on mere speculation"). HHS's prediction here is not reasoned or based on any data or studies, and should not be afforded deference. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) ("[T]he wisdom of agency action is rarely so self-evident that no other explanation is required."); *McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) ("[W]e do not defer to the agency's conclusory or unsupported suppositions.").

Further, because of HHS's sunny, and baseless, prediction that new clinics will appear to provide services to at least 40% of the patient population served by Title X, HHS did not address the potential health consequences of decreased services and their corresponding costs in its cost-benefit analysis. As the Northern District of California recognized, the decreased services could cause a 31% increase in the nation's unintended pregnancy rate, which would lead to "[b]illions of dollars in public costs[.]" *California*, 385 F. Supp. 3d at 1016. Even if the number of clinics were to remain the same, a changed geographic reach would have devastating consequences. *See* 84 Fed. Reg. at 7782 (recognizing that patients will have to travel further to obtain health care); *California*, 385 F. Supp. 3d at 1017–18 (noting that when a rural Indiana county lost a Planned Parenthood clinic, "the county lost free HIV testing services and almost immediately experienced one of the largest and most rapid HIV outbreaks the country has ever seen") (internal quotation marks omitted). An agency governed by the APA must grapple with potential costs, and HHS—an agency with power over public health, no less—failed to do so here. *See State Farm Mut.*, 463 U.S. at 43; *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012).

The majority is correct that we give agencies deference—but only insofar as the agency "examine[s] the relevant data and articulate[s] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm Mut.*, 463 U.S. at 43 (internal quotation marks omitted). The majority fails to hold HHS to that basic standard here.

* * *

In vacating the preliminary injunctions, the majority blesses an executive agency's disregard of the clear limits placed on it by Congress. The consequences will be borne by the millions of women who turn to Title X-funded clinics for lifesaving care and the very contraceptive services that have caused rates of unintended pregnancy—and abortion—to plummet.

I strongly dissent.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

6:19-cv-00317-MC (Lead Case)
6:19-cv-00318-MC (Trailing Case)

STATE OF OREGON ET AL.,
Plaintiffs,
v.

ALEX M. AZAR II ET AL.
Defendants,
and

AMERICAN MEDICAL ASSOCIATION, ET AL.,
Plaintiffs,
v.

ALEX M. AZAR II ET AL.
Defendants.

Filed April 29, 2019

OPINION AND ORDER

MCSHANE, Judge:

Plaintiffs in these consolidated actions are 20 states, the District of Columbia, the American Medical Association, the Oregon Medical Association, the Planned Parenthood Federation and their local affiliates, and individual medical providers. They seek to

enjoin the United States Department of Health and Human Services, the Office of Population Affairs, and their respective leadership (collectively, the "Defendants" or "HHS") from implementing certain rules (the "Final Rule") that would alter the family planning program established by Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq*. The Final Rule was issued by HHS on March 4, 2019, and its effective date is May 3, 2019.

At the heart of their claims, Plaintiffs allege that the Final Rule is antithetical to public health and is a fundamental shift in policy away from Title X's emphasis on nondirective and voluntary family planning between low-income patients and their medical providers. Indeed, the rule would, among other things, dramatically limit medical professionals from discussing abortion options with their patients and completely prohibit them from referring patients seeking an abortion to a qualified provider (the "Gag Rule"). It would also require Title X providers to physically and financially divorce health services funded under Title X from abortion services funded from sources other than Title X (the "Separation Requirement").

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. In the guise of" program integrity," the Gag Rule prevents doctors from behaving like informed professionals. It prevents counselors from providing comprehensive counseling. It prevents low-income women from making an informed and independent medical decision. At the heart of this rule is the arrogant assumption that government is better suited to direct the health care of women than their medical providers. At a time in our

history where government is assessing how we can improve and lower the costs of medical care to all Americans, the Final Rule would create a class of women who are barred from receiving care consistent with accepted and established professional medical standards. On top of that, the Separation Requirement would create such a financial strain on Title X providers that, ironically, it would create a geographic vacuum in family planning that experts warn would lead to substantially more unintended pregnancies and, correspondingly, more abortions.

The harms outlined in the record before me, should the Final Rule be implemented, are extensive and are not rebutted by the government. A review of the scores of declarations from public health policy experts, medical organizations, doctors, and Title X providers lead to the inescapable conclusion that the Final Rule will result in negative health outcomes for low income women and communities. It will result in less contraceptive services, more unintended pregnancies, less early breast cancer detection, less screening for cervical cancer, less HIV screening, and less testing for sexually transmitted disease. HHS's response to these negative health outcomes is one of silence and indifference. Rather than providing contradictory data to support any positive health outcomes, they rationalize that the Final Rule "will ensure compliance with, and implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning." At the same time, despite the nearly fifty-year history of Title X, they cannot point to one instance where Title X funds have been misapplied under past or current rules.

Without revealing what evidence, if any, helped shape its opinions, HHS essentially says, "trust us, this will work out fine." But dramatic changes to the only federal program providing family planning services to millions of clients in marginalized communities requires something more than a mere hunch. The dearth of evidence and lack of transparency in HHS's rulemaking is particularly concerning as HHS earlier concluded that there was "no evidence that [the Gag Rule] can and will work operationally on a national basis in the Title X program." 65 Fed. Reg. at 41,271.

Should the Final Rule go into effect in mere days, the risk of irreparable damage to the health of women and communities is grave. In contrast, keeping the current regulations in place—regulations that "have been used by the program for virtually its entire history," *id.*, and have provided critical medical services for at-risk communities—poses no harm to Defendants.

As discussed below, Plaintiffs are likely to succeed on the merits of their claim that the Final Rule is contrary to law. Additionally, Plaintiffs raise serious questions going to the merits of their claims that the Final Rule is arbitrary and capricious. Plaintiffs have demonstrated the likelihood of "irreparable harm" and that the balance of equities tips sharply in their favor. Plaintiffs' Motions for a Preliminary Injunction are GRANTED.

FACTUAL BACKGROUND

Congress enacted the Title X program, known as the "Population Research and Voluntary Planning Program," in 1970 as part of the Public Health Services Act. Its mission is to provide grants to public and nonprofit organizations "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 (including natural family planning methods, infertility services, and services for adolescents)." 42 U.S.C. § 300(a). Title X targets low income families and individuals and provides family planning services at low or no cost. The stated purpose of Title X is to promote positive birth outcomes and healthy families by allowing individuals to decide the number and the spacing of their children.

Congress authorized HHS to promulgate regulations to effectuate Title X's mission, largely through the award of grants to providers of family planning services to low income individuals. 42 U.S.C. § 300a-4. Title X grants are administered by the Office of the Assistant Secretary for Health through the Office of Population Affairs. The statute and regulations of Title X require that 90 percent of congressional appropriations be used for clinical family planning purposes. Title X funds a broad array of family planning services: contraceptive services, information, and education; natural family planning and education; infertility services; services to adolescents; HIV and sexually transmitted disease screening and referral; breast and cervical cancer screenings; and pregnancy testing.

By all accounts, for nearly 50 years, the Title X program has been a great success in meeting its stated goals. According to HHS's 2017 Summary, the program served over 4 million family planning clients at 3,858 service sites through 6.6 million family planning encounters. Those served are largely from vulnerable populations who would not otherwise have access to health care. Title X clinics provided over 2 million Chlamydia tests, 2.5 million Gonorrhea tests, 2 million HIV tests, and over 700,000 syphilis tests. Title X pro-

viders conducted Pap screening on nearly 650,000 clients and breast exams on 878,492 women. *See* Title X Family Planning Annual Report 2017 Summary, www.hhs.gov/opa/title-x-family-planning/fp-annual-report/fpar-2017 (last visited April 25, 2019). By regularly providing millions of patients with contraceptive services, the Title X program has significantly reduced the rates of unintended pregnancy and abortion. In fact, unintended pregnancies and abortions are now at historic lows, in large part due to Title X. Kost Decl. ¶¶ 7, 35, ECF No. 53; Brindis Decl. ¶ 26, ECF No. 52; Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 New Eng. J. Med. 843, 850 (2016) (noting unintended pregnancy rate in United States dropped to a 30-year low in 2011).

At issue in this case is the agency's interpretation of the congressional mandate found in the final sentence of Title X known as "Section 1008." 42 U.S.C. § 300a-6. This mandate requires that "None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. Historically, HHS has taken the position that medical professionals may provide neutral and factual information, even concerning abortion, as a part of pregnancy counseling. The agency squared such counseling with Section 1008 because "the provision of neutral and factual information about abortion is not considered to promote or encourage abortion as a method of family planning." 65 Fed. Reg. at 41,271. HHS generally allowed the medical professional's objective professional judgment, aided by the patient's particular needs, to drive pregnancy counseling. Earlier rules also allowed abortion referrals.

The Final Rule deviates sharply from the historical interpretation of Section 1008. HHS used the same justification—that the Final Rule will ensure compliance with Section 1008's requirement that no Title X funds "shall be used in programs where abortion is a method of family planning"—in 1988 when it promulgated similar rules. Those rules, like the Final Rule at issue here, prohibited abortion referrals and required strict financial and physical separation between Title X projects and services prohibited by Title X.

Numerous Title X grantees and doctors impacted by the 1988 rule challenged the regulations alleging, as relevant here, that the Gag Rule and Separation Requirement were not authorized by Title X and thus were arbitrary and capricious. The Supreme Court ultimately upheld the 1988 rules. The Court examined Section 1008's prohibition on using Title X funds "in programs where abortion is a method of family planning." The Court, like every other court to examine the statutory language and legislative history of Section 1008, found the statute ambiguous. "If a statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute. The Secretary's construction of Title X may not be disturbed as an abuse of discretion if it reflects a plausible construction of the plain language of the statue and does not otherwise conflict with Congress' expressed intent." *Rust, v. Sullivan*, 500 U.S. 173, 184 (1991) (internal quotations and citation omitted). The fact that the 1988 rules represented a "sharp break with prior interpretations" by HHS did not mean the new rules were invalid, because "the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing ba-

sis."' *Id.* at 185 (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def Council, Inc.*, 467 U.S. 837, 862 (1984)). In rejecting Plaintiffs' arguments challenging the Gag Rule, Justice Rehnquist concluded HHS adequately justified the change from prior policy:

> The Secretary explained that the regulations are a result of his determination, in the wake of the critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute and that it was necessary to provide 'clear and operational guidance' to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning.' 53 Fed. Reg. 2923-2924 (1988). He also determined that the new regulations are more in keeping with the original intent of the statute, are justified by client experience under the prior policy, and are supported by a shift in attitude against the 'elimination of unborn children by abortion.' We believe that these justifications are sufficient to support the Secretary's revised approach. Having concluded that the plain language and legislative history are ambiguous as to Congress' intent in enacting Title X, we must defer to the Secretary's permissible construction of the statute.

Id. at 173.

As for the Separation Requirement, the Court found that "the program integrity requirements are based on a permissible construction of the statute and are not inconsistent with congressional intent." *Id.* at

188. Once again, the Secretary adequately justified his reasoning:

> Indeed, if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities. It is undisputed that Title X was intended to provide primarily prepregnancy preventative services. Certainly the Secretary's interpretation of the statute that separate facilities are necessary, especially in light of the express prohibition of § 1008, cannot be judged unreasonable. Accordingly, we defer to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.

Id at 190.

Although the Court allowed the 1988 rules to stand, HHS never implemented those regulations on a national scale. 65 Fed. Reg. at 41,271. And, in 1993, HHS suspended the 1988 regulations, finding them to be "an inappropriate implementation of the Title X statute." 58 Fed. Reg. at 7464.

In 1996 (five years after the Supreme Court's decision in *Rust*), Congress clarified that its prohibition on Title X abortion funding did not prohibit the nondirective counseling of pregnant women. To the contrary, Congress mandated that "all pregnancy counseling shall be nondirective" with respect to Title X. Omnibus Consolidated Rescissions and Appropriations Act, 1996, Pub. L. No. 104-134, Title II, 110 Stat. 1321 (1996). This congressional mandate has appeared in every subsequent Title X appropriations statute from 1996 until present. *See* Department of Defense and Labor, Health and Human Services, and Education

Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. Law. No 115-245, Title II, 132 Stat. 2981, 3070-71 (September 28, 2018).

In 2000, HHS issued new Title X rules that remain in effect to this day. The 2000 regulations officially revoked the 1988 rules that were validated by the *Rust* court but never implemented by HHS. The agency concluded that the Gag Rule from the 1988 rules "endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients." 65 Fed. Reg. at 41,270. The 2000 rules required the provider to offer the pregnant woman the opportunity to be "provided information and counseling regarding each of the following options: (A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination. 65 Fed. Reg. at 41,279. Regarding nondirective counseling, the 2000 rules provided:

> If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

Id.

Nondirective counseling meant the grantee "may not steer or direct clients toward selecting any" option, including abortion[.]" *Id.* at 41,273. Referrals for abortion were once again allowed, provided the client requested such a referral. *Id.* at 41,274. Finally, HHS

determined that financial separation, rather than financial and physical separation, was sufficient to abide by Section 1008.

Ten years after HHS implemented the 2000 regulations still in place today, Congress spoke again on the matter. In passing the Affordable Care Act in 2010, Congress once again limited the rulemaking authority of HHS. There, Congress expressly prohibited HHS 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 the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

Given the above context, I turn to the Final Rule at issue here. HHS published the Final Rule in the Federal Register on June 1, 2018. During the 60-day public comment period, HHS received more than 500,000 comments. Certain revisions were made to the proposed rule and HHS published the Final Rule in the

Federal Register on March 4, 2019.[1] The rule has an implementation date of May 3, 2019.

As expressed by HHS in its executive summary, the purpose of the Final Rule, as it relates to Section 1008, is "to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning." 84 Fed. Reg. at 7717. For purposes of this litigation, Plaintiffs' claims center on two aspects of the final rule that they refer respectively to as: (1) The Gag Rule; and (2) The Separation Requirement.

Turning first to the Gag Rule, the Final Rule provides that a "Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." 84 Fed. Reg. at 7788-89 (to be codified at 42 C.F.R. § 59.14). Without doubt, the Final Rule limits the provider's options when presented with a pregnant woman.

First, once a patient is identified as pregnant, "she shall be referred to a health care provider for medically necessary prenatal health care." 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14). This referral for prenatal health care is mandatory. Next, the provider may, but is not required to, "provide the following counseling and/or information to her:"

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[1] Plaintiffs filed their complaints the following day, on March 5, 2019. Due to the closely-approaching implementation date, the court set an expedited briefing schedule and, just days ago, heard oral arguments.

(i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;

(ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);

(iii) Referral to social services or adoption agencies; and/or

(iv) Information about maintaining the health of the mother and unborn child during pregnancy.

Id.

If the provider chooses to provide a list of comprehensive health care providers, the list "may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortions." *Id.*

Plaintiffs also challenge the Final Rule's Separation Requirement. The Separation Requirement provides that any "Title X project must be organized so that it is physically and financially separate ... from activities which are prohibited [in the Final Rule]." 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15). According to HHS, complete physical and financial separation between a Title X program and any activities falling outside of Title Xis necessary to: (1) comply with Section 1008; (2) eliminate the "significant risk for public confusion" over whether Title X funds are allocated for abortion-related purposes; and (3) "address the concern that Title X resources could facilitate the development of,

and ongoing use of, infrastructure for non-Title X activities." 84 Fed. Reg. at 7715.

Plaintiffs ask the court to issue a nationwide preliminary injunction restraining HHS from implementing· the Final Rule. Absent an injunction, the Final Rule goes into effect in four days, on May 3, 2019.

STANDARDS

A plaintiff seeking a preliminary injunction must establish: (1) likelihood of success on the merits; (2) irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in his favor; and (4) an injunction is in the public interest. *Winter v. Nat. Res. Def Council, Inc*., 555 U.S. 7, 20 (2008). When, as here, the government is a party, the last two factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). When there are "serious questions going to the merits," a court may still issue a preliminary injunction when "the balance of hardships tips sharply in the plaintiffs favor," and the other two factors are met. *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (quoting *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011)). The court's decision on a motion for a preliminary injunction is not a ruling on the merits. *See Sierra On-Line, Inc. v. Phoenix Software, Inc*., 739 F.2d 1415, 1422 (9th Cir. 1984).

DISCUSSION

Under the APA, a court's review of an agency decision should be searching but narrow, and the reviewing court should take care not to substitute its judgment for that of the agency. *Oregon Wild v. United States*, 107 F. Supp. 3d 1102, 1109 (D. Or. 2015) (citing *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402,416

(1971)). Under this review, the court "shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

As noted, many of the arguments put forward by Plaintiffs are ones the Supreme Court previously rejected when considering the (remarkably similar) rules in *Rust*. At first blush, one could be persuaded that *Rust* controls the outcome here. In fact, most of HHS's arguments—specifically in its written response, where it cited *Rust* on 168 occasions—simply point to *Rust* as evidence the Final Rule is a lawful exercise of agency discretion. *See Defs.' Opp'n*, 17; ECF No. 83 ("*Rust's* on-point statutory holding—and the remarkable overlap between Plaintiffs' arguments and the ones *Rust* rejected—disposes of the claim that the materially indistinguishable Rule is unlawful.").

HHS would seemingly have the court believe *Rust* concluded the Gag Rule and Separation Requirement were required interpretations of Section 1008. But *Rust* contains no such holding. *Rust* merely held that in light of the ambiguous nature behind Congress's intent in enacting Title X generally, and Section 1008 specifically, HHS's interpretation of Section 1008 was not unreasonable:

> The broad language of Title X plainly allows the Secretary's construction of the statute. By its own terms, § 1008 prohibits the use of Title X funds "in programs were abortion is a method of family planning." Title X does not define the term "method of family planning," nor does it enumerate what types of medical and counseling services are entitled to Title X funding.

> Based on the broad directives provided by Congress in Title X in general and § 108 in particular, we are unable to say that the Secretary's construction of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy within the Title X project is impermissible.

Rust, 500 U.S. at 184.

Additionally, the Court clarified that "[a]t no time did Congress directly address the issues of abortion counseling, referral, or advocacy." *Id.* at 185. Given the lack of direction from Congress, and considering HHS provided ample justification for its reasoning in revising the rules, the Court deferred to the agency's "permissible construction of the statute." *Id.* at 187.

Two significant facts, however, separate this case from *Rust*. First, Congress has consistently mandated since 1996 that "that all pregnancy counseling shall be nondirective" with respect to Title X. Omnibus Consolidated Rescissions and Appropriations Act, 1996 Pub. L. No. 104-134, Title II, 110 Stat. 1321, 1321-22 (1996). Second, the 2010 limitations Congress included in the Affordable Care Act significantly limit HHS's rulemaking authority. Therefore, HHS must do more than merely dust off the 30-year old regulations and point to *Rust*.

HHS makes the head-scratching argument that neither of the post-*Rust* laws enacted by Congress can serve as an implied repeal of Section 1008 or overrule *Rust*. HHS argues, "A clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted in the same statute or even in an affiliated

statute." *Defs.' Opp'n*, 19 (quoting *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017)). That premise is certainly correct. But *TC Heartland* involved a statutory term the Supreme Court previously had "definitively and unambiguously held ... has a particular meaning[.]" 137 S. Ct. at 1520. The Court therefore quite appropriately pointed out that "[T]he modification by implication of the settled construction of an earlier and different section is not favored." *Id.* (quoting *United States v. Madigan*, 300 U.S. 500, 506 (1937)). But the rule regarding implied repeal has no application here, where *Rust* expressly held that the statute in question was ambiguous. Again, *Rust* merely held that because Congress had not spoken on the matter, HHS's Gag Rule and Separation Requirement were reasonable interpretations of Section 1008 at that time. But Congress has since spoken on the matter.

Additionally, I note that absolutely nothing in the appropriations mandate that "all pregnancy counseling shall be nondirective," or the express limitations Congress placed on HHS's rulemaking authority in the ACA, necessarily conflict with Section 1008's requirement that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." HHS's vigor in arguing that the appropriations act and the ACA "cannot repeal Section 1008" or "overrule *Rust*" only demonstrates that the Final Rule conflicts with both statutes. After all, not all interpretations place the three statutes at odds with one another. The current regulations, which have been in place for nearly five decades, allow Section 1008, the appropriations language, and the ACA restrictions to live in harmony. *Rust* explicitly commented that the plaintiffs' argument that the legislative

history behind Title X rendered the 1988 rules contrary to law was, in fact, one permissible interpretation. *Rust*, 500 U.S. at 189. But because HHS's interpretation was also a permissible interpretation, deference to the agency's reasonable interpretation carried the day. *Id.* ("While petitioner's interpretation of the legislative history may be a permissible one, it is by no means the only one, and it is certainly not the one found by the Secretary."). The question now is whether, given the two new statutes, HHS's 30-year-old rules remain "one permissible interpretation."

I turn first to the Final Rule's Gag Rule. As noted, the Final Rule prohibits referrals for abortions. HHS argues that although "all pregnancy counseling shall be nondirective," Congress said nothing about referrals. This argument appears a stretch. First, HHS includes referrals within pregnancy counseling in the Final Rule. For example, in its guidance for nondirective pregnancy counseling, the agency states, "Title X projects should not use nondirective pregnancy counseling, *or referrals made for prenatal care or adoption during such counseling*, as an indirect means of encouraging or promoting abortion as a method of family planning." 84 Fed. Reg. at 7747 (emphasis added). The above guidance aligns with Congress's thoughts on referrals. Congress, in ordering HHS to make grants available to assist "*in providing* adoption information and *referrals* to pregnant women on an equal basis *with all other courses of action included in nondirective counseling* to pregnant women," clearly included referrals in nondirective counseling. 42 U.S.C. § 254c-6(a)(l) (emphasis added).

Although common sense, the agency's own guidance, and Congress's statutory language indicate pregnancy counseling includes referrals, a different outcome

would not save the Final Rule from violating the requirement that all pregnancy counseling be nondirective. Regardless of the referral process (discussed further below), the Final Rule blatantly requires that any pregnancy counseling for abortion be directive. For the Final Rule, this is a problem, as it is well established that Congress "may amend substantive law in an appropriations statute, as long as it does so clearly." *Robertson v. Seattle Audobon Soc'y*, 503 U.S. 429,441 (1992). Congress is quite clear on its thoughts regarding pregnancy counseling: "all pregnancy counseling shall be nondirective."

Although the Final Rule does not define "nondirective counseling," it provides guidance on the term. The agency describes "nondirective counseling" as:

> the meaningful presentation of options where the physician or advanced practice provider (APP) is not suggesting or advising one option over another. ... Nondirective counseling does not mean that the counselor is uninvolved in the process or that counseling and education offer no guidance, but instead that clients take an active role in processing their experiences and identifying the direction of the interaction. In nondirective counseling, the Title X physicians and APPs promote the client's self-awareness and empower the client to be informed about a range of options, consistent with the client's expressed need and with the statutory and regulatory requirements governing the Title X program. *In addition, the Title X provider may provide a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some (but not the majority) of which may provide abor-*

> *tion in addition to comprehensive primary care.*"[2]

84 Fed. Reg. at 7716 (internal quotations, citation, and footnote omitted) (emphasis added).

Examining the Final Rule's requirement for abortion counseling confirms it is anything but nondirective. After confirming that the provider need not provide any pregnancy counseling at all, the Final Rule outlines what counseling is permissible should the provider decide to offer such counseling:

> Nondirective counseling is designed to assist the patient in making a free and informed decision. *In nondirective counseling, abortion must not be the only option presented by physicians or APPs*; otherwise the counseling would violate the Congressional directive that all pregnancy counseling be nondirective, but also the prohibitions in this rule on encouraging, advocating, or supporting abortion as a method of family planning, which the Department prohibits in order to implement, among other provisions, section 1008. Each option discussed in such counseling must be presented in a nondirective manner. This involves presenting the options in a factual, objective, and unbiased manner and (consistent with the other Title X requirements and restrictions) offering factual resources that are objective, rather than pre-

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[2] The emphasized portion, concerning a type of referral, which appears in the Final Rule's section on guidance for what "Nondirective pregnancy counseling is," is yet another example that the agency (along with all of the expert opinions submitted in the record) views referrals as simply one portion of the entire counseling process.

> senting the options in a subjective or coercive manner. *Physicians or APPs should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented*, consistent with the obligation of health care providers to provide patients with accurate information to inform their health care decisions.

84 Fed. Reg. at 7747 (emphasis added).

Like nearly every other aspect of the Final Rule, the agency creates one set of rules for abortion, and a separate set of rules for everything else. Back in 1988, this was a permissible interpretation of the then lone congressional requirement that no Title X funds "be used in programs where abortion is a method of family planning." But when implementing a rule in 2019, HHS must comply not only with Section 1008, but also with Congress's requirement that "all pregnancy counseling be nondirective." HHS's mistake, here and throughout the Final Rule, assumes that Section 1008 trumps Congress's other mandates. But as noted above, the statutes are not irreconcilable.

For all pregnancy counseling not involving abortion, the Final Rule allows "the clients [to] take an active role in processing their experiences and identifying the direction of the interaction ... [while allowing the providers to] promote the client's self-awareness and empower the client to be informed about a range of options, *consistent with the client's expressed need*[.]" 84 Fed. Reg. at 7716 (emphasis added). This is not the case, however, if the empowered client wishes to exercise abortion in that range of options. During abortion counseling, the medical professional no longer provides neutral, factual information "consistent with the client's

expressed need[.]" Fed. Reg. at 7716. Instead, the provider must provide counseling regarding some other option the client has no use for, even when it is not requested by the client or even medically relevant.[3] The Gag Rule is the very definition of directive counseling. It makes no difference that HHS labels this process "nondirective counseling," or that HHS states such requirements are necessary to avoid, according to HHS's own interpretation, "the prohibitions in this rule on encouraging, advocating, or supporting abortion as a method of family planning [under Section 1008]." 84 Fed. Reg. at 7747. It is clear that while giving lip service to the requirement that all pregnancy counseling be nondirective, HHS never sought to actually interpret that mandate in coordination with Section 1008. As the Gag Rule is not "in accordance with the law," it violates the APA. 5 U.S.C. § 706(2)(A).

As odd as the pregnancy counseling process is, it pales in comparison to the Final Rule's requirements for abortion referrals. One would expect to find such a process not in a federal program serving millions of clients, but in a Kafka novel. As described above, if a woman seeks to have a legal abortion and requests a referral from her Title X provider, the Final Rule requires a referral for prenatal care. That is, the provider is mandated to refuse to provide the referral the client wants, and instead provide a referral the client nei-

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[3] For some reason—and the Court struggles here with finding any rational relationship to any medical purpose—the Final Rule allows, and in fact encourages, that the provider "should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented[.]" 84 Fed. Reg. at 7747. In other words, the Final Rule encourages the provider to counsel a woman who has chosen to proceed with a legal abortion on the possible risks and side effects to the fetus.

ther needs nor requested. *See* 84 Fed. Reg. 7789 (to be codified at 42. C.F.R. § 59.14(b)) (requiring that after the client is "verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care").

Amazingly, the Final Rule allows the provider, at its whim, to refer the woman not to an abortion clinic, but to an adoption agency. *Id.* § 59.14(b)(l)(iii).[4] Or, the provider may provide a list of primary care providers, none of whom actually perform abortions. *Id.* § 59.14(c)(2). The rule also allows the counselor to provide "[i]nformation about maintaining the health of the ... unborn child during pregnancy." *Id.* § 59.14(b)(l)(iv).

Possibly, the woman might be lucky enough to live near a Title X provider who—in accordance with the professional ethical obligations of medical providers—agrees to refer a woman seeking an abortion to an actual abortion clinic. Even then, the woman is not much closer to actually receiving a proper referral. One would think the provider could simply say, "We do not perform abortions. Title X does not allow Title X funds to be used to perform abortions. But here is a referral to an independent medical provider, who receives no Title X funds, who will help you." But the Final Rule does not allow that. Instead, after referring the woman to a provider of prenatal care (as is mandatory), the provider may provide "[a] list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)[.]" *Id.* § 59.14(b)(l)(ii). If the sympathetic counselor provides this list, HHS al-

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[4] It is difficult to comprehend that Congress would so adamantly require that all pregnancy counseling be nondirective, only to later allow the provider to refer a woman seeking an abortion to an adoption agency.

lows the list to include some providers "which also provide abortion as part of their comprehensive health care services." *Id.* § 59.14(c)(ii). However, in what one imagines would come as a shock to this poor woman, the list is prohibited from including a majority of providers who actually provide abortion services. *Id.* At this point, the woman is staring at multiple names on a list. As is usual in the medical setting, she might ask the provider, whom she trusts, for a single recommendation. At this point, the provider may only say, "I'm sorry, I cannot help you." In the agency's zeal to limit any abortions, even legal abortions provided outside the Title X program, the Final Rule states, "Neither the list nor project staff may identify which providers on the list perform abortions." *Id.*

The Gag Rule is remarkable in striving to make professional health care providers deaf and dumb when counseling a client who wishes to have a legal abortion or is even considering the possibility. The rule handcuffs providers by restricting their responses in such situations to providing their patient with a list of primary care physicians who can assist with their pregnancy without identifying the ones who might perform an abortion. Again, the response is required to be, "I can't help you with that or discuss it. Here is a list of doctors who can assist you with your pre-natal care despite the fact that you are not seeking such care. Some of the providers on this list—but in no case more than half—may provide abortions services, but I can't tell you which ones might. Have a nice day."[5] This is madness. Plaintiffs have shown what is reflected in the

[5] This is as silly as it is insulting. I cannot imagine visiting my urologist's office to request a vasectomy, only to be given a list of fertility clinics. I would think that my doctor had gone mad.

sophistry of the Final Rule itself—that they are likely to succeed on their claim that the Gag Rule is contrary to law. I tum now to the Separation Requirement.

As noted, the Separation Requirement requires physical and financial separation of Title X services and those services prohibited under the Final Rule. 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15). Separation is required not only if the provider itself performs abortions, but when the provider performs any activities that, in HHS's view, "promote ... or support abortion as a method of family planning[.]" *Id.* at 7788-89 (to be codified at 42 C.F.R. § 59.14). In short, any activity prohibited by the Gag Rule must have no connection, physically or financially, from activities allowed under the Final Rule. *See id.* at 7789 (to be codified at 42 C.F.R. § 59.15 (requiring separation of activities prohibited under Section 1008 as well as 42 C.F.R. §§ 59.13, 59.14, 59.16)).

To ensure that a Title X grantee is in compliance with the Separation Requirement, the Final Rule allows the agency to consider the following facts and circumstances:

(a) The existence of separate, accurate accounting records;
(b) The degree of separation from facilities (e.g. treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;
(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

> (d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

Id. at 7789 (to be codified at 42 C.F.R. § 59.15)

In explaining its reasoning for adding physical separation in addition to the previous requirement of financial separation, the agency does not once mention consideration of any limitations Congress imposed under the ACA. Instead, the agency focuses solely on Section 1008 and *Rust*. *Id.* at 7763-7767.

As noted, Congress passed the Affordable Care Act in 2010. The ACA spoke directly to HHS, prohibiting it 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 the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

HHS first argues that Plaintiffs waived any ACA-based challenge to the Final Rule. First, the court is skeptical that an agency may defend an action challenging the scope of the agency's authority solely with an

argument that the plaintiff waived any such challenge. *See Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018) (noting "the waiver rule does not apply to preclude argument where the scope of the agency's power to act is concerned."). HHS's waiver argument relies on the premise that, so long as no one specifically challenges the agency's authority during the notice and comment period, the agency has the freedom to act in blatant violation of its Congressional authorization.

Regardless, I conclude Plaintiffs have not waived any challenge based on the ACA. Waiver does not apply "if an agency has had the opportunity to consider the issue." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007). This is true even if a third party, as opposed to the plaintiffs, put the agency on notice by providing the agency the opportunity to correct its error. *Id.* Here, while not specifically pointing to 42 U.S.C. § 18114, multiple commenters objected under each prong of the statute. *See* AMA Reply, 11-12 n.3; ECF No. 119 (meticulously matching specific comments to each prong of 42 U.S.C. § 18114); *see also* States' Reply, 9 n.7; ECF No. 121 (same).

HHS's other arguments regarding why Section 18114 does not apply to Title X are unpersuasive. HHS argues that had Congress wanted to limit Title X, it would have listed the title in Section 18114. HHS also argues the restrictions are somehow "overbroad" or "open-ended." Simply because Congress specifically sought to limit the general scope of HHS's rulemaking abilities, however, does not somehow render the limitations invalid. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204,208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Con-

gress."). That regulations issued by HHS 30 years ago might clash with limitations Congress later placed on HHS does not mean HHS may ignore the newer restrictions.

That Congress intended in Section 18114 to limit HHS's rulemaking authority appears clear. Before delineating the six new restrictions, Congress stated, "Notwithstanding any other provision of this Act, the Secretary of Health and Human Services *shall not promulgate any regulation that* . ..." 42 U.S.C. § 18114. The Final Rule, of course, is a regulation promulgated by HHS. The agency argues the language, "Notwithstanding any other provision of this Act," means Congress meant the limitations to apply only to regulations the ACA authorized HHS to implement. I disagree. That language merely indicates that the specific limitations in Section 18114 override any conflicting provisions of the ACA. *See Field v. Napolitano*, 663 F.3d 505, 511 (1st Cir. 2011) (noting that statute's use of "Notwithstanding any other provision of law" "clearly signals the drafter's intention that the provisions of 'notwithstanding' section override conflicting provisions of any other section") (quoting *Cisneros v. Alpine Ridge Grp.*, 508 U.S. 10, 18 (1993)). The Supreme Court agrees that "notwithstanding" language indicates the drafter intended "to supersede all other laws" and that a "clearer statement is difficult to imagine." *Cisneros*, 508 U.S. at 18 (citation omitted).

I conclude Plaintiffs have demonstrated the limitations in Section 18114 likely apply to the Final Rule. The first and second limitations prohibit HHS from implementing any regulation that: "(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; [or] (2) impedes timely access to health care services[.]" 42 U.S.C. § 18114. At this

stage, there is at least a strong argument to be made that the Separation Requirement creates unreasonable barriers to Title X clients obtaining appropriate medical care and impedes their timely access to such care. To ensure compliance with the rule, HHS encourages Title X providers to maintain one set of offices for Title X services and physically separate offices for any service prohibited by the Gag Rule. 84 Fed. Reg. at 7789. The provider should ensure the offices do not share entrances or exits, waiting rooms, or even websites. *Id.* The provider must ensure the separate offices maintain "[t]he existence of separate personnel, electronic or paper-based health care record, and workstations[.]" *Id.* Although the declarations indicate the financial burdens will severely strain already tight budgets, I also am mindful of the fact that many of the rules underlying the Separation Requirement would impinge on the ability of providers to engage in nondirective counseling, in contrast with the congressional mandate.

Even assuming, however, that the ACA does not apply to the Final Rule, or that the Separation Requirement does not create impermissible barriers to client care, Plaintiffs have demonstrated, at worst, serious questions going to the merits of their claims that the Final Rule is arbitrary and capricious. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the produce of agency expertise." *Motor Vehicle Manufacturers Ass 'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Based on the record currently before the Court, the Final Rule appears to force medical providers to either drop out of the program or violate their codes of professional ethics. James L. Madara, MD, is a Medical Doctor, the Chief Executive Officer and Executive Vice President of the AMA, and an adjunct professor of pathology at Northwestern University. Madara Decl. ¶ 1; ECF No. 49. The AMA "is the largest professional association of physicians, residents, and medical students in the United States." *Id.* ¶ 5. To call the AMA the leading organization regarding medical ethics is practically an understatement. The AMA literally wrote the book on medical ethics. "The AMA has published the *Code of Medical Ethics of the American Medical Association* since 1847. This was the first modem national medical ethics code in the world and continues to be the most comprehensive and well respected code for physicians, world-wide." *Id.* ¶ 13. Dr. Madara outlines several troubling aspects of the Final Rule:[6]

> 17. "Except in emergency situations in which a patient is incapable of making an informed decision, withholding information without the patient's knowledge or consent is ethically unacceptable." *Code of Medical Ethics* Opinion 2.1.3. *Withholding Information from Patients*.
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> 18. Therefore, patients have the right "to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives ... [P]atients should be able to expect

[6] Dr. Madera alerted HHS to the AMA's concerns during the Final Rule's notice and comment period. Madera Decl. ¶ 3 (citing July 31, 2018 letter—available at http://www.regulations.gov/document?D=HHS-OS-2018-0008-179739—from AMA to HHS).

that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment." *Code of Medical Ethics* Opinion 1.1.3. *Patient Rights*. Further, patients have a right to "expect that their physician will cooperate in coordinating medically indicated care with other health care professionals[.]" *Id.* Finally, physicians should "[h]onor a patient's request not to receive certain medical information." *Code of Medical Ethics* Opinion 2.1.3. *Withholding Information from Patients*.

19. Physicians are ethically obligated to "[b]ase the decision or recommendation [to consult or refer] on the patient's medical needs, as they would for any treatment recommendation, and consult or refer the patient to only health care professionals who have appropriate knowledge and skills and are licensed to provide the services needed." *Code of Medical Ethics* Opinion 1.2.3. *Consultation, Referral, & Second Opinions*.

20. Within the treating relationship, the "physician must be sensitive to the imbalance of power in the patient-physician relationship, as well as to the patient's vulnerability[, and] must not allow differences with the patient or family about political matters to interfere with the delivery of professional care." *Code of Medical Ethics* Opinion 2.3.4. *Political Communications*.

Madara Decl. (ellipses and alterations in original).

Dr. Madera concludes that "the Final Rule would require doctors to violate each of these fundamental ethical and professional norms."[7] Madara Decl. ¶ 21. In examining the Final Rule, it is readily apparent how Dr. Madera reached his conclusion. The Final Rule, by requiring a referral for prenatal care to a woman seeking an abortion, and by requiring that the patient receive unnecessary counseling in addition to abortion counseling, mandates that providers provide medical information that patient does not need and, almost certainly, does not request. Those requirements also prohibit the physician from basing the counseling or referral on the patient's actual medical needs. By requiring that any list provided for an abortion referral contain some providers who do not perform abortions, and by prohibiting physicians from identifying the abortion providers, the Final Rule "is an instruction to physicians to intentionally mislead patients, which, if followed, is an instruction for physicians to directly violate the *Code of Medical Ethics*[.]"[8] Madera Decl. ¶ 25 (citing Opinions 1.1.1, 1.1.3, 1.2.3, 2.1.3, and 2.3.4).

As the Final Rule contradicts this persuasive evidence from the leading expert on medical ethics, HHS must have a plausible explanation outlining its rationale for rejecting the evidence and reaching a different con-

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[7] Although this opinion only references Dr. Madera's declaration, Plaintiffs presented numerous expert opinions, each essentially arriving at the same conclusion reached by Dr. Madera. Other than relying on the Final Rule itself and *Rust*, HHS provided no evidence in rebuttal.

[8] Should the ACA in fact apply to the Final Rule, the objections noted by Dr. Madera indicate the Gag Rule likely violates each of the six limitations Congress imposed on HHS's rulemaking authority.

clusion. *Motor Vehicle Manufacturers Ass'n*, 463 U.S. at 43. Once again, however, HHS's justifications are lacking. HHS simply brushes aside any concerns and, in a generic and conclusory fashion, asserts the Final Rule violates no ethical obligations. As HHS's response to comments is relatively brief, and demonstrates the agency never addressed, and does not appear to have even considered, the specific objections noted above, I include HHS's entire explanation:

> The Department disagrees with commenters contending the proposed rule, to the extent it is finalized here, infringes on the legal, ethical, or professional obligations of medical professionals. Rather, the Department believes that the final rule adequately accommodates medical professionals and their ethical obligations while maintaining the integrity of the Title X program. In general, medical ethics obligations require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance. Under the terms of this final rule, a physician or APP may provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options, including abortion. Although this occurs in a postconception setting, Congress recognizes and permits pregnancy counseling within the Title X program, so long as such counseling is nondirective. The permissive nature of this nondirective pregnancy counseling affords the physician or APP the ability to discuss the risks and side effects of each option, so long as this counsel in no way promotes or refers for abortion as a method of family planning. It

> permits the patient to ask questions and to have those questions answered by a medical professional. Within the limits of the Title X statue and this final rule, the physician or APP is required to refer for medical emergencies and for conditions for which non-Title X care is medically necessary for the health and safety of the mother or child.

84 Fed. Reg. at 7724.

Although acknowledging that medical ethics "require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance," the agency nowhere squares that requirement with the Final Rule's requirement that all abortion counseling provide information not in fact specific to the patient's medical needs. Despite acknowledging providers must share accurate information with the patient, HHS requires any referral for abortion contain, at minimum, an equal amount of information that is of no use to the pregnant woman. That HHS appears to have failed to seriously consider persuasive evidence that the Final Rule would force providers to violate their ethical obligations suggests that the rule is arbitrary and capricious. *See Tesoro Alaska Petroleum Co. v. FE.R.C.*, 234 F.3d 1286, 1294 (D.C. Cir. 2000) ("The Commission's failure to respond meaningfully to the evidence renders its decisions arbitrary and capricious. Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned.").

The Final Rule could well be arbitrary and capricious in other aspects as well. Plaintiffs argue HHS failed to adequately account for the impact the Final Rule will have on women, particularly women in rural

areas. Because the Final Rule forces providers to choose between violating ethical obligations or leaving the Title X program, many providers, including Planned Parenthood, informed HHS during the notice and comment period that if HHS implemented the proposed regulation, the providers would exit the program. Planned Parenthood serves approximately 40% of all Title X patients. Custer Decl. ¶ 8. Planned Parenthood's importance to the program is difficult to overstate. "Rural and sparsely populated areas will be harmed most. In those areas, Planned Parenthood is often the only safety-net reproductive health care provider available to patients seeking publicly funded services. In more than half of the counties were Planned Parenthood health centers were located in 2015 (238 of 415), Planned Parenthood served at least half of the women by obtaining publicly supported contraceptive services from a safety-net health center. In nearly 10% of the rural counties (38 of 415), Planned Parenthood was the only safety-net family planning center." *Id.* ¶ 37 (internal footnotes omitted). Planned Parenthood's absence would create a vacuum for family planning services. "Other safety-net clinics that are not forced from Title X will not be able to pick up the slack and provide care to the 1.6 million women, men, and adolescents who today receive vital family planning services from Planned parenthood health centers that participate in the Title X program." *Id.* ¶ 54.

The elimination of Title X providers would be detrimental to the public health. Many women, but especially low-income women, have no interactions with health care providers outside of a Title X provider. Brandis Decl. ¶ 18. The Final Rule will increase not only unintended (and riskier) pregnancies, *id.* ¶ 23, but abortions as well, *id.* ¶ 26. Reduced access to Title X

health centers will result in less testing, increased STIs, and more women suffering adverse reproductive health symptoms. *Id.* ¶ 29.

One would imagine HHS relied on studies and research to determine the impact on women's health should a provider of nearly half of all Title X services withdraw from the program. If HHS in fact relied on something, it is not shown in this record. In fact, HHS does not acknowledge the Title X program stands to be cut in half on May 3, 2019. Instead, HHS baldly asserts that "these final rules will contribute to more clients being served, gaps in service being closed, and improved client care .... " 84 Fed. Reg. at 7723. HHS anticipates new providers will step forward, providers who earlier stayed away from the program due to abortion-related concerns. But HHS fails to show its work. There is no transparency and no way to find out what, if anything, HHS based its assumptions on. The record is devoid of comments from potential providers ready, willing, and able to fill the 1.6 million woman gap in coverage left by Planned Parenthood's exit. Again, when HHS issued the above findings, it knew that, should it implement the Final Rule, it would lose the provider of nearly half of all Title X services within two months. It could be that HHS relied on some internal reports or studies. But on this record, HHS's unsupported conclusions appear to run "counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

As Plaintiffs have demonstrated a likelihood of success on the merits of their claims that the Final Rule is contrary to law and arbitrary and capricious. I tum next to whether Plaintiffs have shown "that irreparable injury is likely in the absence of an injunction." *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (quoting *Winter*, 555 U.S. at 22). As HHS failed to introduce

any evidence on this issue, the only evidence before me is that if the Final Rule goes into effect, many Title X providers will exit the program because, amongst other reasons, the Final Rule violates established standards of medical ethics. Notably, Planned Parenthood will exit Title X if the rule is implemented. Kost Decl. ¶ 109; ECF No. 53. Although many other providers state they too will exit the program, Planned Parenthood is of unique importance because its "health centers serve 41 % of women who rely on Title X sites for contraceptive care." *Id.* ¶ 110. In Vermont, Planned Parenthood is the lone provider of Title X services. Holmes Decl. ¶¶ 6, 19. In fact, every state plaintiff submitted declarations stating they will lose much, if not all of their current Title X funding should the rule go into effect. States' Br. 35-37. The likely harm to the public health, in the form of an increase in sexually transmitted disease and unexpected pregnancies, is not speculative. Brandis Decl. ¶¶ 31, 47. This harm to the public health will have a detrimental economic impact on the states. The Ninth Circuit has recognized that such economic harm (stemming from likely cuts to birth control), and supported by evidence analogous to the declarations provided here, sufficiently demonstrates a threat of harm to a state's economic interest. *Azar*, 911 F.3d at 571-73. Additionally, the *Azar* court concluded such harm is sufficient to establish a likelihood of irreparable injury. *Id.* at 581 (noting that because the APA permits relief "other than money damages," such economic harm was irreparable) (quoting 5 U.S.C. § 702)).

Additionally, the balance of the equities and the public interest tips sharply in favor of the Plaintiffs. "The public interest is served by compliance with the APA." *Id.* "There is generally no public interest in the perpetuation of unlawful agency action." *League of*

Women Voters of US. v. Newby, 838 F.3d 1, 12 (D.C. Cir. 2016). There is ample evidence at this stage that the Final Rule is unlawful. The unrebutted evidence demonstrates, at this stage of the proceedings, that the Final Rule would force medical providers to violate their ethical and professional obligations. Additionally, there is little harm in preserving the status quo. The current regulations have been in place for nearly 50 years and have an excellent track record. With such substantial questions surrounding the legality of the Final Rule, and with the potential for great harm to low-income women in particular should the rule go into effect, these prongs of the preliminary injunction standard tilt quite heavily in Plaintiffs' favor.

The Ninth Circuit recently outlined concerns regarding overbroad injunctions. *See Azar*, 911 F.3d at 583-84 (noting detrimental impact on development of-law and effects on nonparties). In crafting an injunction, "[t]he scope of remedy must be no broader and no narrower than necessary to redress the injury show by the plaintiff1s]." *Id.* at 584. Here, Planned Parenthood operates in 48 states. Plaintiff AMA's member physicians practice and reside in every state in the country. Madara Decl. ¶ 7. AMA members (physicians and licensed health care practitioners) provide counseling to pregnant women in the Title X program. *Id.* There is ample evidence regarding the potential harm to the public health of not only the plaintiff states, but the nation. Brandis Decl. ¶¶ 35-37, 45-54. Given that the harm to Plaintiffs would occur in every state, and considering the balance of equities and the fact that Plaintiffs have demonstrated significant likelihood on the

merits of their claims that the Final Rule is contrary to law, a nationwide injunction is appropriate.[9]

CONCLUSION

Plaintiffs' motions for a preliminary injunction are GRANTED in full. Defendants, and their agents and officers, are restrained from implementing or enforcing any portion of the Final Rule detailed in 84 Fed. Reg. 7714-7791 (March 4, 2019) and shall preserve the status quo under the current regulations pending further order from the Court. No bond is required.

IT IS SO ORDERED.

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[9] On Friday, HHS filed a response to a notice filed Thursday regarding an injunction issued by Judge Bastian in the Eastern District of Washington. Judge Bastian entered a nationwide injunction prohibiting HHS from implementing the Final Rule. HHS argues there is no longer any likelihood of imminent harm. I disagree. As I understand it, the order submitted as an exhibit to ECF No. 137 is a preliminary ruling which Judge Bastian intends to follow with a final opinion sometime before May 3, 2019. Additionally, the Court understands Judge Chen in the Northern District of California issued an injunction last Friday restraining HHS from implementing the rule in California. HHS here states it is considering appealing Judge Bastian's injunction, and asks this Court to stay this matter. Specifically, HHS states that "Should the government seek and obtain a stay of the Washington Order, the Plaintiffs could move this Court to lift the stay, at which point the Court would be in a position to rule promptly." ECF No. 138, 3. The Court will allow a full briefing regarding whether a stay is appropriate. At this point, a ruling on the pending motion is appropriate. Planned Parenthood provides service for nearly half of the entire Title X program. They are a plaintiff in this action, not the action pending before Judge Bastian.

DATED this 29 day of April, 2019.

/s/ Michael J. McShane

Michael J. McShane
United States District Judge

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

No. 1:19-cv-03040-SAB

STATE OF WASHINGTON,
Plaintiff,
v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants.

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, FEMINIST WOMEN'S HEALTH CENTER, DEBORAH OYER, M.D. AND TERESA GALL, F.N.P.
Plaintiffs,
v.

ALEX M. AZAR II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANE FOLEY, M.D., IN HER OFFICIAL CAPACITY AS DEPUTY ASSISTANCE SECRETARY FOR POPULATION AFFAIRS, AND OFFICE OF POPULATION AFFAIRS
Defendants.

ORDER GRANTING PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

Filed April 25, 2019

Before the Court are Plaintiffs' Motions for Preliminary Injunction, ECF Nos. 9 and 18. A hearing on the motions was held on April 25, 2019. The State of Washington was represented by Jeffrey Sprung, Kristin Beneski and Paul Crisalli. Plaintiffs National Family Planning and Reproductive Health Association, *et al.*, (NFPRHA) were represented by Ruth Harlow, Fiona Kaye, Brigitte Amiri, Elizabeth Deutsch, and Joseph Shaeffer. Defendants were represented by Bradley Humphreys. The Court also received *amicus* briefs from American Academy of Pediatrics, *et al.*; Institute of Policy Integrity; State of Ohio, *et al.*, and Susan B. Anthony List. This Order memorializes the Court's oral ruling.

Introduction

Plaintiffs seek to set aside the Office of Population Affairs (OPA), Department of Health and Human Services ("Department") March 4, 2019 Final Rule that revises the regulations that govern Title X family planning programs. 84 Fed. Reg. 77141-01, 2019 WL 1002719 (Mar. 4, 2019). The new regulations were proposed to "clarify grantee responsibilities under Title X, to remove the requirement for nondirective abortion counseling and referral, to prohibit referral for abortion, and to clarify compliance obligations under state and local laws … to clarify access to family planning services where an employer exercises a religious and moral objection … and to require physical and financial separation to ensure clarity regarding the purpose of

Title X and compliance with the statutory program integrity provisions, and to encourage family participation in family planning decisions, as required by Federal law." *Id.*

Plaintiffs contend the Final Rule is in excess of the agency's statutory authority, is arbitrary and capricious, violates the Administrative Procedures Act, violates Title X requirements, violates congressional Nondirective Mandates, violates Section 1554 of the Patient Protection and Affordable Care Act ("ACA"), and is otherwise unconstitutional.

Plaintiffs assert the Final Rule is not designed to further the purposes of Title X, which is to equalize access to comprehensive, evidence-based, voluntary family planning. Rather it is designed to exclude and eliminate health care providers who provide abortion care and referral—which by extension will impede patients' access to abortion—even when Title X funds are not used to provide abortion care, counseling or referral.

Plaintiffs also believe the Final Rule appears to be designed to limit patients' access to modern, effective, medically approved contraception and family planning health care. Plaintiffs argue the Final Rule was designed by the Department to direct Title X funds to providers who emphasize ineffective and inefficient family planning.

Finally, Plaintiffs believe the Final Rule is politically motivated and not based on facts. Instead, it intentionally ignores comprehensive, ethical, and evidence-based health care, and impermissibly interferes with the patient-doctor relationship.

Defendants assert the Final Rule adopted by the Secretary is consistent with the Administrative Proce-

dures Act, consistent with Title X, the Non-directive Mandates, and Section 1554 of the ACA[1], and is otherwise constitutional.

Defendants believe the Final Rule is indistinguishable from regulations adopted over 30 years ago, which were held to be valid by the United States Supreme Court in *Rust v. Sullivan*, 500 U.S. 173 (1991). Finally, Defendants argue Plaintiffs have not shown, at this early stage in the litigation, that the Final Rule violates Section 1008 of Title X—in fact, Plaintiffs cannot make that showing—primarily because of *Rust*.

At issue in this hearing are Plaintiffs' Motions for Preliminary Injunction. The Final Rule is scheduled to take effect on May 3, 2019. Plaintiffs seek to preserve the status quo pending a final determination on the merits.

Motion Standard

"A preliminary injunction is a matter of equitable discretion and is 'an extraordinary remedy that may only be awarded upon a clear showing that a plaintiff is entitled to such relief.'" *California v. Azar*, 911 F.3d 558, 575 (9th Cir. 2018) (quoting *Winter v. NRDC*, 555 U.S. 7, 22 (2008)). "A party can obtain a preliminary injunction by showing that (1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3) 'the balance of eq-

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[1] Defendants also argue Plaintiffs have waived their argument that the Final Rule violates Section 1554 of the ACA by failing to refer to Section 1554 in their comments prior to the Final Rule being published. It is doubtful that an APA claim asserting that an agency exceeded the scope of its authority to act can be waived. Moreover, it appears that during the rule making process the agency was apprised of the substance of the violation.

uities tips in [its] favor,' and (4) 'an injunction is in the public interest.'" *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (alteration in original) (quoting *Winter*, 555 U.S. at 20). The Ninth Circuit uses a "sliding scale" approach in which the elements are "balanced so that a stronger showing of one element may offset a weaker showing of another." *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017) (quotation omitted). When the government is a party, the last two factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). This means that when the government is a party, the court considers the balance of equities and the public interest together. *Azar*, 911 F.3d at 575. "[B]alancing the equities is not an exact science." *Id.* (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1952) (Frankfurter, J., concurring) ("Balancing the equities … is lawyers' jargon for choosing between conflicting public interests")).

Likelihood of success on the merits is the most important factor; if a movant fails to meet this threshold inquiry, the court need not consider the other factors. *Disney*, 869 F.3d at 856 (citation omitted). A plaintiff seeking preliminary relief must "demonstrate that irreparable injury is likely in the absence of an injunction." *Winter*, 555 U.S. at 22. The analysis focuses on irreparability, "irrespective of the magnitude of the injury." *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir. 1999). Economic harm is not normally considered irreparable. *L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1202 (9th Cir. 1980).

"'[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs' before the Court." *L.A. Haven*

Hospice, Inc. v. Sebelius, 638 F.3d 644, 664 (9th Cir. 2011) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). This is particularly true where there is no class certification. *See Easyriders Freedom F.I.G.H.T. v. Hannigan*, 92 F.3d 1486, 1501 (9th Cir. 1996) ("[I]njunctive relief generally should be limited to apply only to named plaintiffs where there is no class certification."); *Meinhold v. U.S. Dep't of Defense*, 34 F.3d 1469, 1480 (9th Cir.1994) (district court erred in enjoining the defendant from improperly applying a regulation to all military personnel (*citing Califano*, 442 U.S. at 702)).

That being said, there is no bar against nationwide relief in the district courts or courts of appeal, even if the case was not certified as a class action, if such broad relief is necessary to give prevailing parties the relief to which they are entitled. *Bresgal v. Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987).

Federal Administrative Agency Rule-Making

Federal administrative agencies are required to engage in "reasoned decisionmarking." *Michigan v. E.P.A.*, __ U.S. __, 135 S.Ct. 2699 (2015). "Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Id.* (quoting *Allentown Mack Sales & Service, Inc. v. NLRB*, 522 U.S. 359, 374 (1998)).

Administrative Procedures Act

The Administrative Procedure Act "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Under the arbitrary and capricious standard contained in

the APA, a reviewing court may not set aside an agency rule that is rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* at 43. (quotation omitted). An agency rule is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

An agency must consider and respond to significant comments received during the period for public comment. *Perez v. Mortgage Bankers Ass'n*, __ U.S.__, 135 S.Ct. 1199, 1203 (2015). The public interest is served by compliance with the APA. *Azar*, 911 F.3d at 581. "The APA creates a statutory scheme for informal or notice-and-comment rulemaking reflecting a judgment by Congress that the public interest is served by a careful and open review of proposed administrative rules and regulations." *Alcaraz v. Block*, 746 F.2d 593, 610 (9th Cir. 1984) (internal quotation marks and citation omitted). "It does not matter that notice and comment could have changed the substantive result; the public interest is served from proper process itself." *Azar*, 911 F.3d at 581.

History of Title X

"No American woman should be denied access to family planning assistance because of her economic condition."[2]

In 1970, Congress created the Title X program[3] to address low-income individuals' lack of equal access to the same family planning services, including modern, effective medical contraceptive methods such as "the Pill," available to those with greater economic resources. NFPRHA, *et al.* Complaint, 1:19-cv-3045-SAB, ECF No. 1, ¶4. Title X monetary grants support family planning projects that offer a broad range of acceptable and effective family planning methods and services to patients on a voluntary basis, 42 U.S.C. § 300(a), creating a nationwide of Title X health care providers. *Id.* at ¶5. Title X gives those with incomes below or near the federal poverty level free or low-cost access to clinical professional, contraceptive methods and devices, and testing and counseling services related to reproductive health, including pregnancy testing and counseling. *Id.* Over almost five decades, Title X funding has built and sustained a national network of family planning health centers that delivers high-quality care. *Id.* at ¶41. It has enabled millions of low-income patients to prevent unintended pregnancies and protect their reproductive health. *Id.* Approximately 90 federal grants, totaling approximately $260 million, for Title X projects now fund more than 1000 provider organizations across all the states and in the U.S. territories,

[2] President Nixon, *Special Message to the Congress on Problems of Population Growth* (July 18, 1969).

[3] Title X became law as part of the "Family Planning Services and Population Research Act of 1970." Pub. L. No. 91-572, 84 Stat. 1504 (1970).

with more than 3800 health centers offering Title X care. *Id.* at ¶6, ¶52. In 2017, the Title X program served more than four million patients. *Id.*

Washington's Department of Health ("DOH") Family Planning Program is the sole grantee of Title X funds in Washington State. Decl. of Cynthia Harris, ECF No. 11 at ¶14. It provides leadership and oversight to its Family Planning Network of 16 subrecipients offering Title X services at 85 service sites. *Id.* at ¶4. The Family Planning Program collaborates with other programs in the DOH, other state agencies, subrecipient network organizations, and other family planning, primary health care, and social service organizations to ensure that Title X services are available statewide on issues related to women's health, adolescent health, family planning, sexually transmitted infection (STI) and Human Immunodeficiency Virus (HIV) prevention and treatment, intimate partner violence, and unintended pregnancy. *Id.*

NFPRHA represents more than 850 health care organizations in all 50 states, the District of Columbia and the U.S. territories, as well as individual professional members with ties to family planning care. ECF No. 19 at ¶5. NFPRHA currently has more than 65 Title X grantee members and almost 700 Title X subrecipient members. These NFPRHA member organizations operate or fund a network of more than 3,500 health centers that provide family planning services to more than 3.7 million Title X patients each year. *Id.* at ¶7.

The scope of the care provided by Title X programs is summarized in OPA's current Program Requirements:

> All Title X-funded projects are required to offer a broad range of acceptable and effective medically (U.S. Food and Drug Administration (FDA)) approved contraceptive methods and related services on a voluntary and confidential basis. Title X services include the delivery of related preventive health services, including patient education and counseling; cervical and breast cancer screening; sexually transmitted disease (STD) and human immunodeficiency virus (HIV) prevention education, testing and referral; and pregnancy diagnosis and counseling.

POA, *Program Requirements for Title X Funded Family Planning Projects*, at 5 (Apr. 2014), https://www.hhs.gov/opa.sites/default/files/Title-X-2014-Program Requirements.pdf ("Program Requirements"). Title X projects also provide basis infertility services, such as testing and counseling. 1:19-cv-3045-SAB, ECF No. 1, at ¶43.

The Title X statute has always provided that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6 ("Section 1008"). The statute authorizes the Secretary to promulgate regulations governing the program. 42 U.S.C. § 300a-4.

The Secretary adopted regulations in 1971 and they remained in effect until 1988 when the Secretary adopted final regulations that drastically altered the landscape in which Title X grantees operated. To summarize, the 1988 regulations:

- Prohibited Title X projects from counseling or referring clients for abortion as a method of family planning;

- Required grantees to separate their Title X project—physically and financially—from prohibited abortion-related activities

- Established compliance standards for family planning projects

- Prohibited certain actions that promote, encourage, or advocate abortion as method of family planning, such as using project funds for lobbying for abortion, developing and disseminating materials advocating abortion, or taking legal action to make abortion available as a method of family planning.

Those regulations were challenged in federal courts and ultimately upheld by the United States Supreme Court. *See Rust v. Sullivan*, 500 U.S. 173 (1991)[4]. The 1988 rules were never fully implemented due to ongoing litigation and bipartisan concern over its invasion of the medical provider-patient relation. State of Washington, Complaint, ECF No. 1 at ¶30.

In 1993, President Clinton suspended the 1988 Regulations by way of a Presidential memorandum to the Department:

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[4] In *Rust*, the United States Supreme Court held that (1) the regulations were based on permissible construction of the statute prohibiting the use of Title X funds in programs in which abortion is a method of family planning; (2) the regulations do not violate First Amendment free speech rights of Title X fund recipients, their staffs or their patients by impermissibly imposing viewpoint-discriminatory conditions on government subsidies; and (3) regulations do not violate a woman's Fifth Amendment right to choose whether to terminate a pregnancy and do not impermissibly infringe on doctor-patient relationship. 500 U.S. at 184-203.

Title X of the Public Health Services Act [this subchapter] provides Federal funding for family planning clinics to provide services for low-income patients. The Act specifies that Title X funds may not be used for the performance of abortions, but places no restrictions on the ability of clinics that receive Title X funds to provide abortion counseling and referrals or to perform abortions using non-Title X funds. During the first 18 years of the program, medical professionals at Title X clinics provided complete, uncensored information, including nondirective abortion counseling. In February 1988, the Department of Health and Human Services adopted regulations, which have become known as the "Gag Rule," prohibiting Title X recipients from providing their patients with information, counseling or referrals concerning abortion. Subsequent attempts by the Bush Administration to modify the Gag Rule and ensuing litigation have created confusion and uncertainty about the current legal status of the regulations.

The Gag Rule endangers women's lives and health by preventing them from receiving complete and accurate medical information and interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their patients. Furthermore, the Gag Rule contravenes the clear intent of a majority of the members of both the United States Senate and House of Representatives, which twice passed legislation to block

> the Gag Rule's enforcement but failed to override Presidential vetoes.
>
> For these reasons, you have informed me that you will suspend the Gag Rule pending the promulgation of new regulations in accordance with the "notice and comment" procedures of the Administrative Procedure Act [5 U.S.C.A. §§ 551 et seq., 701 et seq.].

"The Title X Gag Rule," Memorandum for the Secretary of Health and Human Services, 1993 WL 366490 (Jan. 22, 1993).

New regulations were finalized in 2000, 65 Fed. Reg. 41270 (Jul. 3, 2000), *codified at* 42 C.F.R. Pt. 59, and these regulations remain in effect unless and until the new Final Rule is implemented.

Congressional Intent / The Department's Program Requirements

Plaintiffs argue that laws passed by Congress since *Rust* limit the Department's discretion in implementing Title X regulations. These laws include Section 1554 of the ACA and congressional Non-directive Mandates contained in appropriation bills. They also rely on the Department's own program requirements to support their arguments.

1. § 1554 of the ACA

Section 1554 of the ACA states:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
>
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

2. Appropriations Mandate

With the Non-directive Mandate, Congress has explicitly required every year since 1996 that "all pregnancy counseling [in Title X projects] shall be non-directive." NFPRHA, *et al.* Complaint, 1:19-cv-3045-SAB, ECF No. 1, at ¶78. Non-directive counseling provides the patient with all options relating to her pregnancy, including abortion. *Id.* at ¶76. Congress has been providing Non-directive Mandates in its appropriations bills for the past 24 years.

3. Department of Health and Human Services Program Requirements / Quality Family Planning

Title X grantees are required to follow the Quality Family Planning (QFP) guidelines, issued by the Centers for Disease Control and Prevention and OPA. State of Washington, Complaint, ECF No. 1, at ¶45. This document reflects evidence-based best practices for providing quality family planning services in the United States.[5] It requires that options counseling should be provided to pregnant patients as recommended by the American College of Obstetricians and Gynecologists and others, including that patients with unwanted pregnancy should be "fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption, and abortion." *Id.* at ¶46.

The Department's Program Requirements require Title X projects to provide nondirective pregnancy counseling. *Id.* at ¶44.

Federal Conscience Laws

In the Executive Summary of the Final Rule, the Department indicates that one of the purposes of revising the Title X regulations was to eliminate provisions which are inconsistent with the health care conscience statutory provisions. 84 Fed. Reg. 7714, 7716. These provisions include the Church Amendment, the Coats-Snowe Amendment and the Weldon Amendment. *Id.*

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[5] "Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs," Morbidity and Mortality Weekly Report Vol. 62, No. 4 (April 25, 2014), *available at* https:www.cdc.gov/mmwr/pdf/rr/rr6304.pdf (last accessed April 24, 2019) (the QFP).

4. The Church Amendment

"The Church Amendments, among other things, prohibit certain HHS grantees from discriminating in the employment of, or the extension of staff privileges to, any health care professional because they refused, because of their religious beliefs or moral convictions, to perform or assist in the performance of any lawful sterilization or abortion procedures. The Church Amendments also prohibit individuals from being required to perform or assist in the performance of any health service program or research activity funded in whole or in part under a program administered by the Secretary contrary to their religious beliefs or moral convictions. *See* 42 U.S.C. 300a-7." 84 Fed. Reg. at 7716, n.7.

5. 1996 Coats-Snowe Amendment

"The Coats-Snowe Amendment bars the federal government and any State or local government that receives federal financial assistance from discriminating against a health care entity, as that term is defined in the Amendment, who refuses, among other things, to provide referrals for induced abortions. *See* 42 U.S.C. 238n(a)." 84 Fed. Reg. at 7716, n.8.

6. 2005 Weldon Amendment

"The Weldon Amendment was added to the annual 2005 health spending bill and has been included in subsequent appropriations bills." 84 Fed. Reg. at 7716, n. 9. "The Weldon Amendment bars the use of appropriated funds on a federal agency or programs, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that

the health care entity does not, among other things, refer for abortions." *Id.*

Analysis

As set forth above, the Ninth Circuit uses a sliding scale approach in determining whether it is appropriate to grant a preliminary injunction. Although Plaintiffs have met their burden of showing that all four factors tip in their favor, the irreparable harm and balance of equities factors tip so strongly in Plaintiffs' favor that a strong showing of likelihood on the merits was not necessary.

7. Likelihood of Success on the Merits

Plaintiffs have presented reasonable arguments that indicate they are likely to succeed on the merits, thus meeting the threshold inquiry. In so finding, the Court has not concluded that Plaintiffs will definitely prevail on the merits, nor has it concluded that they are more likely going to prevail. The preliminary injunction standard requires neither of these conclusions. *See Azar*, 911 F.3d at 582 ("The purpose of such interim equitable relief is not to conclusively determine the rights of the parties but to balance the equities as the litigation moves forward.") (quoting *Trump v. Int'l Refugee Assistance Proj.*, __ U.S. __, 137 S.Ct. 2080, 2087 (2017)). Rather, it requires a determination that Plaintiff has made a colorable claim—a claim that has merit and a likely chance of success.

First, Plaintiffs have presented initial facts and argument that the separation requirement in the Final Rule forces clinics that provide abortion services to maintain separate facilities and finances for Title X programs will more likely than not increase their expenses unnecessarily and unreasonably.

Second, Plaintiffs have presented initial facts and argument that the Final Rule gag requirement would be inconsistent with ethical, comprehensive, and evidence-based health care.

Third, Plaintiffs have presented initial facts and argument that the Final Rule violates Title X regulations, the Non-directive Mandates and Section 1554 of the Affordable Care Act and is also arbitrary and capricious.

Specifically, Plaintiffs have demonstrated the Final Rule likely violates the central purpose of Title X, which is to equalize access to comprehensive, evidence-based, and voluntary family planning. They have presented facts and argument that the Final Rule violates the Non-directive Mandate because it requires all pregnant patients to receive referrals for pre-natal care, regardless of whether the patient wants to continue the pregnancy, and regardless of the best medical advice and treatment that might be recommended for that patient.

They have also presented facts and argument that the Final Rule likely violates Section 1554 of the ACA because the Final Rule creates unreasonable barriers for patients to obtain appropriate medical care; impedes timely access to health care services; interferes with communications regarding a full range of treatment options between the patient and the heath care provider, restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions, and violates the principles of informed consent and the ethical standards of health care professions.

Fourth, Plaintiffs, with the help from *Amicus* parties, have presented facts and argument that the Final Rule is arbitrary and capricious because it reverses

long-standing positions of the Department without proper consideration of sound medical opinions and the economic and non-economic consequences.

Finally, Plaintiffs have presented facts and argument that the Department failed to consider important factors, acted counter to and in disregard of the evidence in the administrative record and offered no reasoned analysis based on the record. Rather, it seems the Department has relied on the record made 30 years ago, but not the record made in 2018-19.

8. Irreparable Harm

Plaintiffs have demonstrated they are likely to suffer irreparable harm in the absence of a preliminary injunction by presenting facts and argument that the Final Rule may or likely will: (1) seriously disrupt or destroy the existing network of Title X providers in both the State of Washington and throughout the entire nation—this network has been carefully knit together over the past 45 years and there is no evidence presented by the Department that Title X is being violated or ignored by this network of providers; (2) impose additional and unnecessary costs on the State of Washington and other states; (3) harm the health of the patients who rely on the existing Title X providers; and (4) drive many Title X providers from the system either because of the increased costs imposed by the new separation requirements or because they cannot or will not comply with the allegedly unprofessional gag rule requirements.

Washington State has shown that it is not legally or logistically feasible for Washington to continue accepting any Title X funding subject to the Final Rule. At the minimum, Washington stands to lose more than $28

million in savings from the loss of federal dollars. It has demonstrated the harmful consequences of the Final Rule will uniquely impact rural and uninsured patients. If the Final Rule is implemented, over half of Washington counties would be unserved by a Title X-funded family planning provider. Students at Washington colleges and universities will be especially hurt by the Final Rule. DOH reports it does not have the funding that would be required to comply with the Final Rule, nor would it be able to comply with the May 3, 2019 deadline.

NFPRHA currently has more than 65 Title X grantee members and almost 700 Title X sub-recipient members. These NFPRHA member organizations operate or fund a network of more than 3,500 health centers that provide family planning services to more than 3.7 million Title X patients each year. NFPRHA has shown that upon its effective date, the Final Rule will cause all current NFPRHA members grantees, subrecipients, and their individual Title X clinicians to face a Hobson's Choice that harms patients as well as the providers. Faced with this difficult choice, many NFPRHA members will leave the network once the Final Rule becomes effective, thereby leaving low-income individuals without Title X providers.

It is worth noting that Plaintiffs have submitted substantial evidence of harm, including declarations from Karl Eastlund, President and CEO of Planned Parenthood of Greater Washington and North Idaho, ECF No. 10; Cynthia Harris, program manager for the Family Planning Program, Washington DOH, ECF No. 11; Anuj Khattar, M.D., primary care physician and reproductive health provider, ECF No. 12; Dr. Judy Kimelman, practitioner at Seattle Obstetrics & Gynecology Group, ECF No. 13; Bob Marsalli, CEO of the

Washington Association for Community Health, ECF No. 14; David Schumacher, Director of the Office of Financial Management, State of Washington, ECF No. 15; Dr. Judy Zerzan-Thul, Chief Medical Officer for the Washington State Health Care Authority, ECF No. 16; Clare M. Coleman, President and CEO of the National Family Planning & Reproductive Health Association, ECF No. 19; Dr. Kathryn Kost, Acting Vice President of Domestic Research at the Guttmacher Institute, ECF No. 20; Connie Cantrell, Executive Director of the Feminist Women's Health Center, ECF No. 21; Kristin A. Adams, Ph.D, President and CEO of the Indiana Family Health Council, ECF No. 22; J. Elisabeth Kruse, M.S., C.N.M., A.R.N.P, Lead Clinician for Sexual and Reproductive Health and Family Planning at the Public Health Department for Seattle and King County, Washington, ECF No. 23; Tessa Madden, M.D., M.P.H., Director of the Family Planning Division, Department of Obstetrics and Gynecology, Washington University School of Medicine, ECF No. 24; Heather Maisen, Manager of the Family Planning Program in the Public Health Department for Seattle and King County, Washington, ECF No. 25; and Sarah Prager, M.D., Title X Director of the Feminist Women's Health Center, ECF No. 26.

Yet, the Government's response in this case is dismissive, speculative, and not based on any evidence presented in the record before this Court.

9. Balance of Equities/Public Interest

The balance of equities and the public interest strongly favors a preliminary injunction, which tips the scale sharply in favor of Plaintiffs.

There is no public interest in the perpetration of unlawful agency action. Preserving the status quo will not harm the Government and delaying the effective date of the Final Rule will cost it nothing. There is no hurry for the Final Rule to become effective and the effective date of May 3, 2019 is arbitrary and unnecessary.

On the other hand, there is substantial equity and public interest in continuing the existing structure and network of health care providers, which carefully balances the Title X, the congressional Non-directive Mandates, and Section 1554 of the Affordable Care Act, while the legality of the new Final Rule is reviewed and decided by the Court.

Accordingly, **IT IS HEREBY ORDERED**:

1. The State of Washington's Motion for Preliminary Injunction, ECF No. 9, is **GRANTED**.

2. National Family Planning & Reproductive Health Center, *et al.*'s Motion for Preliminary Injunction, ECF No. 18, is **GRANTED**.

3. Defendants and their officers, agents, servants, employees, and attorneys, and any person in active concert or participation with them, are **ENJOINED** from implementing or enforcing the Final Rule entitled *Compliance with Statutory Program Integrity Requirements*, 84 Fed. Reg. 7714-01 (March 4, 2019), in any manner or in any respect, and shall preserve the status quo pursuant to regulations under 42 C.F.R., Pt. 59 in effect as of the date of April 24, 2019, until further order of the Court.

4. No bond shall be required pursuant to Fed. R. Civ. P. 65(c).

IT IS SO ORDERED. The Clerk of Court is directed to enter this Order and forward copies to counsel.

DATED this 25th day of April 2019.

(SEAL)

/s/ Stanley A. Bastian
Stanley A. Bastian
United States District Judge

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Case No. 19-cv-01184-EMC

STATE OF CALIFORNIA,

Plaintiff,

v.

ALEX M. AZAR II, ET AL.,

Defendants.

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

ESSENTIAL ACCESS HEALTH, INC., ET AL.,

Plaintiffs,

v.

ALEX M. AZAR II, ET AL.,

Defendants.

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

Docket No. 26, C-19-1184

Docket No. 25, C-19-1195

EDWARD M. CHEN, United States District Judge

Title X of the Public Health Service Act provides federal funding for family-planning services. In the quarter-century since 1993, the Department of Health and Human Services' ("HHS") guidelines, while prohibiting funding of abortion services pursuant to Title X, have required Title X grantees to provide neutral, fac-

tual counseling to pregnant clients and to maintain financial separation between their Title X activities and their abortion services. This permitted grantees to operate effectively while complying with Title X. On March 4, 2019, HHS promulgated new regulations implementing Title X which substantially changes those guidelines in a manner that jeopardizes the provision of essential and counseling and care to thousands of women. *See* 84 Fed. Reg. 7714 (2019) (the "Final Rule"). According to Plaintiffs, the Final Rule will create daunting barriers to California women seeking timely, effective reproductive health care, impose medically and ethically unsound restrictions on Title X providers attempting to provide patient-centered care, and inflict severe public health consequences and costs on the State. They contend the Final Rule violates recent acts of Congress, substantive and procedural provisions of the Administrative Procedures Act ("APA"), and the First and Fifth Amendments to the U.S. Constitution.

The Final Rule goes into effect on May 3, 2019. Plaintiffs in these coordinated actions, the State of California and Essential Access Health, seek to preliminarily enjoin the implementation of the Final Rule.

Unless enjoined, the Final Rule will irreparably harm individual patients and public health in California as a whole. The Final Rule commands medical professionals to provide incomplete and misleading information to women seeking to terminate their pregnancies contrary to what patients want and need, delaying and potentially frustrating their attempts to obtain time-sensitive care, and thereby jeopardizing their health and welfare. The Final Rule threatens to decimate the network of Title X providers in California and drastically restrict patients' access to a wide range of vital services, including contraceptive resources and

screenings for sexually transmitted infections, reproductive cancers, and HIV. As a result, the Final Rule is likely to inflict significant public health consequences and costs on the State and frustrate Essential Access's organizational mission to promote access to quality healthcare. In contrast, Defendants are unable to articulate any real harm they will suffer if the Final Rule is preliminarily enjoined during the pendency of this action.

Plaintiffs have shown that the Final Rule likely violates Congressional directives that Title X providers must be permitted to give pregnant patients neutral, factual information regarding the full range of their medical options, and must not be compelled to act in a way that is contrary to medical ethics. The record evidence indicates that HHS promulgated the Final Rule, which represents a sharp break from prior policy, without engaging in any reasoned decisionmaking. In particular, HHS cited speculative, unsubstantiated fears about the misuse of Title X funds as justification for its change in policy and touted anticipated benefits of the Final Rule that have no basis in the record, while cursorily dismissing overwhelming evidence of the significant adverse impact the Rule will have. The Final Rule is thus contrary to law and arbitrary and capricious.

Having considered the parties' briefs and accompanying submissions, as well as the oral argument of counsel and amici briefs filed herein, the Court finds that Plaintiffs have established they are likely to succeed on the merits on several of their claims, are likely to suffer irreparable injury if the Final Rule is not enjoined, and the balance of hardships and the public interest tip sharply in favor of granting injunctive relief. Accordingly, Plaintiffs' motions for a preliminary injunction are **GRANTED in part and DENIED in**

part.[1] The Court enjoins implementation of the Final Rule but limits the injunction to California.

I. BACKGROUND

A. Statutory and Regulatory Background

1. Title X

The Public Health Service Act ("PHSA"), an expansive statutory scheme that consolidated existing public health laws and established various agencies and grant programs to support health care and research, was enacted in 1944. In 1970, Congress amended the PHSA to add "Title X—Population Research and Voluntary Family Planning Programs." Pub. L. No. 91-572, § 6, 84 Stat. 1504, 1506–08 (1970) (codified at 42 U.S.C. §§ 300–300a-6). Title X 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." 42 U.S.C. § 300(a). Such grants and contracts must "be made in accordance with such regulations as the Secretary may promulgate." *Id.* § 300a-4.

[1] The recent injunction issued against Defendants' implementation of the Final Rule by Judge Bastian in *State of Washington v. Azar*, No. 1:19-cv-3040 (E.D. Wash. filed Mar. 5, 2019), does not obviate this Court's duty to resolve the dispute before it. *See Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 435 (E.D.N.Y. 2018) (finding "no authority for the proposition that Plaintiffs cannot establish irreparable harm simply because another court has already enjoined the same challenged action"); *e.g., Kravitz v. United States Dep't of Commerce*, 366 F. Supp. 3d 681 (D. Md. 2019); *State v. Ross*, 358 F. Supp. 3d 965, 1050 (N.D. Cal. 2019); *Nat'l Ass'n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 461 (D.D.C. 2018).

Congress explained that its purpose in enacting Title X was:

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

Pub. L. No. 91-572 § 2, 84 Stat. 1504.

Per Section 1008 of the PHSA, "[n]one of the funds appropriated under [Title X] shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6.

2. <u>The 1971 Regulations, 1981 Guidance, 1988 Regulations, and *Rust v. Sullivan*</u>

Consistent with Section 1008, HHS has never permitted Title X grantees to use Title X funds to perform or subsidize abortions. *See* 42 C.F.R. §§ 59.5(a)(5), 59.9 (1986). However, the agency had long interpreted Title X to allow grantees to provide pregnant women with nondirective counseling and referrals about their medical options, including abortion. The initial regulations, issued in 1971, stated that Section 1008 only required that a Title X "project will not provide abortions as a method of family planning." 36 Fed. Reg. 18,465, 18,466 (1971). "During the mid-1970s, HHS General Counsel memoranda made a further distinction between directive ('encouraging or promoting' abortion) and nondirective ('neutral') counseling on abortion, prohibiting the former and permitting the latter." *Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992). This distinction was reaffirmed in 1981, when HHS issued guidelines "requir[ing] nondirective 'options counsleling' [*sic*] on pregnancy termination (abortion), prenatal care, and adoption and foster care when a woman with an unintended pregnancy requests information on her options, followed by referral for these services if she so requests." 53 Fed. Reg. 2922, 2923 (1988). Thus, early on, HHS distinguished nondirective counseling (and referrals) from the actual provision of abortion services, permitting the former but prohibiting the latter.

That policy was reversed in 1988 when HHS promulgated new regulations to provide "'clear and operational guidance' to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning." *Id.* at 2923–24. The term "family planning" was redefined to encompass solely

"preconceptional counseling, education, and general reproductive health care," while expressly excluding "pregnancy care (including obstetric or prenatal care)." 42 C.F.R. § 59.2 (1989).

The thrust of the 1988 regulations was reflected in three main provisions. First, they provided that a "Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning," even in response to a client's specific request. *Id.* § 59.8(a)(1). Second, the regulations prohibited a Title X project from engaging in any activities that "encourage, promote or advocate abortion as a method of family planning." *Id.* § 59.10(a). Third, Title X projects were required to be "physically and financially separate" from prohibited abortion activities. *Id.* § 59.9. The regulations enumerated nonexclusive factors for the Secretary of HHS to consult in determining whether the separation requirement was met, including the existence of separate accounting records and separate personnel, and the degree of physical separation of the project from facilities for prohibited activities. *Id.* The regulations made clear that "[m]ere bookkeeping separation of Title X funds from other monies is not sufficient." *Id.*

The 1988 regulations were subject to legal challenge, and were upheld by the Supreme Court against a facial challenge by Title X grantees in *Rust v. Sullivan*, 500 U.S. 173, 111 S.Ct. 1759, 114 L.Ed.2d 233 (1991). The *Rust* plaintiffs objected to the regulations on statutory and constitutional grounds. They argued that the regulations were arbitrary and capricious and exceeded the Secretary's authority under Title X, that the regulations' proscription of abortion counseling and referral violated the First Amendment, and that the regulations

violated a woman's Fifth Amendment right to choose whether to terminate her pregnancy. *Id.* at 183, 192, 201, 111 S.Ct. 1759.

The Supreme Court found none of these claims availing. It rejected the plaintiffs' first statutory claim after applying *Chevron* deference to the Secretary's construction of Title X. The Court determined that statutory text and legislative history of Title X were ambiguous regarding abortion counseling and referral as well as the separation of Title X and non-Title X services. *Id.* at 184, 111 S.Ct. 1759 ("The language of § 1008—that '[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity."). In the face of that ambiguity, the Court decided that the Secretary's construction of the statute "to require a ban on counseling, referral, and advocacy within the Title X project" was reasonable, noting that the "broad language" of "§ 1008 prohibits the use of Title X funds 'in programs where abortion is a method of family planning'" and that "the legislative history is ambiguous and fails to shed light on relevant congressional intent." *Id.* at 184–85, 111 S.Ct. 1759. Similarly, the Court ruled that the Secretary's construction of Title X to require physical and financial separation between Title X projects and abortion activities was permissible. *Id.* at 188–90, 111 S.Ct. 1759. Importantly, even after finding the 1988 regulations facially reasonable under *Chevron*, the Court required the Secretary to justify his change of interpretation from the prior rules with a "reasoned analysis." *Id.* at 187, 111 S.Ct. 1759 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). In this

regard, the Court observed that the Secretary's decision to reverse course from the prior regulations was justified in part because it responded to "critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG) that prior policy failed to implement properly the statute and that it was necessary to provide 'clear and operational guidance to grantees about how to preserve the distinction between Title X programs and abortion as a method of family planning,'" as well as "client experience under the prior policy" and "a shift in attitude against the elimination of unborn children by abortion." *Id.* (quoting 53 Fed. Reg. at 2923–24).

Rust further held that the regulations did not "violate the First Amendment by impermissibly discriminating based on viewpoint" because "[t]he Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way." *Id.* at 192–93, 111 S.Ct. 1759. The Court noted its previous holding that "the government may 'make a value judgment favoring childbirth over abortion, and ... implement that judgment by the allocation of public funds.'" *Id.* (quoting *Maher v. Roe*, 432 U.S. 464, 474, 97 S.Ct. 2376, 53 L.Ed.2d 484 (1977)) (alteration in original). *Rust* thus determined that "[t]he Secretary's regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities." *Id.* at 196, 111 S.Ct. 1759. Grantees "remain[ed] free ... to pursue abortion-related activities when they [we]re not acting under the auspices of the Title X project." *Id.* at 198, 111 S.Ct. 1759. The Court cautioned, however,

that it was "not ... suggest[ing] that funding by the Government, even when coupled with the freedom of the fund recipients to speak outside the scope of the Government-funded project, is invariably sufficient to justify Government control over the content of expression." *Id.* at 199, 111 S.Ct. 1759.

Lastly, the Court ruled that the 1988 regulations did not impermissibly burden a woman's Fifth Amendment right to choose whether to terminate her pregnancy. Citing the principle that "the Due Process Clauses generally confer no affirmative right to governmental aid," the Court held that "[t]he Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and may validly choose to fund childbirth over abortion." *Id.* at 201, 111 S.Ct. 1759 (quoting *Webster v. Reprod. Health Servs.*, 492 U.S. 490, 507, 109 S.Ct. 3040, 106 L.Ed.2d 410 (1989)). In support of this holding, *Rust* reasoned that "[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X." *Id.* at 202, 111 S.Ct. 1759. The Court also found unpersuasive the plaintiffs' contention that "the regulations violate a woman's Fifth Amendment right to medical self-determination and to make informed medical decisions free of government-imposed harm" by "depriving a Title X client of information concerning abortion as a method of family planning." *Id.* The Court observed that under the regulations, "a doctor's ability to provide, and a woman's right to receive, information concerning abortion and abortion-related services outside the context of the Title X project remains unfettered." *Id.* at 203, 111 S.Ct. 1759.

3. <u>1993 Suspension of the 1988 Regulations and Promulgation of the 2000 Regulations</u>

Although they survived legal challenges, the 1988 regulations were never fully implemented. The Secretary suspended the regulations in 1993 "based, in part, upon her conclusion that the 'Gag Rule' is an inappropriate implementation of the Title X statute because it unduly restricts the information and other services provided to individuals under this program." 58 Fed. Reg. 7462, 7462 (1993). As a result, after 1993, Title X grantees returned to operating under the 1981 guidelines.

In 2000, HHS formally issued new regulations "revoking the regulations published on February 2, 1988" and largely restoring the 1981 regulatory scheme. 65 Fed. Reg. 41270 (2000); 65 Fed. Reg. 41281 (2000). Most notably, under the 2000 regulations, Title X grantees were required to "[o]ffer pregnant women the opportunity to be provided information and counseling regarding ... [p]regnancy termination" and "provide neutral, factual information and nondirective counseling on each of the options, and referral" upon request. 42 C.F.R. § 59.5(a)(5) (July 3, 2000). Grantees' non-Title X abortion activities had to be "separate and distinct" from Title X activities, but "[c]ertain kinds of shared facilities [we]re permissible, so long as it [wa]s possible to distinguish between the Title X supported activities and non-Title X abortion-related activities." 65 Fed. Reg. at 41281. For example, common waiting rooms and staff were permissible, as long as the costs and salaries were properly pro-rated and allocated. *Id.* The agency provided the following explanation for doing away with the physical separation requirement:

> If a Title X grantee can demonstrate by its financial records, counseling and service protocols, administrative procedures, and other means that—within the identified set of Title X-supported activities—promotion or encouragement of abortion as a method of family planning does not occur, then it is hard to see what additional statutory protection is afforded by the imposition of a requirement for "physical" separation. Indeed, in the light of the enforcement history noted above, it is not unreasonable to say that the standard of "physical" separation has, as a practical matter, had little relevance or applicability in the Title X program to date. Moreover, the practical difficulty of drawing lines in this area, both as experienced prior to 1988 and as evident in the history of the Gag Rule itself, suggests that this legal interpretation is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services.

65 Fed. Reg. at 41276.

4. Statutory Developments

Two statutory developments since *Rust* are germane to this case. First, in every year since 1996, Congress has specified in HHS appropriations acts (part of annual omnibus appropriations acts containing a subsection specific to HHS funding) that "amounts provided to [Title X] projects under such title shall not be expended for abortions, [and] that *all pregnancy counseling shall be nondirective*." *E.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropria-

tions Act, Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018) (emphasis added).

Second, in Section 1554 of the Affordable Care Act ("ACA"), enacted in 2010, Congress directed that HHS:

> shall not promulgate any regulation that—
>
> > (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
> >
> > (2) impedes timely access to health care services;
> >
> > (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
> >
> > (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
> >
> > (5) violates the principles of informed consent and the ethical standards of health care professionals; or
> >
> > (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114. As discussed below, these laws affect the enforcement of Title X.

B. The Final Rule

On March 4, 2019, HHS promulgated the Final Rule that is the subject of this suit. 84 Fed. Reg. 7714. The Final Rule represents a sharp break from the 2000

regulations, and a return in many aspects to the 1988 regulations. Its key provisions are detailed below.

1. Restrictions on Abortion Counseling and Referrals

The Final Rule contains several overlapping provisions regarding abortion counseling. It directs that Title X grantees may "[n]ot provide, promote, refer for, or support abortion as a method of family planning." 42 C.F.R. § 59.5(a)(5) (2019).[2] Similarly, it provides that "[a] Title X project may not encourage, promote or advocate abortion as a method of family planning." § 59.16(a)(1). And "[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." § 59.14(a). The Final Rule does not define what it means to "encourage," "promote," or "support" abortions. Nor does it fully illuminate the lines between permissible provision of information and impermissible encouragement, promotion, and support.

However, when a Title X client is confirmed to be pregnant, the Final Rule requires that the client "shall be referred to a health care provider for medically necessary prenatal health care." § 59.14(b)(1). Such referral is mandated even if the client has decided not to carry the pregnancy to term. The "Title X provider may"—but is not required to—provide "[n]ondirective pregnancy counseling." *Id.* That counseling can only be "provided by physicians or advanced practice providers [("APPs")]," *id.*, defined as "a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose,

[2] Unless otherwise indicated, all citations in the form of "§ ___" are to the Final Rule published at 84 Fed. Reg. at 7786–91.

treat, and counsel patients," § 59.2. As a result, medical professionals without a graduate level degree, such as registered nurses or licensed practical nurses, cannot provide such counseling.

The Final Rule forbids Title X grantees from making referrals for abortion services. *See* § 59.5(a)(5) (A Title X project "must.... [n]ot provide, promote, refer for, or support abortion as a method of family planning."); § 59.14(a) ("A Title X project may not ... refer for ... abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion."). Even if a client specifically requests a referral to an abortion provider, the Title X project can at most provide "[a] list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)." § 59.14(b)(1)(ii), (c)(2). The list cannot include specialty clinics that do not also provide comprehensive primary health care. Further, the referral list "may be limited to those that do not provide abortion." § 59.14(c)(2). If the referral list includes abortion providers, those providers may not comprise "the majority" of the providers on the list, and "[n]either the list nor project staff may identify which providers on the list perform abortion." *Id.* Hence, a Title X project may provide a client seeking an abortion a referral list of only providers who do not perform abortions without so indicating. A Title X project responding to a client's request for an abortion referral can, at most, provide a list on which more than half of the providers do not provide abortions. And the project cannot tell the patient which of the providers actually performs abortions. With respect to medical emergencies, the Final Rule states: "In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an

appropriate provider of medical services needed to address the emergency." § 59.14(b)(2). The Final Rule provides as the single example of a qualifying emergency "an ectopic pregnancy." § 59.14(e)(2).

These counseling and referral restrictions represent a sharp break from the 2000 regulations, as well as the prior 1981 guidelines effective since 1993. Until now, Title X grantees have been required[3] to offer pregnant women nondirective pregnancy counseling and referral upon request. 42 C.F.R. § 59.5(a)(5). Grantees were not required to refer a woman who did not intend to continue her pregnancy to prenatal care, and no restrictions were placed on referral lists.

2. Requirement of Physical and Financial Separation

Under the Final Rule, "[a] Title X project must be organized so that it is physically and financially separate ... from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program." § 59.15. "In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities," and "[m]ere bookkeeping separation of Title X funds from other monies is not sufficient." *Id.* The Secretary will determine whether such objective integrity and independence exist by looking to relevant factors that include: "The existence of separate, accurate accounting records"; "[t]he degree of separation [of] facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and web-

[3] An exception is made for grantees with moral and religious objections to abortion. *See* 76 Fed. Reg. 9968 (2011).

sites)"; "[t]he existence of separate personnel, electronic or paper-based health care records, and workstations"; and the "extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent." *Id.*

The new separation requirements again represent a marked departure from the current rule. Under the 2000 regulations, grantees' abortion activities were required to be financially separate from their Title X activities, but "[c]ertain kinds of shared facilities [we]re permissible, so long as it [wa]s possible to distinguish between the Title X supported activities and non-Title X abortion-related activities." 65 Fed. Reg. at 41281. For example, common waiting rooms and staff were permissible, as long as the costs and salaries were properly pro-rated and allocated. *Id.*

3. Removal of 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 Final 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).

4. Encouragement of Family Participation

The Final Rule requires 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 fami-

ly participation (or the specific reason why such family participation was not encouraged)." § 59.5(a)(14).

The 2000 regulations contained no such requirement, although Title X itself provides that "[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection." 42 U.S.C. § 300(a).

C. Procedural Background

The motions currently before the Court arise from two lawsuits. The first is brought by the State of California ("California"). *See State of California v. Azar et al.*, No. 3:19-cv-1184-EMC, 2019 WL 1023794 (N.D. Cal. filed March 4, 2019) ("*California*"), Docket No. 1 ¶ 1. The second is brought by Essential Access Health, Inc. and Dr. Melissa Marshall (collectively, "Essential Access"). *See Essential Access Health, Inc., et al. v. Azar et al.*, No. 3:19-cv-1195-EMC (N.D. Cal. filed March 4, 2019) ("*Essential Access*"), Docket No. 1 ¶¶ 15–16. California's Title X network is the largest in the nation. *California* Docket No. 1 ¶ 3. Essential Access is a non-profit corporation that is California's sole Title X grantee and administers the state's Title X program. *Essential Access* Docket No. 1 ¶ 15. Dr. Marshall is the Chief Executive Officer of CommuniCare Health Centers in Yolo County, California, which has been part of the State's Title X network since 1993. *Id.* ¶ 16. California, Essential Access Health, and Dr. Marshall are hereinafter referred to collectively as "Plaintiffs." Defendants are HHS and Alex M. Azar, II, sued in his official capacity as Secretary of HHS.

California and Essential Access filed their respective motions for preliminary injunction on March 21, 2019. *California* Docket No. 26 ("California Mot."); *Es-*

sential Access Docket No. 25 ("Essential Mot."). Defendants filed a consolidated opposition on April 8, 2019. *California* Docket No. 61 ("Opp."). Plaintiffs filed replies on April 11, 2019. *California* Docket No. 84 ("California Reply"); *Essential Access* Docket No. 63 ("Essential Reply"). The Court held a hearing on the motions on April 18, 2019.

II. LEGAL STANDARD

A preliminary injunction is a matter of equitable discretion and "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008). Its "purpose ... is to preserve the status quo and the rights of the parties until a final judgment issues in the cause." *U.S. Philips Corp. v. KBC Bank N.V.*, 590 F.3d 1091, 1094 (9th Cir. 2010).

A party seeking a preliminary injunction must meet one of two variants of the same standard. The traditional *Winter* standard requires the movant to show "that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20, 129 S.Ct. 365. Under the "sliding scale" variant of the same standard, "if a plaintiff can only show that there are 'serious questions going to the merits'—a lesser showing than likelihood of success on the merits—then a preliminary injunction may still issue if the 'balance of hardships tips *sharply* in the plaintiff's favor,' and the other two *Winter* factors are satisfied." *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017) (emphasis in original) (quoting *Shell Offshore, Inc. v. Greenpeace, Inc.*,

709 F.3d 1281, 1291 (9th Cir. 2013)). In other words, irrespective of the robustness of the showing on the merits required, a plaintiff must demonstrate it is likely to suffer irreparable injury in the absence of preliminary relief. Accordingly, the Court begins by addressing that factor.

III. DISCUSSION

A. Likelihood of Irreparable Harm, the Balance of Equities, and the Public Interest

The record evidence establishes that the irreparable injury, balance of hardships, and public interest factors tip sharply in Plaintiffs' favor. *All. for the Wild Rockies*, 865 F.3d at 1217.

1. Harm to California's Public Health and Essential Access's Organizational Mission

Plaintiffs are likely to suffer several forms of irreparable harm unless the Final Rule is enjoined pending resolution of this case on the merits. The first type of harm is to California's public health and to Essential Access's organizational mission to promote access to high-quality healthcare. *See State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1074 (N.D. Cal. 2018) (finding irreparable harm from agency rule that "will have irreparable consequences for public health") (citing *Sierra Club v. U.S. Dep't of Agric., Rural Utilities Serv.*, 841 F. Supp. 2d 349, 358–59 (D.D.C. 2012)); *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013) (finding irreparable harm where "organizational plaintiffs have shown ongoing harms to their organizational missions as a result of the statute"); *League of Women Voters of United States v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (holding that obstacles that "make it more difficult for the [organizations] to accomplish their

primary mission ... provide injury for purposes both of standing and irreparable harm").

California's efforts to advance its public health objectives by "provid[ing] women and men a means by which they decide for themselves the number, timing, and spacing of their children," Cantwell Decl. ¶ 3, and Essential Access's mission "to champion and promote quality sexual and reproductive health care for all," Rabinovitz Decl. ¶ 3, are in accord. Both will be undermined by the Final Rule qualitatively and quantitatively.

First, the Final Rule will directly compromise providers' ability to deliver effective care and force them to obstruct and delay patients with pressing medical needs. Abortion is a time-sensitive procedure; the medical risks and costs associated with it "increase with any delay." Kost Decl. ¶ 93. Yet, the Final Rule erects barrier after barrier between patients trying to make an informed decision about whether to continue their pregnancies and their clinicians. A clinician *must* refer a pregnant patient to prenatal care that focuses on carrying the pregnancy to term, even if the patient has made clear her decision to terminate her pregnancy. *Id.* ¶¶ 87, 91. The clinician *cannot* refer the patient to a provider of abortion services, even if the patient specifically requests such a referral. *Id.* ¶ 88. At most the clinician may provide a referral list. Most of the list must be non-abortion providers—in other words, most of the list must be *non-responsive* to what the patient requests. *Id.* And the clinician is *barred* from even identifying to the patient which providers on the referral list are the ones she asked for (providers of abortion services), so the patient must expend further time and effort figuring out for herself which providers on the list in fact can give her the care she wants and needs. *Id.*

Incredibly, the Final Rule does not require a clinician who furnishes a patient with a referral list that is wholly non-responsive to even *notify her that the list does not contain a single provider of the services she requested. Id.* This pregnancy counseling process is thus, as the President of Essential Access aptly puts it, a "charade" from beginning to end. Rabinovitz Decl. ¶ 50. The overall effect of the Final Rule is to "harm and confuse all patients" during a medically and emotionally sensitive period and "ultimately threaten their health and well-being." Kost Decl. ¶¶ 90, 92, 94.

Second, the Final Rule threatens to drastically reduce access to the wide array of services provided by Title X projects by driving large numbers of providers out of the program. Compliance with the physical separation requirement, which in many cases effectively requires providers to establish "mirror" facilities and staff, would be cost-prohibitive for many providers in California's Title X network. *See* Rabinovitz Decl. ¶ 43; Nestor Decl. ¶ 13; McKinney Decl. ¶ 10; Forer Decl. ¶ 31. In addition, a significant number of Title X projects have indicated that they will likely drop out of the program because they believe the Final Rule compels them to compromise the quality of care they provide and violate their ethical obligations. Sub-recipients of Essential Access's Title X funds representing 233 clinic sites serving over 774,000 patients "would leave or consider leaving" Title X if they are prohibited from referring patients for abortion services. Rabinovitz Decl. ¶ 42. Sub-recipients representing 194 clinic sites serving over 682,000 patients "will leave or consider leaving" if they are required by the Final Rule to encourage family involvement where an adolescent patient seeks confidential services. *Id.; see, e.g.*, Nestor Decl. ¶¶ 11–12; McKinney Decl. ¶ 9. Likewise, "Planned Parenthood

affiliates and their health centers"—which serve over 40% of all Title X patients nationwide—"would be forced to discontinue their participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15–16.

The net effect of so many providers leaving Title X will be a significant reduction in the availability of important medical services. The substantial Title X funding Essential Access currently receives—approximately $ 20 million per year—provides "comprehensive sexual and reproductive health care for more than 1 million" patients in California annually. Rabinovitz Decl. ¶¶ 1, 13–15. Essential Access has submitted evidence that the vast majority of its subrecipients—85 percent—would be forced to lay off staff, cut training, and reduce outreach and education activities without that funding. *Id.* ¶ 44. A third would have to reduce clinic hours. *Id.* Some would have to shut down core services and programs entirely. *See, e.g.*, Thomas Decl. ¶¶ 11–13 (Fresno Economic Opportunities Commission "will not be able to operate" HEARTT, its family planning and reproductive health service for youth, without Title X funds); Nestor Decl. ¶¶ 5–10, 14 (Without Title X funds, the San Francisco Department of Public Health will have to "substantially curtail" its training programs, public education and outreach projects, and "special projects to address emerging public health challenges"); Marshall Decl. ¶ 28 ("Without Title X funding, CommuniCare will not run the outreach services that inform young people of its teen clinic services, nor provide teen clinic services at all."); Wilburn Decl. ¶¶ 16–21, ("The loss of Title X funds will be nearly fatal to [the Community Action Partnership of San Luis Obispo County]'s Health and

Prevention Division," including its outreach programs, teen program, and Hepatitis C testing services).

If Title X funding is reduced, patients in California accordingly stand to lose access to a wide range of "vital health services," many of which have nothing to do with abortion, since Title X providers "serve as a trusted entry point for medical care generally." California Mot. at 24; *see, e.g.*, Rabinovitz Decl. ¶ 12 ("In 2017 alone, Essential Access sub-recipients ... provided more than 1.6 million family planning visits" and administered "more than 148,000 Pap tests, more than 118,000 clinical breast exams, more than 642,000 chlamydia screenings, more than 700,000 gonorrhea screenings, and more than 341,000 HIV tests."); Brindis Decl. ¶¶ 59–60; Tuttle Decl. ¶ 8; McCarthy Decl. ¶ 7; Wilburn Decl. ¶¶ 17–19. In particular, "[i]n less populous regions, the Rule will create 'contraceptive deserts' where women in need of Title X-funded contraceptive services will be unable to find an affordable, well-qualified provider within their county." California Mot. at 21. Nationwide, in one-fifth of U.S. counties the only safety-net family planning center is a Title X site. Kost Decl. ¶ 78. Should any of these sites drop out of the Title X program as a result of the Final Rule, many individuals would have no access to high-quality, affordable family planning care in their counties at all. *Id.* In California specifically, eighteen counties would be left without a single Title X-funded health center if all the family planning providers that perform abortions were to close. Rabinovitz Decl. ¶ 43.

Even among providers who remain in Title X, service capacity will decrease because the requirement that pregnancy counseling can only be provided by physicians and APPs excludes "vast numbers of medical professionals" who currently provide such counsel-

ing. Rabinovitz Decl. ¶ 52; McKinney Decl. ¶ 11; Kost Decl. ¶ 86. This will compound an already "severe crisis in physician and nurse practitioner availability," creating even more critical shortages in counseling resources. Castellano-Garcia Decl. ¶ 11. Many Title X grantees do not have enough physicians and APPs on staff to serve their patients, so those patients will have to either wait for much longer to receive counseling that is often time-sensitive, or simply will not receive the family-planning information they need. *See, e.g.*, McKinney Decl. ¶ 11; Forer Decl. ¶ 30.

Third, the quality of Title X services will be compromised. Patients served by Title X-funded providers use more effective contraceptive methods at higher rates than those served by non-Title X-funded providers. Rabinovitz Decl. ¶ 46. Title X patients "are more likely [than non-Title X patients] to adopt or continue using long-acting and reversible contraceptive methods ('LARCs')," which "are highly effective [in preventing pregnancy] because they obviate the need for daily administration or use at the time of intercourse." *Id.*; *see also* Kost Decl. ¶¶ 119–121 (describing a 35 percent reduction in women using LARCs after Texas "made a series of changes to its family planning program ..., which included disqualifying agencies providing abortion"). "Diminishing access to LARCs may result in a greater number of unintended pregnancies." Rabinovitz Decl. ¶ 46. Moreover, the Final Rule's separation provision requires health centers to maintain duplicate records systems. Such non-integrated records systems threaten patient health by increasing the risk of error due to "incomplete medical histories, missing data, lost test results, incorrect medication, dosage instructions, and allergy warnings, and other miscommunications across patient records." *Id.* ¶ 70.

Ultimately, the consequence of the reduced availability and quality of health services is worse health outcomes for patients and the public as a whole. The number of unintended pregnancies will increase, which is "likely to result in premature births, low birth weight infants, and congenital defects." Cantwell Decl. ¶¶ 24, 29; Brindis Decl. ¶¶ 52–55. Indeed, the Final Rule could have the perverse effect of *increasing* abortion rates, since "[o]ver half of unintended pregnancies end in miscarriage or abortion." California Mot. at 23; Tosh Decl. ¶ 25 (citing report documenting that 45% of unintended pregnancies result in abortion, and another 13% result in miscarriages). Instances of STIs and other conditions that would otherwise be diagnosed by Title X-funded testing will also likely increase. *See* Brindis Decl. ¶¶ 59–65 (citing study estimating that in 2017, Title X-funded testing "averted approximately 90 to 400 cases of HIV and 47,740 to 56,670 other STIs," diagnosed "many pelvic inflammatory disease (PID) cases, ectopic pregnancies, ... infertility cases" and "reproductive cancers"); Kost Decl. ¶ 82.

In short, there is substantial evidence in the record before the Court which establishes that California's public health and Essential Access's mission to promote quality sexual and reproductive care will be irreparably harmed unless the Final Rule is enjoined.

2. Economic Harm to California

Next, the economic harms that flow from the Final Rule's detrimental effects on public health also constitute irreparable harm to California. *See California v. Health & Human Servs.*, 351 F. Supp. 3d 1267, 1297 (N.D. Cal. 2019) ("*HHS*") (finding irreparable harm to plaintiff states where HHS rule creating exemptions to the ACA contraceptive mandate will cause "tens of

thousands of women" to lose contraceptive coverage, and the states "document[ed] the fiscal harm that will flow to them as a result"); *see also California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) ("*Azar*") (affirming finding of irreparable economic harm to states from the same HHS rules "because the states will not be able to recover monetary damages" for their APA claims per 5 U.S.C. § 702).

California's state Medicaid program, Medi-Cal, "is the primary funder for low-income Californians' healthcare services." Cantwell Decl. ¶ 28. Via Medi-Cal, the Final Rule's impact on public health translates to substantial financial and administrative burdens for California. For example, Medi-Cal insures 64% of unplanned births in the state. Tosh Decl. ¶¶ 26, 44. It is estimated that each unintended pregnancy in California costs the public fisc $ 6,557 in medical, welfare, and other social service costs. *Id.* ¶ 27. Moreover, Medi-Cal "would likely also bear a portion of the costs associated with any delays in the diagnosis and treatment of STIs or breast or cervical cancer." Cantwell Decl. ¶ 30.

3. <u>Economic Harm to Essential Access</u>

Essential Access will also suffer irreparable economic harm if the Final Rule's physical separation requirement becomes effective. Because that requirement is so stringent, Essential Access estimates that it "will be forced to spend exorbitant sums to construct a 'mirror' office," at the cost of $ 325,000 in the first year and $ 212,500 every year thereafter. Essential Reply at 13; Rabinovitz Decl. ¶ 66. Its sub-recipients estimate that compliance with the separation requirement will cost an average of $ 119,000 per agency. Rabinovitz Decl. ¶ 69. Bringing its infrastructure into compliance with the separation requirement will also require Es-

sential Access to divert resources it "otherwise devotes to its core operations and its mission." Essential Mot. at 32 (citing Rabinovitz Decl. ¶ 67); *see E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094, 1116 (N.D. Cal. 2018) (holding that organizational plaintiffs " 'have established a likelihood of irreparable harm' based on their showing of serious 'ongoing harms to their organizational missions,' including diversion of resources") (quoting *Valle del Sol*, 732 F.3d at 1029). As with the economic harm to California, Essential Access's economic harm is irreparable because it "will not be able to recover monetary damages" for its APA claims. *Azar*, 911 F.3d at 581 (citing 5 U.S.C. § 702).

4. Defendants' Responses to Plaintiffs' Evidence of Irreparable Harm

Defendants attack Plaintiffs' assertions of irreparable harm on several grounds.

First, Defendants do not dispute that damage to public health can constitute irreparable harm, but instead claim that the public health impact California is describing depends on the response of regulated third parties—*i.e.*, recipients of Title X funding—to the Final Rule, and therefore that the "chain of events necessary to create these speculative harms" is too "attenuated." Opp. at 43 (citing *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 562, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)). Not so.

To begin with, Defendants ignore that the Final Rule's harm to Title X patients described above directly undermines California's public health objectives. Moreover, uncontroverted record evidence Plaintiffs have submitted shows that the harms they describe are not speculative; they are "*likely* in the absence of an injunction." *Winter*, 555 U.S. at 22, 129 S.Ct. 365 (em-

phasis in original). As detailed above, Planned Parenthood has stated unequivocally that its whole network of health centers "would be forced to discontinue their participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15. So have many Title X providers in California's network. *See, e.g.*, Nestor Decl. ¶ 11; McKinney Decl. ¶ 9. Indeed, one has already dropped out of Title X as of April 4, 2019 in response to the Final Rule. *Essential Access* Docket No. 64 (Supplemental Rabinovitz Decl.) ¶ 5. Hundreds more have indicated that they "would leave or consider leaving" Title X if the Final Rule is implemented. Rabinovitz Decl. ¶ 42.

Equally unambiguous are the adverse health consequences that will follow from the mass departure of Title X providers. The inverse correlation between the availability of publicly-funded contraceptives and the rate of unintended pregnancies is well-documented in the record. *See* Brindis Decl., Exh. B at 11, 12 n.73 (citing a 2015 report showing that 286,700 unintended pregnancies were averted in California in a single year as a result of publicly funded contraceptive services); Rich Decl., Exh. L at 31–32 ("Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200 unplanned births and 277,800 abortions. Without services provided by these providers, the U.S. unintended pregnancy rate would have been 31% higher."). Plaintiffs have also cited three case studies documenting the adverse health consequences that directly resulted when family planning services providers that offer abortion-related services were excluded from public funding. *See* Brindis Decl., Exh. B at 6–7 (Indiana county that cut funding to Planned Parenthood facility almost immediately experienced "one of the largest and

most rapid HIV outbreaks the country has ever seen"); Kost Decl. ¶¶ 119–22 (disqualifying agencies that provided abortion services from public funding in Texas and Iowa led to marked decreases in family planning services rendered and the use of effective contraceptives).

Moreover, there is already a "severe" shortage of physician and nurse practitioner availability, so implementation of the Final Rule's physician and APP requirement will directly exacerbate patients' lack of access to pregnancy counseling. Castellano-Garcia Decl. ¶ 11; McKinney Decl. ¶ 11; Forer Decl. ¶ 30. The resulting shortfall in service capacity caused would manifest immediately, before any final decision on the merits in this case will be reached. *See* 11A Charles Alan Wright et al., Federal Practice and Procedure § 2948.1 (3d ed. 2013) ("Perhaps the single most important prerequisite for the issuance of a preliminary injunction is a demonstration that if it is not granted the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered."). Nothing about this chain of causation is attenuated.

What *is* speculative is Defendants' assurance that any gap left by an exodus in current Title X providers will be fully filled by new providers entering the program. Defendants point to HHS's claim in the Final Rule that it "does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." 84 Fed. Reg. at 7782; *see also id.* at 7756. But this claim is not backed by any dis-

cernible evidence or analysis.[4] *See* Part III.C.2.f., *infra* (discussing HHS's analysis of the expected costs and benefits of the Final Rule). In fact, at oral argument, when pressed for any record evidence substantiating this (highly consequential) assertion, Defendants' counsel could offer none. Counsel insisted that it is "just intuitive" that new grantees will fully replace departing ones in the "fluid marketplace" for medical services. Intuition is no rebuttal to Plaintiffs' evidence of threatened irreparable harm. Nor is Defendants' "intuition" presumed as a matter of logic and common sense. Plaintiffs note that nationwide, in one-fifth of U.S. counties, including rural counties in California, the only safety-net family planning center is a Title X site. Kost Decl. ¶ 78; *see also* Rabinovitz Decl. ¶ 51 (stating that in some rural areas of California, a patient would have to travel more than five hours in order to access an abortion provider that qualifies for a referral under the Final Rule). It defies common sense to assume that in these regions, new healthcare centers will simply materialize and seamlessly assume the client load of exiting grantees.

Second, Defendants insist that the claimed harm to Essential Access is not imminent. Opp. at 43–44. This argument is unavailing for the same reason that the expected harm to California is not speculative—Plaintiffs' evidence demonstrates that access to and the quality of family planning services will be adversely af-

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[4] Given the lack of evidence that new grantees will enter the Title X program, it is hardly surprising that Defendants do not appear to have considered how much time it would take these hypothetical new grantees to become operational Title X providers, and what the impact on patients might be from even a temporary disruption in services.

fected as soon as the Final Rule goes into effect. With respect to compliance costs, the process for establishing a physically and financially separate "mirror" office would "requir[e] Essential Access to expend resources on planning and implantation of operational changes *immediately* after the Final Rule takes effect."[5] Rabinovitz Decl. ¶ 66 (emphasis added); *see id.* ¶ 68. The same time pressure extends to Essential Access's subrecipients. McKinney Decl. ¶ 10. Furthermore, as to Essential Access' ability to deliver quality health care, it cannot be ignored that abortion is a time-sensitive procedure, and the medical risks and costs associated with it "increase with any delay." Kost Decl. ¶ 93; *cf. Chalk v. U.S. Dist. Court Cent. Dist. of California*, 840 F.2d 701, 710 (9th Cir. 1988) (finding that time-sensitive nature of AIDS diagnosis is a "factor favoring a preliminary injunction"). The Final Rule, by requiring Title X projects to provide incomplete and perhaps even misleading information to patients, and prohibiting projects from referring patients to abortion providers, forces patients to expend more time and effort to secure information and referrals regarding abortions. In doing so, it increases the health risks and limits the care options for pregnant women, whether they have already decided to obtain an abortion or are simply seeking more information to guide their determination of whether to continue their pregnancies. *See* Kost Decl. ¶ 94 ("[T]he inability to make a fully informed decision on how to proceed with a pregnancy would be especially harmful for women with severe diabetes, heart conditions, HIV/AIDS and estrogen-dependent tu-

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[5] The Final Rule sets a compliance date for the physical separation requirement of March 4, 2020. 84 Fed. Reg. at 7791. But of course, grantees will have to begin the process for bringing their operations into compliance far before that.

mors—all conditions that could be exacerbated by continuing a pregnancy."). In other words, the Final Rule is likely to jeopardize patients' welfare as soon as it is implemented, thus impairing both patient health and Essential Access' central mission.

Third, Defendants argue that the alleged harm to Essential Access's sub-recipients and Title X patients is not harm to Essential Access itself. *See* Opp. at 43. This argument misses the point. As noted above, Essential Access's organizational mission is to "promote quality sexual and reproductive health care for all." Rabinovitz Decl. ¶ 3. It works toward this mission in part by distributing Title X funds to its sub-recipients to facilitate their provision of family planning services to patients. *Id.* ¶ 6. Thus, the potentially detrimental impact the Final Rule will have on those sub-recipients' capacities to provide services to Title X patients is just one manifestation of the harm that Essential Access will suffer with respect to its organizational mission.

Fourth, Defendants recite the proposition that "ordinary compliance costs are typically insufficient to constitute irreparable harm." Opp. at 45 (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005)). "But as the Ninth Circuit recently reiterated, the general rule that '[e]conomic harm is not normally considered irreparable' does not apply where there is no adequate remedy to recover those damages, such as in APA cases." *E. Bay Sanctuary Covenant*, 354 F. Supp. 3d at 1116 (quoting *Azar*, 911 F.3d at 581). In *East Bay Sanctuary*, the court found that the plaintiffs established a likelihood of irreparable harm "based on their showing of serious 'ongoing harms to their organizational missions,' including diversion of resources and the non-speculative loss of substantial funding from other sources." 354 F. Supp. 3d at 1116 (citing *Valle del*

Sol, 732 F.3d at 1029). The same reasoning obtains here, because Essential Access and its sub-recipients will not be able to recover for the substantial costs they would need to expend to come into compliance with the new separation requirements even if the Final Rule is found to violate the APA.

Accordingly, Plaintiffs have satisfied the irreparable harm prong of the preliminary injunction inquiry.

B. The Balance of Equities and the Public Interest

Where the government is a party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Here, both factors weigh in favor of preliminarily enjoining the Final Rule.

On Plaintiffs' side is their interest in averting the "potentially dire public health and fiscal consequences from the implementation of the Final Rules," *HHS*, 351 F. Supp. 3d at 1298, discussed above. The Final Rule threatens to impair the health and welfare of women who benefit from Title X-funded services and Plaintiffs' mission to provide quality healthcare. Moreover, there are the "substantial costs stemming from a higher rate of unintended pregnancies that are likely to occur if women lose access to the [family planning] coverage afforded under the rules now in place." *Id.* And Plaintiffs are not the only ones that will suffer hardship absent an injunction. *See Golden Gate Rest. Ass'n v. City & Cty. of San Francisco*, 512 F.3d 1112, 1126 (9th Cir. 2008) ("In considering the public interest, we may consider the hardship to all individuals covered by the [challenged law], not limited to parties...."). As explained above, public health problems will adversely impact the general public. *See Stormans, Inc. v. Se-*

lecky, 586 F.3d 1109, 1139 (9th Cir. 2009) ("The 'general public has an interest in the health' of state residents.") (quoting *Golden Gate Rest. Ass'n*, 512 F.3d at 1126). A group of thirteen municipalities has also submitted an amicus brief explaining that they will be harmed by the Final Rule in analogous ways to California by the implementation of the Final Rule. *See Essential Access* Docket No. 62 at 7–13. Each of these municipalities receives substantial Title X funding annually and they collectively serve hundreds of thousands of patients through their Title X programs. *See id.* at 4–7.

On the other hand, Defendants identify no substantiated harm if a preliminary injunction were to issue. They have not documented any substantial abuse of Title X funds. *See* Part III.C.2.b., *infra.* The only harm Defendants currently assert is that which the government will suffer "if it 'is enjoined by a court from effectuating statutes enacted by representatives of its people.'" Opp. at 46 (quoting *Maryland v. King*, 567 U.S. 1301, 133 S.Ct. 1, 183 L.Ed.2d 667 (2012) (Roberts, C.J., in chambers)). But as Judge Gilliam pointed out in another case: "Here, of course, the 'representatives of the people'—the United States Congress—passed the [relevant statute], and the precise question in this case is whether the Executive's attempt to implement the Final Rules is inconsistent with Congress's directives." *HHS*, 351 F. Supp. 3d at 1299. As set forth in detail below, this Court finds a high likelihood that the Final Rule was promulgated in violation of substantive statutory law and APA-mandated procedures, and "[t]here is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (citations omitted). "To the contrary, there is a substantial public interest 'in having governmental agen-

cies abide by the federal laws that govern their existence and operations.'" *Id.* (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). It may be true that Defendants intend the Final Rule to represent the government's "value judgment favoring childbirth over abortion," Opp. at 46 (quoting *Rust*, 500 U.S. at 192–93, 111 S.Ct. 1759), but that value judgment cannot be effectuated in an unlawful manner or in violation of other Congressional directives.

Hence, the balance of hardships and the public interest tip sharply in favor of Plaintiffs. Although injunctive relief is thus warranted "if [Plaintiffs] can only show that there are 'serious questions going to the merits,'" *All. for the Wild Rockies*, 865 F.3d at 1217, for the reasons discussed below, Plaintiffs have done more than show "serious questions." They have established they are likely to succeed on the merits of many of their claims.

C. Likelihood of Success on the Merits/Serious Questions Going to the Merits

California argues that it is likely to succeed on its APA claims because the Final Rule is not in accordance with law and exceeds statutory authority, in violation of 5 U.S.C. § 706(2)(A) and (2)(C). California also contends the Rule is arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).[6] California Mot. at 10–19. Essential Access makes similar arguments under the APA, as well as an additional contention that the Final Rule was promulgated without proper notice and com-

[6] California's complaint also alleges that the Final Rule denies women equal protection of the laws in violation of the Fifth Amendment. *See California* Docket No. 1 ¶¶ 221–29. However, California does not rely on that claim in its preliminary injunction motion.

ment. Essential Mot. at 9–21. It also presses two constitutional claims: that the Final Rule infringes upon Dr. Marshall's First Amendment rights, and that it is void for vagueness under the Fifth Amendment Due Process Clause. *Id.* at 21–25. Each claim is addressed below.

1. <u>The Final Rule is Not in Accordance with Law</u>

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, 123 S.Ct. 832, 154 L.Ed.2d 863 (2003) (emphasis in original). Defendants assert that the Final Rule cannot be unlawful under § 706(2)(A) because it is "materially indistinguishable from [the 1988 rule] the Supreme Court has already upheld" in *Rust.* Opp. at 8. Plaintiffs, however, rely on HHS Appropriations Acts and the ACA, which were enacted after *Rust* was decided, so their claim is not automatically foreclosed by *Rust.* The Court therefore must determine whether the Final Rule is inconsistent with the Appropriations Acts and the ACA.

a. <u>The Nondirective Counseling Provision</u>

The most recent "Department of Defense and Labor, Health and Human Services, and Education Appropriations Act" provides:

> For carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, $ 286,479,000: *Provided*, That amounts provided to said projects under such

> title shall not be expended for abortions, *that all pregnancy counseling shall be nondirective*, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

Pub. L. No. 115-245, Div. B, Tit. II, 132 Stat 2981, 3070–71 (2018) (emphasis added). This "Nondirective Counseling Provision" has been included in HHS appropriations acts ("Appropriations Acts") every year since 1996 in substantially similar form. *See, e.g.*, Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321, 1321–22 (1996) (requiring that "all pregnancy counseling shall be nondirective....").

According to Plaintiffs, the provisions of the Final Rule that restrict abortion counseling and referral conflict with the Nondirective Counseling Provision. *See* California Mot. at 11–12; Essential Mot. at 13–14. Defendants in their briefing initially took this to mean that Plaintiffs were arguing that "the nondirective provision implicitly repealed section 1008 and *Rust*," Opp. at 14, because *Rust* upheld similar provisions in the 1988 regulations as a permissible construction of Section 1008. However, Defendants subsequently recognized that the doctrine of implied repeal is not apposite here because the Nondirective Counseling Provision and Section 1008 are not in irreconcilable conflict. *See Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 154–55, 96 S.Ct. 1989, 48 L.Ed.2d 540 (1976) (explaining that repeals by implication come into play "where provisions in the two acts are in irreconcilable conflict") (citation omitted); Opp. at 16 ("There is no conflict—much less an irrecon-

cilable one—between Title X ... and the nondirective provision."). *Rust* did not purport to interpret Section 1008 as requiring directive counseling in favor of birth; rather, it held that HHS's 1988 rule was one permissible interpretation, not the only permissible interpretation. *See Rust*, 500 U.S. at 184, 111 S.Ct. 1759 ("The language of § 1008—that '[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning'—does not speak directly to the issues of counseling, referral, advocacy, or program integrity."). Indeed, at oral argument, Defendants' counsel agreed with Plaintiffs that Section 1008 and the Nondirective Counseling Provision can be read in harmony—requiring pregnancy counseling under Title X to be nondirective does not necessarily run afoul of Section 1008's general proscription that no Title X funds "shall be used in programs where abortion is a method of family planning." That is demonstrated by HHS's 2000 regulations, which proscribed funding of abortions but permitted nondirective pregnancy counseling.[7]

The question is whether the Final Rule, as one interpretation of Section 1008, is inconsistent with the Appropriations Acts' mandate that "pregnancy counseling" be "nondirective." HHS does not dispute that it has an obligation to comply with the Nondirective Counseling Provision. It wrote in the notice of proposed rulemaking for the Final Rule that "[s]ince it originally created the Title X program in 1970, Congress has, from time to time, imposed additional requirements on it," including "the annual Title X appropriation includes

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[7] Apart from the brief period when the 1988 regulations were effective, HHS has consistently interpreted Section 1008 to allow nondirective pregnancy counseling.

the provisos that 'all pregnancy counseling shall be nondirective.'" 83 Fed. Reg. 25502, 25502 (2018) ("Proposed Rule"); *id.* at 25507 n.11 ("That counseling on abortion be nondirective is required by the appropriations law applicable to Title X."). Similarly, the Final Rule states that Title X "projects *must* comply with Congress's requirement that pregnancy counseling be nondirective, and the Department *must* enforce that requirement." 84 Fed. Reg. at 7747 (emphases added).

As Defendants see it, however, the Final Rule is not inconsistent with the Nondirective Counseling Provision because § 59.14(b)(1) of the Final Rule allows a Title X provider to "choose to provide ... [n]ondirective pregnancy counseling" to a pregnant patient. Plaintiffs contend, on the other hand, that the Final Rule is inconsistent with the Nondirective Counseling Provision because it mandates referrals to prenatal care while categorically barring referrals for "abortion as a method of family planning," and imposes unreasonable restrictions on the provision of referral lists for patients seeking an abortion. Plaintiffs also argue that even without the referral prohibition and restrictions, the Final Rule "effectively prohibits nondirective counseling ... by issuing a vague prohibition on providers who 'encourage' or 'promote' abortion." California Mot. at 11. Plaintiffs believe this "unclear guidance will likely cause providers to forgo discussions altogether for fear of violating the Rule." *Id.* at 12.

i. "Nondirective Counseling" Includes Referrals

The first part of the parties' dispute focuses on whether "nondirective counseling" under the Appropriations Acts encompasses referrals. It does, as indicated by statute, regulations, and industry practice. First, Congress expressed its understanding in the

PHSA that "nondirective counseling" includes referral. *See* 42 U.S.C. § 254c-6(a)(1)[8] (providing that HHS shall make training grants "providing adoption information *and referrals* to pregnant women on an equal basis with all other courses of action *included in nondirective counseling* to pregnant women") (emphases added). The PHSA and the HHS Appropriations Acts appear to be the only instances in which Congress has used the term "nondirective counseling," and Defendants have not argued otherwise. Notably, the Final Rule, in interpreting Title X, incorporates the definition of "nondirective counseling" from § 254c-6(a)(1) of the PHSA in the context of adoption. 84 Fed. Reg. at 7733 ("Congress has expressed its intent that postconception adoption information and *referrals be included as part of any nondirective counseling* in Title X projects when it passed [§ 254c-6(a)(1)].") (emphasis added). Congress' use of the identical term "nondirective counseling" should be read consistently across the PHSA and the HHS Appropriations Acts to include referrals as part of counseling. *See Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130, 115 S.Ct. 1278, 131 L.Ed.2d 160 (1995) (teaching that, in interpreting an ambiguous statutory phrase, "[i]t is particularly illuminating to compare" two different statutes employing the "virtually identical" phrase); *cf. Erlenbaugh v. United States*, 409 U.S. 239, 243, 93 S.Ct. 477, 34 L.Ed.2d 446 (1972) ("[A] legislative body generally uses a particular word with a consistent meaning in a given context.").

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[8] Section 254c-6(a)(1) was enacted in 2000, four years after the Nondirective Counseling Provision was first enacted. As noted above, the Nondirective Counseling Provision has been included in every HHS Appropriations Act since 1996, including from 2000 to 2019.

Second, as a matter of regulatory law, HHS itself characterizes referrals as part of counseling throughout the Final Rule. *See id.* at 7730 ("[N]ondirective pregnancy counseling can include counseling on adoption, and corresponding referrals to adoption agencies."); 7733–34 ("Title X providers may provide adoption counseling, information, and referral as a voluntary family planning service for non-pregnant clients ... as part of nondirective postconception counseling...."). The Final Rule, in this regard, is not unique. As early as 1981, HHS has defined counseling in its Title X Guidelines to include referral. *See* U.S. Dep't of Health and Human Services, *Program Guidelines for Project Grants for Family Planning Services* § 8.2 (1981) ("Post-examination *counseling* should be provided to assure that the client ... receives appropriate *referral* for additional services as needed.") (emphases added).

Third, the accepted usage within the medical field of "nondirective counseling" supports Plaintiffs' position. *See Louisiana Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 357, 106 S.Ct. 1890, 90 L.Ed.2d 369 (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, 94 S.Ct. 2223, 41 L.Ed.2d 1 (1974)); *Alabama Power Co. v. EPA*, 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."). This is reflected in the HHS Office of Population Affairs' ("OPA") own "Quality Family Planning" guidelines ("QFP Guidelines"), which are incorporated into the agency's Title X Family

Planning Guidelines.[9] *See* Center for Disease Control and Prevention, Providing Quality Family Planning Services (2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf; Rich Decl., Exh. A at 5. The "Pregnancy Testing and Counseling" section of the QFP Guidelines instructs that "[pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals."[10] Brindis Decl., Exh. C at 13–14. The QFP Guidelines then advise that "[o]ptions counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG [the American College of Obstetricians and Gynecologists] and AAP [the American Academy of Pediatrics]." *Id.* at 14. "Both ACOG and AAP are explicit in their recommendations that all pregnant individuals, including adolescents, be provided with factual, nondirective pregnancy options counseling that includes information on and timely referral for abortion services." Kost Decl. ¶ 25. The American Medical Association's 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 preg-

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[9] The OPA website continues to refer providers of family planning services to these guidelines. *See* HHS Office of Population Affairs, Quality Family Planning, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html (last visited April 2, 2019) ("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.").

[10] Understanding referral to be a part of the counseling process also conforms to common sense. A patient would presumably be rather taken aback if, for instance, upon receiving an initial diagnosis of cancer from her doctor, the doctor then refuses to provide a referral for further testing and medically appropriate treatment.

nancy and to provide any and all appropriate referrals, including for abortion services, are contrary to the AMA's Code of Medical Ethics." Rich Decl., Exh. I at 3. *See also* Rabinovitz Decl. ¶ 33 ("Nondirective counseling ... requires nondirective referrals for particular services—including abortion—upon request of the patient.").

That Congress intended "nondirective counseling" include nondirective "referrals" is reinforced by the fact that Congress repeatedly enacted the Nondirective Counseling Provision in substantially the same form every year since 1996. Throughout these last 23 years the HHS regulations have consistently interpreted Title X to "require[ ], in the event of an unplanned pregnancy and where the patient requests such action, [grantees] to provide nondirective counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects." 58 Fed. Reg. at 7464. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." *Lorillard v. Pons*, 434 U.S. 575, 580, 98 S.Ct. 866, 55 L.Ed.2d 40 (1978) (citations omitted); *see Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1154–55 (9th Cir. 2010).

Defendants counter by relying on general dictionary definitions to urge that " '[c]ounseling' does not, in its common usage, necessarily include within its definition the act of 'referral.'" Opp. at 17 (quoting Black's Law Dictionary (10th ed. 2014)). But the Court need not resort to indications of common usage because there is ample statutory, regulatory, and industry guidance on the meaning of "counseling" in the specific context of medical services at issue here. *See United States v. Lettiere*, 640 F.3d 1271, 1274 (9th Cir. 2011)

("Only in the absence of a statutory definition does this court normally look to the ordinary meaning or dictionary definition of a term."); *see also United States v. Costello*, 666 F.3d 1040, 1044 (7th Cir. 2012) (cautioning that "[d]ictionary definitions are acontextual, whereas the meaning of sentences depends critically on context, including all sorts of background understandings").

Next, Defendants point to various instances in the Final Rule where the phrase "counseling and referral" is used. *See, e.g.*, 84 Fed. Reg. at 7730 ("[T]he Department believes that Title X providers can provide certain counseling and referrals in a postconception setting...."), 7747 ("Nondirective counseling and referrals for postconception services ... are the appropriate approach in the context of pregnancy...."), 7778 ("[T]he final rule eliminates the requirement that Title X projects provide abortion counseling and referral."). To Defendants, the conjunction "and" indicates that counseling and referral are discrete activities. Absent any other interpretive guidance, this may be a plausible reading. But given the express references to counseling as "including" referral in the PHSA, elsewhere in HHS regulations, and in the Final Rules, the phrase "counseling and referral" occasionally used by HHS is more sensibly read as simply describing sequential aspects of the same process.

Finally, Defendants cite a 1992 bill that expressly sought to "reverse[ ] the regulations issued in 1988 and upheld by the Supreme Court in 1991 to restrict the provision of information on abortion to Title-Ten patients." Opp. at 17 (quoting H.R Rep. No. 102-204, at 1 (1991)). The bill, which was passed by Congress but vetoed by President George H. W. Bush, defined "pregnancy management options" to mean "nondirective counseling and referrals." S. 323, 102nd Cong. § 2

(1992). Defendants contend that Congress' later enactment of the Nondirective Counseling Provision *without* specific mention of "referral" as in the 1992 bill signifies that Congress intended to exclude referral from the scope of nondirective counseling mandated by the subsequent Appropriations Acts. *See* Opp. at 18. This argument ignores important context. The 1992 bill was introduced in the immediate wake of and as an explicit response to the *Rust* decision. Because *Rust* upheld the 1988 regulations that expressly banned abortion counseling and referrals, it is not surprising that Congress felt the need to specify in explicit terms that it was putting both abortion-related counseling and referral back on the table. But by the time Congress enacted the Nondirective Counseling Provision in 1996, the pre-1988 regulatory scheme that treated abortion referrals as a part of counseling had already been restored. *See* 58 Fed. Reg. 7462. Since 1993, the HHS regulations have permitted abortion referrals. This obviated the need for the Nondirective Counseling Provision to make explicit reference to both counseling and referral.

Although Defendants invoke the proposition that "[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language," *United States v. Novak*, 476 F.3d 1041, 1071 (9th Cir. 2007), it is hazardous to apply this principle to divine the intent of a Congress that passed the Nondirective Counseling Provision four years after the vetoed 1992 bill given the different historical contexts of the 1992 bill and the subsequent 1996 Appropriations Act. *See Cohen v. United States*, 650 F.3d 717, 730 (D.C. Cir. 2011) ("[I]t is the enacted text rather than the unenacted legislative history that prevails.") (citation omitted). De-

fendants cite nothing in the legislative history suggesting that Congress in 1996 considered, and rejected, a version of the Nondirective Counseling Provision that expressly required abortion referral or that Congress otherwise intended to exclude referrals from the provision.

In sum, the Court finds that the statutory language, PHSA, Title X regulations, and usage within the medical field all indicate that nondirective counseling includes nondirective referrals.

ii. The Final Rule's Referral Restrictions Violate the Nondirective Counseling Provision

Applying this definition, sections 59.14(a), 59.14(b)(1), and 59.14(c)(2) of the Final Rule likely violate the Nondirective Counseling Provision. "Nondirective pregnancy counseling is the meaningful presentation of options where the [medical professional] is not suggesting or advising one option over another." 84 Fed. Reg. at 7716; *see* 42 U.S.C. § 254c-6(a)(1) (providing that nondirective pregnancy counseling involves "providing adoption information and referrals to pregnant women on an equal basis with all other courses of action"). To be nondirective, the medical professional must "present[ ] the options in a factual, objective, and unbiased manner and ... rather than present[ ] the options in a subjective or coercive manner." 84 Fed. Reg. at 7747.

The categorical prohibition on providing referrals for abortion in § 59.14(a) is not nondirective because it prevents Title X projects from presenting abortion on an equal basis with other pregnancy options.[11] In con-

[11] The overlapping prohibition on abortion referrals in § 59.5(a)(5) violates the Nondirective Counseling Provision for the

trast to § 59.14(a), § 59.14(b)(1) mandates that every pregnant patient be referred to "prenatal health care," even a patient who has expressly stated that she does not want prenatal care. This differential treatment is not "nondirective." The mandate compels providers to present the options in a coercive manner and pushes patients to pursue one option over another; it does not allow "clients [to] take an active role in processing their experiences and identifying the direction of the interaction." 84 Fed. Reg. at 7716. Indeed, Defendants conceded at oral argument that if referral is considered a part of counseling, § 59.14(b)(1) violates the Nondirective Counseling Provision.

Defendants also acknowledged that the referral list restrictions in § 59.14(c)(2) stand and fall together with the prohibition on abortion referrals in § 59.14(a). Section 59.14(c)(2) allows Title X projects to provide a client with a referral list "limited to those that do not provide abortion," even if the client specifically requests an abortion referral. It further prevents projects from providing a referral list on which "the majority" of the providers perform abortion services, and from "identify[ing] which providers on the list perform abortion." Far from meaningfully presenting a patient with her medical options, such a "non-referral referral list" (as Plaintiffs' counsel labels it) is likely to cause confusion and delay in her attempt to obtain care. The patient would have to spend time working through the list to determine which referrals actually provide the services she asked for—time she may not have given the time-sensitive nature of decisions about pregnancy

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same reason. *See* § 59.5(a)(5) (Title X projects may "[n]ot provide, promote, refer for, or support abortion as a method of family planning.").

and related care. Imposing these onerous restrictions only on abortion information does not place abortion on an equal basis with all other courses of action.

iii. The Final Rule's Counseling Restrictions Violate the Nondirective Counseling Provision Apart From Referrals

There is also merit to Plaintiffs' contention that, the referral prohibition aside, the Final Rule one-sidedly chills counseling regarding abortion. Sections 59.5(a)(5) and 59.14(a) bar providers from doing anything to "promote" or "support" abortion. *See also* § 59.16(a)(1) ("A Title X project may not encourage, promote or advocate abortion as a method of family planning."). At oral argument, Defendants' counsel struggled to draw a clear boundary between mentioning or describing abortion as a pregnancy option within the permissible scope of nondirective counseling and "promoting" or "supporting" abortion impermissible under §§ 59.5(a)(5) and 59.14(a). Essentially, counsel was only able to offer a circular definition: A provider can avoid "promoting" or "supporting" abortion by counseling nondirectively, and a provider can counsel nondirectively by not "promoting" or "supporting" abortion. This interpretive murkiness is telling. It suggests that providers desiring to explain the abortion option have to walk on eggshells to avoid a potential transgression of the Final Rule, whereas those describing the option of continuing the pregnancy face no comparable risk. This lack of symmetry created by §§ 59.5(a)(5) and 59.14(a) is likely to chill discussions of abortion and thus inhibits neutral and unbiased counseling.

Accordingly, Plaintiffs have established a likelihood of success on the merits of their claim that sections 59.14(a), 59.14(b)(1), and 59.14(c)(2) violate the Non-

directive Counseling Provision of the Appropriations Acts and are thus not in accordance with law.

b. Section 1554 of the ACA

Plaintiffs next argue that the Final Rule violates Section 1554 of the ACA. *See* California Mot. at 12–13; Essential Mot. at 10–13. Section 1554 provides:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that–
>
> > (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
> >
> > (2) impedes timely access to health care services;
> >
> > (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
> >
> > (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
> >
> > (5) violates the principles of informed consent and the ethical standards of health care professionals; or
> >
> > (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114.

i. Defendants' Threshold Arguments Do Not Foreclose Plaintiffs' Section 1554 Claim

Before proceedings to the merits of Plaintiffs' Section 1554 claim, the Court first addresses several threshold issues raised by Defendants.

(a) Plaintiffs' Section 1554 Claim Has Not Been Waived

First, Defendants argue that Plaintiffs have waived any challenge based on Section 1554 because they did not raise the issue with HHS during the notice and comment period. Opp. at 19. It is a "general rule" that courts "will not review challenges to agency action raised for the first time on appeal." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1023 (9th Cir. 2007) (citing *Exxon Mobil Corp. v. E.P.A.*, 217 F.3d 1246, 1249 (9th Cir. 2000)). Parties may thus "waive[ ] their right to judicial review" of arguments "not made before the administrative agency" or "in the comment to the proposed rule." *Exxon Mobil*, 217 F.3d at 1249. Plaintiffs concede that neither they nor any other commenter specifically notified HHS during the comment period that the Proposed Rule may violate Section 1554. However, they assert that numerous commenters stated that the Final Rule violated the ACA, and therefore that HHS was "provided sufficient notice ... to afford it the opportunity to rectify the [Section 1554] violations that the plaintiffs alleged." *Native Ecosystems v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002). Plaintiffs compiled these comments in a supplemental submission to the Court. *See California* Docket No. 97.

In reviewing whether these comments are sufficient to overcome waiver, the Court heeds the Ninth Circuit's guidance that "the exhaustion requirement should be interpreted broadly." *Nat'l Parks & Conser-*

vation Ass'n v. Bureau of Land Mgmt., 606 F.3d 1058, 1065 (9th Cir. 2010). "Plaintiffs need not state their claims in precise legal terms, and need only raise an issue 'with sufficient clarity to allow the decision maker to understand and rule on the issue raised.'" *Id.* (quoting *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 968 (9th Cir. 2006)).

Applying this permissive standard, the Court finds that, although it is a close call, Plaintiffs have raised at least a serious question as to whether their Section 1554 claim has been adequately exhausted. The record suggests that commenters raised issues pertaining to Section 1554 with sufficient clarity to provide notice to HHS. Several comments specifically contend the Final Rule violates the ACA. *See, e.g.*, *California* Docket No. 97 ¶ 2 ("The proposed definition of what would be considered a 'medically approved' family planning method ... would effectively limit access and coverage of reproductive health choices expanded upon in the ACA...."), ¶ 4 ("This proposed change is ... contrary to the Affordable Care Act....").

In themselves, these comments may not be specific enough to suggest that the Final Rule violates any specific provision of the ACA. But they were complemented by numerous comments using identical or substantially identical language to Section 1554 to describe how the Final Rule would impede access to care. *Compare, e.g.*, § 1554(1) ("... creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care"), *with California* Docket No. 97 ¶ 6 ("The Proposed Rule seeks to create barriers to access to women's healthcare, including abortion.") *and* ¶ 7 (The Proposed Rule "would create barriers to access for an even larger number of women nationwide."); § 1554(2) ("... impedes timely access to health care services"), *with*

California Docket No. 97 ¶ 14 (The Proposed Rule "would prevent Title X providers from sharing complete and accurate medical information necessary to ensure that their patients are able to ... obtain timely care.") *and* ¶ 17 ("This proposed gag on providers will prevent patients from accessing health care in a timely manner."); § 1554(3) ("... interferes with communications regarding a full range of treatment options between the patient and the provider"), *with California* Docket No. 97 ¶ 20 ("The NPRM would ban Title X providers from giving women full information about their health care options.") *and* ¶ 22 ("The proposed rule limits how Title X providers can discuss and/or counsel on the full-range of sexual and reproductive health care options with their patients."); § 1554(4) ("... restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions"), *with California* Docket No. 97 ¶ 25 (The Final Rule "undermines the right to information by censoring health care providers from informing patients of all their options related to abortion.").

The comments raising concerns regarding medical ethics and informed consent per § 1554(5) are particularly specific. *Compare* § 1554(5) ("... violates the principles of informed consent and the ethical standards of health care professionals"), *with California* Docket No. 97 ¶ 26 ("The Proposed Rule requires physicians to disregard their Code of Medical Ethics...."), ¶ 27 ("The Proposed Rule directly conflicts with the recommendations of major medical professional associations, including the American College of Obstetricians and Gynecologists and the American College of Physicians...."), ¶ 31 ("[T]he rule's proposed ban on abortion referral and its chilling effect (or possibly an effective ban) on abortion

counseling are repudiations of ethical and professional standards around informed consent....”). The terms “ethical standards” and “informed consent” are commonly understood within the medical field to refer to established standards, including those published by the American College of Physicians (“ACP”) and the American College of Obstetricians and Gynecologists (“ACOG”). HHS has long referenced these ethical standards in connection with Title X, including throughout its QFP Guidelines. *See, e.g.*, QFP Guidelines at 13; 65 Fed. Reg. at 41273–74.

To be sure, these comments did not explicitly reference Section 1554, but the Ninth Circuit has repeatedly emphasized that commenters “need not state their claims in precise legal terms” to exhaust them, *Nat’l Parks*, 606 F.3d at 1065, and “alerting the agency in general terms will be enough if the agency has been given a chance to bring its expertise to bear to resolve the claim,” *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) (citation and alteration omitted). *See, e.g.*, *Oregon Nat. Desert Ass’n v. McDaniel*, 751 F. Supp. 2d 1151, 1165 (D. Or. 2011) (finding no waiver where plaintiff raised the issue underlying its Wilderness Act claim by complaining to the agency that its action would harm “500,000 acres of recommended future wilderness,” “even though it never actually invoked the Wilderness Act before the agency”); *Sierra Forest Legacy v. U.S. Forest Serv.*, 652 F. Supp. 2d 1065, 1081 (N.D. Cal. 2009). And here, HHS acknowledged that it had received many comments objecting that the Final Rule created barriers to patients’ access to care, interfered with provider-patient communications, and violated principles of medical ethics, and addressed them (albeit unsatisfactorily, *see* Part III.C.2., *infra*). *See, e.g.*, 84 Fed. Reg. at 7722–24, 7745 (ac-

knowledging comments regarding barriers to access to care and medical ethics).

That HHS dismissed the concerns raised in these comments, which were couched in the same terms as Section 1554's prohibitions, indicates that the commenters "raise[d] [the] issue with sufficient clarity to allow the decision maker to understand and rule on the issue raised," *Nat'l Parks*, 606 F.3d at 1065, and that the agency's response would likely have been no different even if the commenters had specifically cited Section 1554.[12] *See Native Ecosystems*, 304 F.3d at 899 (holding that where "the administrative decisionmaker understood plaintiffs to raise the issue" and "addressed this concern in its decision," there is no waiver); *Nat. Res. Def. Council v. E.P.A.*, 755 F.3d 1010, 1023 (D.C. Cir. 2014) (holding that an issue "expressly addressed by" the agency "is properly before the court").

Accordingly, the Court concludes that Plaintiffs have raised a serious question that their Section 1554 claim was not waived.

(b) Section 1554 Limits the Secretary's Authority under Title X

Second, Defendants argue that Section 1554 does not affect the scope of HHS's rulemaking authority under Title X. Defendants reason that the prefatory language in Section 1554, "[n]otwithstanding any other provision of this Act," limits the scope of Section 1554 to the ACA. 42 U.S.C. § 18114. According to Defendants, if Congress had intended for Section 1554 to sweep more broadly beyond the ACA, it could have

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[12] Notably, HHS specifically discussed Section 1554 in a concurrent rulemaking. *See* 83 Fed. Reg. 57536, 57551–52 (2018).

written the statute to say, "notwithstanding any other provision of law." Opp. at 21–22.

However, the plain text of Section 1554 does not limit its application to the ACA. "Notwithstanding any other provision of this Act" simply means that the Secretary cannot engage in the type of rulemaking proscribed by Section 1554 even if another provision of the ACA could be construed to permit it—the directive of Section 1554 is to be given primacy. This meaning is underscored by the expansive second clause of Section 1554: "the Secretary of Health and Human Services shall not promulgate *any regulation*...." 42 U.S.C. § 18114 (emphasis added). The literal text of Section 1554 does not support Defendants' construction.

That Section 1554 has application beyond the ACA is neither surprising nor unusual; surrounding provisions do too. *See, e.g.*, 42 U.S.C. § 18116(a) (nondiscrimination provision that extends to all federally-funded health programs). Moreover, where Congress wanted a provision to apply only to the ACA, it said so explicitly. For example, Section 1553 directs that "[t]he Federal Government, and any State or local government or health care provider that *receives Federal financial assistance under this Act* ... may not subject an individual or institutional health care entity to discrimination...." 42 U.S.C. § 18113(a) (emphasis added). Similarly, Section 1555 provides that "[n]o individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any Federal health insurance program *created under this Act*." 42 U.S.C. § 18115 (emphasis added). The "clear" and "express" language in these sections limiting their applicability to the ACA demonstrates that "Congress knows how to limit the [statute] when it wishes to do so." *Miller v.*

Clinton, 687 F.3d 1332, 1340 (D.C. Cir. 2012). Congress did not use such express language in Section 1554.

Defendants invoke two other principles of statutory interpretation to argue that Section 1554 does not apply to Title X. Neither advances Defendants' cause. The first is the "principle that Congress 'does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.'" Opp. at 20 (quoting *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001)). In Defendants' telling, it is implausible that Congress would have "abrogated a Supreme Court decision on an *extremely* controversial subject"—*Rust*—by means of an ancillary ACA provision. *Id.* (emphasis in original). But this account is fundamentally flawed because when the ACA was enacted in 2010, the counseling and referral restrictions in *Rust* had long been rescinded, so Section 1554 was entirely consistent with the prevailing Title X regulatory scheme. And as noted above, *Rust* merely upheld one interpretation of Title X; it did not purport to definitively interpret Title X itself. Thus, Section 1554, to the extent it bars the "gag rule," would not abrogate Section 1008.

The second principle is that "the specific [statute] governs the general." Opp. at 22 (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384, 112 S.Ct. 2031, 119 L.Ed.2d 157 (1992)). Defendants assert that Section 1008, as a specific prohibition on funding abortion as a method of family planning within Title X, trumps the more general Section 1554. *See id.* at 23. This "canon is impotent, however, unless the compared statutes are 'irreconcilably conflicting.'" *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 698–99 (D.C. Cir. 2014) (citation omitted). For the reasons just discussed, Section 1008 and Section 1554 are not irreconcilably

conflicting. And Defendants recognize as much. *See* Opp. at 21. The former forbids the use of Title X funds "in programs where abortion is a method of family planning," 42 U.S.C. § 300a-6, whereas the latter limits HHS's authority to promulgate any regulation which violates the principles of informed consent and ethical standards of medical professionals, *id.* § 18114. These "two statutes are capable of co-existence." *Morton*, 417 U.S. at 551, 94 S.Ct. 2474. The pre-Final Rule regulatory scheme gives effect to both. It prevents impermissible use of Title X funds by enforcing financial separation between projects that receive Title X funding and projects that perform services prohibited under Section 1008. At the same time, it permits Title X projects to give patients nondirective counseling and referrals to abortion service providers upon request, in compliance with Section 1554(5).

Because there is no "irreconcilable conflict" between the two statutes, Defendants' contention that Plaintiffs' claim relies on the premise that Section 1554 impliedly repealed Section 1008 is likewise inapposite. *See* Opp. at 20; *Radzanower*, 426 U.S. at 154–55, 96 S.Ct. 1989 (one statute can be found to have impliedly repealed another "where provisions in the two acts are in irreconcilable conflict").

(c) Section 1554 is Not Unreviewably Broad

Third, Defendants suggest that Section 1554 is so "open-ended" that "it is a substantial question whether section 1554 claims are reviewable under the APA at all." Opp. at 22. Defendants cite *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971) for the proposition that there are times when "statutes are drawn in such broad terms that in a given case there is no law to apply," frustrat-

ing judicial review. *Id.* at 410, 91 S.Ct. 814. But *Overton Park* made clear that this is "a very narrow exception" to the APA only to be applied in "rare instances." *Id.* This is not one of those rare instances. Other, arguably more open-ended statutory commands have been held to permit judicial review. *See, e.g.*, *Morgan Stanley Capital Group Inc. v. Pub. Util. Dist. No. 1 of Snohomish County*, 554 U.S. 527, 128 S.Ct. 2733, 171 L.Ed.2d 607 (2008) (wholesale electricity rates must be "just and reasonable"); *Pac. Nw. Generating Co-op. v. Bonneville Power Admin.*, 596 F.3d 1065, 1077 (9th Cir. 2010) (agency must operate "consistent with sound business principles"); *City of Los Angeles v. U.S. Dep't. of Commerce*, 307 F.3d 859, 869 n.6 (9th Cir. 2002) (Secretary of Commerce must use statistical sampling "if he considers it feasible"); *Keating v. FAA*, 610 F.2d 611, 612 (9th Cir. 1979) (agency must make decision "in the public interest"). Section 1554 is not a statute "drawn so that the court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985).

(d) The Constitutional Reasoning in *Rust* Does Not Foreclose Plaintiffs' Section 1554 Claim

Finally, Defendants, citing reasoning from *Rust*, made a further suggestion at oral argument that Plaintiffs' Section 1554 claim is meritless because, even if the Final Rule impeded patients' access to care, "[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X." *Rust*, 500 U.S. at 202, 111 S.Ct. 1759. This belated challenge is both legally and factually misguided.

As a legal matter, Defendants are importing language from *Rust*'s constitutional holding in an attempt to extinguish Plaintiffs' statutory claim. The *Rust* Court decided that the 1988 regulations did not impermissibly burden a woman's Fifth Amendment right to choose whether to terminate her pregnancy because "Congress' refusal to fund abortion counseling and advocacy leaves a pregnant woman with the same choices as if the Government had chosen not to fund family-planning services at all." *Id.* It was in this context of evaluating a constitutional claim that the Court reasoned the regulations left patients no worse off than if Title X did not exist. *See id.* By contrast, Plaintiffs' claim here is that the Final Rule violates a specific statutory prohibition. The statutory mandates of Section 1554 are far more specific than the constitutional requirement asserted in *Rust.* The claim under Section 1554 is a matter of statutory interpretation to which *Rust* is inapposite.

Moreover, as a factual matter, the Final Rule's referral list restrictions go far beyond anything in the 1988 regulations. The new restrictions: (1) permit a Title X project to give a patient who *specifically requests* a referral for abortion a referral list that contains *no* abortion providers; (2) require the project to compile a list of providers, a majority of whom are *not* responsive to the patient's request; (3) prevents the project from identifying which providers on the list *are* responsive to the patient's needs; and (4) *does not require the project to even alert the patient that the list is incomplete and non-responsive. See* § 59.14(c)(2). Because of these provisions, patients in need of time-sensitive medical care will be delayed or altogether prevented from obtaining that care because they will receive referrals that they do not realize are not for the services they

requested. *See* Rich Decl., Exh. K at 2. In other words, under the Final Rule, the Government would be subsidizing the misdirection of unsuspecting patients. Unlike in *Rust*, the Final Rule may well make patients *worse* off than if they had not sought help from a Title X project to begin with.[13]

ii. The Final Rule Violates Section 1554

Having found that Plaintiffs' claim under Section 1554 is not foreclosed, the Court must determine whether the Final Rule in fact violates that provision of the ACA. Plaintiffs assert that the Final Rule's restrictions on counseling and referral and requirement for providers to encourage family participation in family planning decisions are contrary to Section 1554. The Court agrees.

The Court has already detailed extensively the ways in which the Final Rule's overlapping restrictions on pregnancy counseling (including referral and referral lists) obfuscate and obstruct patients from receiving information and treatment for their pressing medical needs. *See* Parts III.A.1 and III.C.1.a., *supra*; Kost Decl. ¶¶ 88–93; Rabinovitz Decl. ¶ 50; Marshall Decl. ¶ 22. There is no question that these restrictions "create[]

[13] After it received commenters' objections that the referral restrictions "will deprive women of the information they need about abortion or where to obtain one," HHS offered a rather astonishing response: "[I]n the Department's view, it is not necessary for women's health that the federal government use the Title X program to ... give to women who seek abortion the names of abortion providers. Information about abortion and abortion providers is *widely available and easily accessible, including on the internet*." 84 Fed. Reg. at 7746 (emphasis added). The Court does not share Defendants' belief that misleading counseling provided by a medical professional is rendered harmless by information available "on the internet."

... unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impede[ ] timely access to health care services," "interfere[ ] with communications regarding a full range of treatment options between the patient and the provider," and "restrict[ ] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions" in violation of subparts (1)–(4) of Section 1554. Defendants do not even contest this.

Separately, the Final Rule's prohibition on providing abortion referrals, restrictions on the content of referral lists, and mandate on referrals for prenatal care are also squarely at odds with established ethical standards and therefore Section 1554(5). Indeed, they are inconsistent with HHS's own QFP Guidelines, which provide that once a patient receives a positive pregnancy test:

> Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. 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 Guidelines at 14. The QFP Guidelines further instruct that "[p]roviders of family planning services should offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obste-

tricians and Gynecologists (ACOG)." *Id.* at 13. In turn, ACOG explains that physicians have an ethical obligation to "provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion." Rich Decl., Exh. G at 6.

Clearly, the Final Rule's blanket prohibition on abortion referrals does not comport with providers' ethical obligation to provide "[r]eferral to appropriate providers of follow-up care ... at the request of the client." QFP Guidelines at 14. And § 59.14(c)(2)'s restrictions that prevent Title X from providing any abortion referrals to a patient who specifically requests such a referral, and from identifying which providers on a referral list perform abortion services, do not "help the client identify options for care." *Id.* Comments in the record show that associations of medical professionals overwhelmingly agree that the Final Rule's counseling and referral restrictions violate principles of medical ethics and informed consent. *See, e.g.*, Rich Decl., Exh. B at 4–5 (California Medical Association stating that restrictions "directly conflict[ ] with the requirements of medical professional associations, including [ACOG]."); Exh. D at 4 (American Academy of Nursing stating that restrictions "violate[ ] basic ethics of the profession," including the Code of Ethics for Nurses); Exh. E at 7 (Guttmacher Institute stating that restrictions "constitute[ ] an unacceptable repudiation of the doctrine of informed consent by denying Title X patients factual, unbiased information on abortion"); Exh. G at 3–6 (ACOG stating that restrictions violate its Code of Professional Ethics); Exh. I at 3 (American Medical Association stating restrictions "are contrary to the AMA's Code of Medical Ethics"); Exh. K at 2

(American Public Health Association stating that "[t]he gag rule violates core ethical standards"); Exh. N at 3 (American Academy of Pediatrics stating that restrictions "conflict[ ] with medical practice guidelines, including those of the American Academy of Pediatrics."); Exh. P at 4–5 (American College of Physicians stating that restrictions violate "the ethical principle of respect for patient autonomy"); *see also* Marshall Decl. ¶ 15; Spirtos Decl. ¶ 18; Kost Decl. ¶¶ 84–85.

The requirement in § 59.14(b)(1) that all pregnant Title X clients "shall be referred to a health care provider for medically necessary prenatal health care," even if it goes against a patient's wishes, violates ethical standards. As ACOG explains, this provision "require[s] the provision of counseling, information, and referral for services that the patient has clearly stated she does not wish to receive." Rich Decl., Exh. G at 3, 6.

Moreover, as the American Public Health Association details, § 59.14(b)(1) also violates ethical principles because while it allows Title X providers to abstain from providing nondirective counseling due to moral or religious reasons, "it does not contain any requirement that those providers advise patients of their refusal." Rich Decl., Exh. K at 2. "Therefore, patients will not even know if they are getting complete information." *Id.*

Finally, the Final Rule's "family participation" requirement also violates ethical standards. 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)." There is an exception to the documentation requirement where a provider "suspects the minor to be the victim of child abuse or incest." § 59.2(1)(i). The American Academy of Pediatrics ("AAP") notes that healthcare professionals already "highly encourage[ ] the involvement of families in the care of adolescents and young adults as much as possible," and "[a]s a consequence, most adolescents already involve their families in decisions about family planning." Rich Decl., Exh. N at 6. However, the new requirement in the Final Rule 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." *Id.* AAP explains that "clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not 'practicable,' or unrealistic or even harmful to encourage the minor to involve their parents or guardian." *Id.* In these situations, requiring clinicians to nevertheless encourage family participation and document those efforts would both force them to breach their ethical obligations and "drive some minors away from returning for critical health services."[14] *Id.* Other com-

[14] Courts have long recognized that "in matters concerning sexual conduct, minors frequently are reluctant, either because of embarrassment or fear, to inform their parents of medical conditions relating to such conduct, and consequently that there is a considerable risk that minors will postpone or avoid seeking needed medical care if they are required to obtain parental consent before receiving medical care for such conditions." *Am. Acad. of Pediatrics v. Lungren*, 16 Cal. 4th 307, 317–18, 66 Cal.Rptr.2d 210, 940 P.2d 797 (1997); *Ballard v. Anderson*, 4 Cal. 3d 873, 880, 95 Cal.Rptr. 1, 484 P.2d 1345 (1971) ("[A]n unmarried pregnant minor understandably might be reluctant to seek parental consent for

menters, including ACOG, echo AAP's conclusion that § 59.5(a)(14) violates medical ethics. *See id.*, Exh. G at 14.

Accordingly, Plaintiffs have demonstrated that they are likely to succeed on the merits of their claim that §§ 59.5(a)(5), 59.5(a)(14), 59.14(a), 59.14(b)(1), 59.14(c)(2), and 59.16(a)(1) of the Final Rule are not in accordance with Section 1554.

2. <u>The Promulgation of the Final Rule was Arbitrary and Capricious</u>

Under the APA, agency action must be set aside if it is arbitrary or capricious. 5 U.S.C. § 706(2)(A). An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). Although "a court is not to substitute its judgment for that of the agency," *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513, 129 S.Ct. 1800, 173 L.Ed.2d 738 (2009) (citation omitted), it nevertheless "retain[s] a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking," *Judulang v. Holder*, 565 U.S. 42, 53, 132 S.Ct. 476, 181 L.Ed.2d 449 (2011).

In particular, an agency which changes its position must give a reasoned explanation for the change. "[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."

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medical care related to her pregnancy and that the parents of such a minor might refuse consent for reasons unrelated to the health of the minor.").

Fox Television, 556 U.S. at 515, 129 S.Ct. 1800 (emphasis in original). Typically, the agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better." *Id.* (emphases in original). "This means that the agency need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate." *Id.* But "[s]ometimes it must—when, for example, its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." *Id.* at 515–16, 129 S.Ct. 1800. Indeed, "even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation." *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015).

"Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856.

a. Plaintiffs' Arbitrary and Capricious Claims are Not Foreclosed by *Rust*

Defendants contend Plaintiffs' arbitrary and capricious claims are foreclosed by *Rust. See* Opp. at 24–26. This argument is meritless. When it decided *Rust* in

1991, the Supreme Court found that "the Secretary amply justified his change of interpretation [from the pre-1988 regulations] with a 'reasoned analysis,'" based on "critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG), that prior policy failed to implement properly the statute." *Rust*, 500 U.S. at 187, 111 S.Ct. 1759. "He also determined that the new regulations are more in keeping with the original intent of the statute, are justified by client experience under the prior policy, and are supported by a shift in attitude against the 'elimination of unborn children by abortion.'" *Id.*

The justifications supporting the 1988 regulations upheld in *Rust* cannot insulate the Final Rule from review now, almost three decades later. In promulgating the Final Rule, HHS did not purport to rely on the 1988 regulations. *See Michigan v. E.P.A.*, ––– U.S. ––––, 135 S. Ct. 2699, 2710, 192 L.Ed.2d 674 (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 *ipse dixit* 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.). Unlike the 1988 regulations considered in *Rust*, the Final Rule was not enacted in response to critical reports of the GAO and OIG, and makes no mention of negative "client experiences" under the current regulations that have been in effect since 1993. Nor does the Final Rule cite any instances of actual co-mingling or misuse of Title X funds. Accordingly, that *Rust* upheld the 1988 regulations does not dispose of Plaintiffs' APA challenge to the Final

Rule here. This Court must conduct the arbitrary and capricious analysis anew.

As another threshold issue, Defendants contended at oral argument that Plaintiffs' arbitrary and capricious claims are foreclosed by the *Chevron* analysis in *Rust.* According to Defendants, the mere fact that the 1988 regulations were a permissible interpretation of Title X alone supplies the reasoned basis HHS needs to justify the Final Rule under the APA. This argument is belied by *Rust* itself. If a reasonable and permissible statutory interpretation was all that was needed for the 1988 regulations to pass muster under arbitrary and capricious review, the Supreme Court would have said so. Although the ambiguous language of Section 1008 and equivalent legislative history of Title X might arguably have sustained the 1988 regulations, as noted above, the Court nevertheless scrutinized the evidentiary basis given for the 1988 regulations to ensure that they were the product of a "reasoned analysis." *Rust*, 500 U.S. at 187, 111 S.Ct. 1759.

On this point, Defendants overlook important differences between *Chevron* and arbitrary-and-capricious review. As the Ninth Circuit has delineated, "*Chevron* ... analyzes the reasonableness of an agency's interpretation [of a statute], while 'arbitrary and capricious' review under the APA focuses on the reasonableness of an agency's decision-making *processes*." *CHW W. Bay v. Thompson*, 246 F.3d 1218, 1223 (9th Cir. 2001) (emphasis in original) (citation omitted). Here, it is precisely the reasonableness of HHS's decisionmaking process in promulgating the Final Rule that Plaintiffs challenge. Hence, the lens of arbitrary-and-capricious review must be applied. *See Encino Motorcars, LLC v. Navarro*, —— U.S. ——, 136 S. Ct. 2117, 2125, 195 L.Ed.2d 382 (2016) ("[W]here a proper chal-

lenge is raised to the agency procedures, and those procedures are defective, a court should not accord *Chevron* deference to the agency interpretation."); *New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 324 (2d Cir. 2003) ("When the question is not one of the agency's authority but of the reasonableness of its actions, the 'arbitrary and capricious' standard of the APA governs."). It would be particularly inappropriate to conflate *Chevron* and *State Farm* in this case because, as detailed below, Plaintiffs have persuasively shown that the Final Rule "was issued without the reasoned explanation that was required in light of [HHS]'s change in position and the significant reliance interests involved." *Encino Motorcars*, 136 S. Ct. at 2126.

Accordingly, the Court proceeds to the merits of Plaintiffs' arbitrary and capricious claims to determine whether the Final Rule is supported generally by a reasoned analysis, and in particular to the extent the Final Rule represents a change in position which requires a "more detailed justification," whether HHS sufficiently justified its change in position.

b. The Physical Separation Requirement is Arbitrary and Capricious

Plaintiffs contend the physical separation requirement in § 59.15 is arbitrary and capricious. *See* California Mot. at 17; Essential Mot. at 15–17. The record reveals that Plaintiffs are likely correct. HHS relied on speculative fears of theoretical abuse of Title X funds to justify imposing the physical separation requirement and turned a blind eye to voluminous evidence documenting the significant adverse impact the requirement would have on the Title X network and patient health. The agency's actions fell short of reasoned decisionmaking.

i. Defendants Relied on Speculative Justifications Belied by the Record

The Final Rule cites the following justification for requiring physical separation:

> [S]hared facilities create a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities, and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics. Even with the strictest accounting and charging of expenses, a shared facility greatly increases the risk of confusion and the likelihood that a violation of the Title X prohibition will occur.

84 Fed. Reg. at 7764. Defendants' opposition brief affirms that the physical separation requirement is based on "the need for prophylactic measures to address the risk and the perception that taxpayer funds will be used to fund abortion." Opp. at 30.

Defendants' repeated use of words like "risk," "likelihood," "prophylactic," and "specter" is telling; Defendants fail to point to any evidence in the record of *actual* co-mingling or misuse of Title X funds. HHS primarily relies on two sources to justify its concerns about insufficient separation. The first is an "anecdotal story" from 2007 about a California clinic's community outreach activities. 84 Fed. Reg. at 7774. But this anecdote, by Defendants' own admission, does not actually involve the misuse of Title X funds at all. It is an "example of abuse of federal funds in a *different* program," Medicaid. Opp. at 29 n.3 (emphasis added); *see* 84 Fed.

Reg. at 7725 ("The Department agrees with comments stating that demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused...."). The second is a 2014 Guttmacher Institute report indicating that "abortions are increasingly performed at sites that focus primarily on contraceptive and family planning services—sites that could be recipients of Title X funds." 84 Fed. Reg. at 7765. But this report provides no support for HHS's position. By the agency's own interpretation, the report merely shows that abortions are being performed at "sites that *could* be recipients of Title X funds," *id.* (emphasis added); it does not say that those sites actually *are* Title X projects. Even assuming that abortions are being performed at actual Title X sites, there is no basis for concluding that this would constitute a violation of Title X. It is important here to remember the Supreme Court's explanation in *Rust* that

> Title X expressly distinguishes between a Title X *grantee* and a Title X *project.* The grantee, which normally is a health-care organization, may receive funds from a variety of sources for a variety of purposes. The grantee receives Title X funds, however, for the specific and limited purpose of establishing and operating a Title X project.... The Title X *grantee* can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds.

500 U.S. at 196, 111 S.Ct. 1759 (emphases in original) (citing 42 U.S.C. § 300(a)). Thus, the mere fact that abortions are being performed at the site of a Title X

grantee does not mean that the Title X *project* operating within the grantee is misusing Title X funds to perform abortions. HHS cites no evidence to contradict its prior finding that financial separation and the concomitant review and rigorous audit of Title X grantees' financial records was a sufficient safeguard. *See* 65 Fed. Reg. at 41275–76.[15]

The evidence HHS cites for its concern about public "perception that Title X funds being used" in relation with prohibited abortion activities, 84 Fed. Reg. at 7764, is equally without a reasoned basis. According to the agency, in response to the Proposed Rule, it received comments from "many commenters that oppose defining 'family planning' to exclude abortion and that urge the Department to define the term to include abortion." *Id.* at 7729. Far from showing that the public erroneously believes Title X funds are being used to fund abortion-related activities, these comments suggest the very opposite—that the commenters understand Title X funds *cannot* currently be used for abortion, but would like HHS to change its definition of "family planning" to include abortion so that Title X funds *can* potentially be used for abortion-related activities.

Defendants advance another argument: they believe that "the collocation of a Title X clinic with an abortion clinic permits the abortion clinic to achieve economies of scale" and therefore "support[s] abortion as a method of family planning" with Title X funds. *Id.*

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[15] To the extent there may have been isolated instances of misuse or co-mingling of Title X funds in the past that were not cited in the Final Rule, there is no indication they escaped detection from the financial audits conducted under the 2000 regulations.

at 7766. But the notion that any use of Title X funds that might indirectly benefit an abortion clinic is necessarily misuse is a radical one that goes far beyond any rationale for physical separation approved in *Rust.* It ignores a pivotal distinction drawn in *Rust*: "Title X expressly distinguishes between a Title X *grantee* and a Title X *project*," and a "Title X *grantee* can continue to ... provide abortion-related services" so long as it does so "through programs that are separate and independent from the project that receives Title X funds." 500 U.S. at 196, 111 S.Ct. 1759 (emphases in original). HHS's sweeping new argument would obliterate the Court's carefully drawn distinction. The limitless reach of the agency's rationale is also "illogical on its own terms." *Am. Fed'n of Gov't Emps., Local 2924 v. Fed. Labor Relations Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006). A grantee that, pursuant to the Final Rule, maintains separate facilities and medical records between its Title X services and abortion services can still benefit from economies of scale in, for example, rent (if the grantee rents separate spaces within the same building) and medical record system (if the grantee purchases its separate systems from the same vendor). *See id.* (an agency's decision is arbitrary and capricious if "illogical on its own terms"); *Illinois Pub. Telecom. Ass'n v. F.C.C.*, 117 F.3d 555, 566 (D.C. Cir.) (an agency's "seemingly illogical" decision is arbitrary and capricious), *decision clarified on reh'g*, 123 F.3d 693 (D.C. Cir. 1997).

In sum, the asserted fear of misuse of Title X funds purporting to animate HHS's decision to fundamentally depart from its current regulations and impose an onerous physical separation requirement are not substantiated by the record. To the contrary, HHS reported as recently as October 2018 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.

Defendants contend they do not need to justify the Final Rule by reference to an extant problem, because "agencies can ... adopt prophylactic rules to prevent potential problems before they arise." *Stilwell v. Office of Thrift Supervision*, 569 F.3d 514, 519 (D.C. Cir. 2009) (Kavanaugh, J.). However, "[t]hough an agency's predictive judgments about the likely economic effects of a rule are entitled to deference, deference to such judgments must be based on some logic and evidence, not sheer speculation." *Sorenson Commc'ns Inc. v. F.C.C.*, 755 F.3d 702, 708 (D.C. Cir. 2014) (citations, internal quotation marks and alterations omitted). In *Sorenson Communications*, the D.C. Circuit found arbitrary and capricious a rule providing that the Federal Communications Commission ("FCC") would only reimburse service providers for captioning-enabled phones they sold to hearing-impaired individuals if those phones cost $ 75 or more. *Id.* at 705. The FCC "claim[ed] the $ 75 Rule w[ould] deter fraudulent acquisition and use of [captioning-enabled phones]. Yet the agency offer[ed] no evidence suggesting there is fraud to deter." *Id.* at 707. The court faulted the FCC for promulgating the rule without an evidentiary basis, asking, "where is the evidence that [the] technology is being fraudulently used?" *Id.* at 708. The court rejected the FCC's assertion "that it may rely on its predictive judgment to ignore these questions" and concluded that the agency had "failed to articulate a satisfactory explanation for

its action" because its claimed fear of fraud was speculative. *Id.* at 708–09; *see also Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 839 (D.C. Cir. 2006) (finding that agency action premised on addressing "a claimed record of abuse" is arbitrary and capricious because the agency "provided no evidence of a real problem" with abuse); *Arizona Cattle Growers' Ass'n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (holding agency action to be arbitrary and capricious where the basis of the action is "speculation ... not supported by the record.").

Likewise here, HHS purports to rely on its predictive judgment that Title X funds will be misused without the physical separation requirement, but the Final Rule provides no evidence that indicates this projection is anything but speculation. Quite the opposite, the projection is at odds with the agency's repeated assurances from as early as 2000 and as recently as 2018 that the existing separation requirements are sufficient to prevent abuse within the Title X program. Accordingly, HHS has failed to "articulate a satisfactory explanation" for the physical separation requirement as required by the APA, and is thus arbitrary and capricious. *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856.

ii. HHS Failed to Provide a "More Detailed Justification" for Its Change in Policy

The arbitrary nature of the change in policy becomes even more clear when HHS's decisionmaking is measured against its obligation to supply "a more detailed justification" for adding the physical separation requirement; a detailed justification is required because its decision relied "upon factual findings that contradict those which underlay its prior policy" and because "its

prior policy has engendered serious reliance interests." *Fox Television*, 556 U.S. at 515, 129 S.Ct. 1800.

HHS clearly set forth the factual findings underlying its decision in 2000 to rescind the physical separation requirement in the 1988 regulations. It noted, on the one hand, that mandating physical separation conferred no discernible benefits. The agency reasoned that it had "traditionally viewed" financial separation—"demonstrate[d] by [a Title X grantee's] financial records, counseling and service protocols, administrative procedures, and other means"—as sufficient. 65 Fed. Reg. at 41276. And "since Title X grantees are subject to rigorous financial audits, it can be determined whether program funds have been spent on permissible family planning services, without additional requirements being necessary." *Id.* at 41275. Thus, "it is hard to see what additional statutory protection is afforded by the imposition of a requirement for 'physical' separation." *Id.* at 41276. On the other hand, HHS concluded that a physical separation requirement "is not likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services." *Id.* The agency took seriously comments objecting that physical separation would be "costly[ ] and medically unwise." *Id.* at 41275. In particular, requiring separation of staff and facilities would: "be inefficient and cost ineffective," especially "for small and rural clinics that may be the only accessible Title X family planning and/or abortion providers for a large population of low-income women"; be "inconsistent with public health principles, which recommend integrated health care"; and "burden women, by making them make multiple appointments or trips to visit different staff or facilities." *Id.* at 41275–76 (internal quotation marks omitted).

By contrast, in reinstating the physical separation requirement in the Final Rule, HHS stated that "it no longer believes financial separation is sufficient without physical separation." 84 Fed. Reg. at 7764. It also "disagree[d]" with commenters who protested "that the physical and financial separation requirements will destabilize the network of Title X providers" by imposing significant compliance costs. *Id.* at 7766. Instead, the agency "believes that, overall, the final 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.* These factual findings upon which the Final Rule rests "contradict those which underlay [HHS's] prior policy." *Fox Television*, 556 U.S. at 515, 129 S.Ct. 1800.

The prior separation policy also engendered "serious reliance interests" with respect to regulated entities, including Plaintiffs. Essential Access has detailed the significant investment it has made in its physical infrastructure, programming, and records systems over the years in reliance on the longstanding rule that financial separation between its Title X and non-Title X activities complies with Section 1008. For example, core to Essential Access's mission of promoting quality reproductive care is its training arm, the Learning Exchange, which "trained more than 6,000 clinicians and allied health professionals from forty-nine states on providing quality sexual and reproductive health care" in 2017. Rabinovitz Decl. ¶ 61. Based on the current regulations, the Learning Exchange programming includes "training on pregnancy options, including how to provide patients with medically accurate, unbiased, non-judgmental information about abortion, adoption, and parenting." *Id.* ¶ 62. Similarly, Essential Access

provides "extensive" non-Title X-funded public education and awareness programming, reaching over 650,000 adolescents, about comprehensive sexual and reproductive health. *Id.* ¶ 64. The Final Rule would require Essential Access to completely overhaul this programming and reallocate its resources in order to comply with the new requirement that any activities relating to abortion must be conducted "with a separate staff, under a separate roof, using separate workstations, email addresses, and phone numbers." *Id.* ¶ 65. This entails "extraordinary expenses." *Id.* ¶ 66.

Essential Access sub-recipients likewise would need to revamp their "medical record systems and financial records, undertake extensive renovations, and hire new staff and personnel," which are integrated in reliance on the current regulations. *Id.* ¶ 69. *See also* Nestor Decl. ¶¶ 5–6, 13 (San Francisco Department of Public Health uses Title X funds to train its clinical staff members on "contraceptive counseling" and "pregnancy testing and counseling," but it "cannot bear the cost of setting up separate facilities" and "separate personnel" to bifurcate its Title X and non-Title X services); Forer Decl. ¶¶ 7, 31 (Title X grantee Venice Family Clinic provides "fully integrated primary healthcare services," including family planning services, and it would be "financially impossible for [its] three Title X funded clinic sites to build entirely separate adjoining sites"); McKinney Decl. ¶¶ 8, 10 (Title X grantee Westside Family Health Center, which does not provide abortions but does "provide nondirective pregnancy counseling and referrals for abortion when requested," cannot afford to "rent or purchase separate property to provide non-directive counseling or referrals for abortion services"). As Plaintiffs' counsel explained at oral argument, these investments made in

integrated staff and systems mean that a reversal of course by the agency now would engender more costs than would have been incurred if the separation requirement had been in force years ago.

The reliance interests these Title X grantees have demonstrated are similar to those recognized by the Supreme Court as warranting a more detailed explanation of an agency's change in policy. *See Encino Motorcars*, 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"). Defendants attempt to distinguish *Encino Motorcars* on the basis that it "concerned private parties' substantive statutory rights," where "the challenged regulations here concern discretionary funding decisions" and grants that are "generally available for only one year." Opp. at 31. But courts have recognized serious reliance interests in discretionary grants of benefits that do not arise from statute—in, for example, the Deferred Action for Childhood Arrivals program, a form of time-limited discretionary relief from deportation created by an executive branch memorandum. *See Regents of Univ. of California v. United States Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1022, 1045 (N.D. Cal.), *aff'd sub nom. Regents of the Univ. of California v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476 (9th Cir. 2018); *Nat'l Ass'n for the Advancement of Colored People v. Trump*, 315 F. Supp. 3d 457, 473 (D.D.C. 2018); *Batalla Vidal v. Nielsen*, 279 F.

Supp. 3d 401, 431 (E.D.N.Y. 2018). To the extent Defendants suggest that any reliance on the current Title X regulations was unreasonable because agency policy can change at any time, that argument ignores the fact that the type of review described in *Fox Television* was specifically made in the context of a change in an agency's policy, not a statute. As the Court in *Fox Television* explained, one purpose of arbitrary-and-capricious review of agency action is precisely to safeguard reliance interests from being upended by erratic policy shifts by administrative agencies. *See* 556 U.S. at 515, 129 S.Ct. 1800. Here, Title X grantees have relied on HHS consistently interpreting Section 1008 to require only financial separation for over a quarter century; that the Supreme Court required a more detailed explanation from an agency changing a policy that had engendered "decades of industry reliance" reflects that regulated entities are justified in structuring their affairs in reliance on longstanding agency policy. *Encino Motorcars*, 136 S. Ct. at 2126.

At bottom, HHS has not demonstrated there are "good reasons" for the physical separation requirement or provided a "more detailed justification" for the change in policy. *Id.*

iii. HHS Failed to Provide Any Explanation for Its Estimates of Compliance Costs

The promulgation of the physical separation requirement is arbitrary and capricious for a second, independent reason. During the notice-and-comment period, commenters provided HHS with substantial evidence that imposing a physical separation requirement on Title X grantees would create significant (and in many cases, prohibitive) compliance costs, drastically reduce access to Title X services, and lead to serious

disruptions in care for Title X patients. Instead of engaging with these concerns, HHS summarily dismissed them, maintaining that "overall, the final 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." 84 Fed. Reg. at 7766. In doing so, the agency "entirely failed to consider an important aspect of the problem" and "offered an explanation for its decision that runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856.

With respect to compliance costs, HHS's analysis at every stage of the rulemaking has been mystifying. Initially, the Proposed Rule "estimate[d] that an average of between $ 10,000 and $ 30,000, with a central estimate of $ 20,000, would be incurred [by each affected Title X site] to come into compliance with physical separation requirements in the first year following publication of a final rule." 83 Fed. Reg. at 25525. In reaching these figures, the agency quoted several costs grantees are likely to incur to "evaluate[ ] ... whether they comply with the proposed physical separation requirements." *Id.* But merely *evaluating* the compliance status of a Title X site is only the first of many steps in the process of actually *coming into compliance* with the physical separation requirement. For instance, sites will need to maintain separate accounting and health records, as well as separate physical facilities (including "treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites.)" § 59.15(a)–(c). There is no mention of the costs of complying with these requirements in the Proposed

Rule.[16] Also conspicuously absent is any estimate of compliance costs beyond the first year.

Many Title X grantees submitted detailed comments explaining that their compliance costs would be much higher than estimated in the Proposed Rule. Planned Parenthood estimated that just the capital costs of renovation and construction would be "nearly $ 625,000 per affected service site." Rich Decl., Exh. M at 31–32 (providing extensive calculations). The National Family Planning and Reproductive Health Association wrote that "[i]t would cost hundreds of thousands of dollars or more to locate and open a facility, staff it, purchase separate workstations, set up separate record-keeping systems, etc.," and estimated capital costs of compliance at $ 300,000. *Id.*, Exh. L at 37. Commenters further pointed out that the separation requirement would create "significant" ongoing costs, "including contracts for goods and services and staff time," that "the Department fails to acknowledge in the first year and every subsequent year." Rich Decl., Exh. M at 32.

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[16] HHS's own "Guidelines for Regulatory Impact Analysis" ("HHS Guidelines") set forth in ample detail how the agency should estimate the costs for "[r]egulated entities ... to comply with regulatory requirements." U.S. Dep't of Health and Human Services, *Guidelines for Regulatory Impact Analysis* at 32 (2016), https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf. These costs explicitly include "purchasing computers and software to support administrative tasks," "installing or retrofitting new equipment," "capital expenditures to acquire buildings or land," and "annual costs of labor, utilities, and other resources." *Id.* at 32–33. The HHS Guidelines teach that "analysts generally use market data to estimate such costs." *Id.* Here, HHS referenced no data, market or otherwise, as the basis for its compliance cost estimates.

Notwithstanding these comments, the Final Rule changed very little after receiving these comments. HHS revised its central estimate from $ 20,000 per affected site to $ 30,000. *See* 84 Fed. Reg. at 7781–82. It criticized the "extremely high cost estimates" provided by commenters as "based on assumptions that they would have to build new facilities in order to comply with the requirements for physical separation." *Id.* at 7781. The agency suggested that "entities will usually choose the lowest cost method to come into compliance," such as "shift[ing] their abortion services, and potentially other services not financed by Title X, to distinct [existing] facilities, a change which likely entails only minor costs." *Id.* This suggestion ignores that commenters had already addressed the possibility of "renovating facilities in order to comply," short of building new ones, and still concluded that renovation costs vastly exceeded the agency's estimates. Rich Decl., Exh. M at 31. Moreover, HHS's claim that shifting existing services "entails only minor costs" is wholly conclusory. Its final estimate of $ 30,000 per site has no more discernible evidentiary basis than its initial estimate of $ 20,000—a figure seemingly pulled from thin air—and is an order of magnitude lower than the evidence-backed calculations provided by commenters. Furthermore, HHS also offered no response to commenters' descriptions of their ongoing compliance costs beyond the first year.

HHS also ignored consequential costs of compliance. Numerous commenters explained to HHS that because compliance with the physical separation requirement would be "prohibitive in terms of cost and feasibility" large numbers of Title X providers would be forced to leave the program. Rich Decl., Exh. L at 16–17, Exh. C at 16–17, Exh. G at 11–12, Exh. H at 10–

11, Exh. M at 32–34. Plaintiffs have provided ample evidence demonstrating that without Title X funding, these providers would be able to serve far fewer clients, including evidence that Title X funds services for more than 1 million patients in California every year, and that 85 percent of Essential Access subrecipients will have to lay off staff and cut services and programming without Title X funding. *See* Part III.A.1., *supra*; Rabinovitz Decl. ¶¶ 1, 14–15. The withdrawal of Planned Parenthood alone would create a massive vacuum in services as its health centers currently serve more than 40% of all Title X patients. Rich Decl., Exh. M at 15–16. "[O]ther types of Title X sites would need to increase their client caseloads by 70 percent" just to make up for the shortfall created by Planned Parenthood's departure. *Id.* at 16. "[T]he departure of a large number of Title X-funded providers ... would reduce access to family planning care with attendant negative impacts on health outcomes and population health." *Id.* at 33. The "adverse health consequences" to patients would include "unintended pregnancies, undetected STDs, and other poor health outcomes." *Id.*; *see id.*, Exh. G at 12–13; U.S. Dep't of Health and Human Services, *Title X Family Planning Annual Report: 2016 National Summary* at 1 (2017) ("For many clients, Title X providers are their only ongoing source of health care and health education."), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf. Further, the physical separation requirement would "force patients to make multiple appointments and trips" for their family planning needs, Rich Decl., Exh. C at 17, creating "unnecessary costs to patients and providers" and "interfer[ing] with the integration of care," *id.*, Exh. M at 33–34. While these costs are more difficult to estimate given their consequential

nature, HHS largely ignored these potentially enormous costs.

Instead, in response, HHS cites only a "Christian Medical Association and Freedom2Care poll conducted on May 3, 2011, which found that 91 percent of physicians who practiced medicine based on the principles of their faith said they would be forced to leave medicine if coerced into violating the faith tenets and medical ethics principles that guide their practice of medicine." 84 Fed. Reg. at 7780 n.138. Based on this poll, the agency suggests that "[w]ith the final rule's added emphasis on protecting rights of conscience, more individuals may enter the Title X family planning program, helping to meet that unmet need for care." *Id.* at 7781. The flaws in this leap of logic are myriad. Fundamentally, the poll did not ask doctors anything about Title X specifically. For example, does the permissive ability to provide nondirective abortion counseling and referral actually violate their beliefs? Have the 2000 regulations deterred them from participating in Title X because of their beliefs? Would they join Title X projects if they were not required to provide nondirective counseling and referral for abortions? More to the point, have these doctors been deterred from joining Title X projects because other projects do not have physically separate facilities? On its face, this would seem to be a non-sequitur. There is particular reason to question the assumption that large numbers of doctors are being discouraged from joining Title X because of their beliefs about abortion because HHS has already implemented rules that, since 2008, have recognized that Title X program requirements must be enforced consistent with federal laws that protect moral and religious conscience. *See* 73 Fed. Reg. 78072 (2008); 76 Fed. Reg. 9968 (2011). In any event, there is no evidence there are

enough such would-be doctors who would be prompted by the Final Rule to join Title X to fill the vacuum left by exiting providers. HHS offers no other data or evidence in support of its momentous claim that "the final rule will contribute to more clients being served, gaps in services being closed, and improved client care." 84 Fed. Reg. at 7766.

HHS's conclusory response to commenters' evidence-backed concerns about the serious problems the physical separation requirement will cause flies in the face of established APA principles. *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"); *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 341–42 (D.C. Cir. 1989) (holding that agency's "conclusory statement" dismissing plaintiff's concern that public disclosure of plaintiff's sensitive documents would cause competitive harm was so inadequate as to render the agency's decision "unreviewable"). "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. E.P.A.*, ––– U.S. ––––, 135 S. Ct. 2699, 2707, 192 L.Ed.2d 674 (2015) (emphasis in original). Here, HHS has "brushed aside critical facts," *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017), and given "no consideration to the disruption" the physical separation requirement would cause, *Regents of Univ. of California v. United States Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1045 (N.D. Cal.), *aff'd*, 908 F.3d 476 (9th Cir. 2018). As such, the promulgation of the physical separation requirement "runs counter to the evidence before the agency" and is arbitrary and capricious under traditional APA principles, *State Farm*, 463 U.S. at 43, 103

S.Ct. 2856, and even more so under *Fox Television*, 556 U.S. at 515, 129 S.Ct. 1800 (requiring agency to provide a "more detailed justification" for a change in policy and show "that there are good reasons" for the change).

c. The Counseling and Referral Restrictions are Arbitrary and Capricious

Plaintiffs next challenge the promulgation of the Final Rule's restrictions on abortion counseling and referral as arbitrary and capricious. *See* California Mot. at 17–18; Essential Mot. at 17–18.

Defendants' justification for reinstating restrictions on abortion counseling and referrals is 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; *see* Opp. at 31–32. These conscience laws do not provide a reasoned explanation for the Final Rule's counseling restrictions for two reasons.

First, as noted above, there are already HHS regulations on the books that ensure Title X's implementation is consistent with the conscience laws. In 2008, the agency announced that it "would not enforce [the abortion counseling and referral] requirement on objecting grantees or applicants." 73 Fed. Reg. at 78087. This rule was partially repealed in 2011 and replaced with a "new process for enforcing those [conscience] protections" whereby the HHS Office for Civil Rights addresses any complaints of discrimination under the conscience laws. 76 Fed. Reg. at 9969. The agency emphasized that the "partial rescission of the 2008 Final Rule [in 2011] does not alter or affect the federal statutory health care provider conscience protections." *Id.* HHS fails to explain why a more sweeping set of restrictions is necessary in light of the existing safeguards tailored

to ensure Title X's compliance with federal conscience laws. *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).

Second, the conscience laws prohibit federal, state, and local governments "from engaging in discrimination against a health care entity on the basis that it does not, among other things, refer for abortion." *Id.* This means HHS may not require Title X grantees to provide abortion referrals over their objections. But this does not concern grantees which *do not* have moral or religious objections to abortion. The conscience laws do not provide a basis for HHS to bar *all* Title X grantees from providing abortion referrals. Given the lack of a reasoned basis for the counseling and referral restrictions, those provisions of the Final Rule are arbitrary and capricious under the traditional *State Farm* analysis.

As with the physical separation requirement, this aspect of the Final Rule, which significantly alters the longstanding prior regulatory scheme requires a more detailed justification under *Fox Television.* The counseling and referral restrictions are based in part on factual findings discussed in the Final Rule that contradict those which underlay the 2000 regulations. In 2000, HHS justified its formal rescission of the 1988 "gag rule" on the following grounds: it "endangers women's lives and health by preventing them from receiving complete and accurate medical information"; it "interferes with the doctor-patient relationship by prohibiting information that medical professionals are otherwise ethically and legally required to provide to their

patients"; "requiring a referral for prenatal care ... where the client rejected those options would seem coercive and inconsistent with the concerns underlying the 'nondirective' counseling requirement"; and it is "consistent with the prevailing medical standards recommended by national medical groups." 65 Fed. Reg. at 41270–75. In contrast, HHS now asserts the restrictions in the Final Rule are warranted because "it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers"; "[r]eferring for adoption or prenatal care, but not for abortion, does not ... make pregnancy counseling directive"; and the restrictions "will [not] require health care professionals to violate medical ethics, regulations concerning the practice of medicine, or malpractice liability standards." 84 Fed. Reg. at 7746–48. This factual finding conflicts with those underlying the prior HHS guidelines, so HHS must "provide a more detailed justification" for the counseling and referral restrictions. *Fox Television*, 556 U.S. at 515–16, 129 S.Ct. 1800. It has not done so. The agency's claim that the restrictions are needed for Title X to comply with conscience laws rings hollow given that its existing regulations already ensure compliance, and in any event the restrictions go far beyond what the conscience laws require.

d. The "Physician or APP" Requirement is Arbitrary and Capricious

Plaintiffs further contend that the requirement in § 59.14(b)(1)(i) that nondirective pregnancy counseling can only be "provided by physicians or advanced practice providers" is arbitrary and capricious, because there is a "complete absence of justification" for the re-

quirement. Essential Mot. at 18; California Mot. at 18–19. Defendants offer two responses, both of which make little sense. First, Defendants point out that the Final Rule is more permissive than the Proposed Rule, because the Proposed Rule restricted pregnancy counseling to physicians only, whereas the Final Rule allows physicians and APPs to take on counseling duties. Opp. at 32–33. This observation is neither here nor there, because neither the Proposed Rule nor the Final Rule explains *why* pregnancy counseling should be limited to physicians or APPs. The physician-and-APP limitation, while more permissive than the physician-only limitation initially proposed, is just as arbitrary.

Second, Defendants claim that "HHS considered which types of health care professionals to include [as qualified to provide pregnancy counseling], and reasonably drew the line at APPs, who have 'advanced medical degrees, licensing, and certification requirements.'" *Id.* (quoting 84 Fed. Reg at 7728 n.41). But this merely recites the Final Rule's definition of APP; again, Defendants cannot point to any part of the Final Rule where HHS explains *why* "advanced medical degrees, licensing, and certification requirements" are necessary to qualify someone to provide pregnancy counseling. The agency certainly did not address voluminous evidence that non-APP personnel with the proper training have long been capably providing pregnancy counseling. *See, e.g.*, Kost Decl. ¶ 86 (citing Guttmacher Institute report that in 2010, 65% of Title X sites "rel[ied] on trained health educators, registered nurses and other qualified providers (excluding physicians and advanced practice clinicians) to counsel patients in selecting contraceptive methods"); Forer Decl. ¶ 29. HHS apparently 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).

The APA requires an agency to "articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856. Moreover, the change in policy based on conflicting factual findings and which engender serious reliance interests require "good reason" and a "more detailed justification." *Fox Television*, 556 U.S. at 515, 129 S.Ct. 1800. HHS has articulated no explanation at all for the APP requirement and thus fails both tests. Accordingly, Plaintiffs are likely to succeed on the merits of their claim that § 59.14(b)(1)(i) is arbitrary and capricious.

e. The Removal of the "Medically Approved" Requirement is Arbitrary and Capricious

The 2000 regulations required Title X projects to "[p]rovide a broad range of acceptable and effective *medically approved* family planning methods ... and services." 42 C.F.R. § 59.5(a)(1) (2000) (emphasis added). The Final 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). Plaintiffs argue HHS failed to provide a reasoned basis for this change. Again, they are correct.

HHS provided one justification for removing the "medically approved" language. According to the agency, "[t]he 'medically approved' language risked creating confusion about what kind of approval is required for a method to be deemed 'medically approved.'" 84 Fed. Reg. at 7741. As Plaintiffs point out, however, HHS cannot identify a single instance in the eighteen years

since the 2000 regulations added the "medically approved" requirement where a regulated entity has expressed confusion about the meaning of the term. Indeed, numerous comments submitted during rulemaking demonstrated that Title X providers understood "medically approved" to mean contraceptive methods that have been approved by the Food and Drug Administration, because that is what HHS has made clear it means. Throughout its QFP Guidelines, HHS emphasizes repeatedly that providers of family planning services should provide "a full range of *FDA-approved* contraceptive methods." QFP Guidelines at 7 (emphasis added); *id.* at 2, 10, 11, 23, 24, 39. Numerous medical associations and experts in reproductive health told the agency that they understood "medically approved" to mean "FDA approved." *See, e.g.*, Rich Decl., Exh. E at 2 (Guttmacher Institute); Exh. G at 8 (ACOG); Exh. I at 3 (AMA); Exh. K at 5 (APHA).

The only confusion evinced anywhere in the record is of the agency's own creation. In the Final Rule, instead of citing its QFP Guidelines, HHS hypothesized: "Family planning methods and services are often provided through licensed health care professionals. Thus, it is true of all family planning methods or services provided by Title X providers that at least one medical professional or clinic has 'approved' the method or service, by virtue of providing it to the client." 84 Fed. Reg. at 7732. In disregarding the industry-accepted understanding of "medically approved" and instead suggesting that a single individual—who may be but is not necessarily a "licensed health care professional"—may be able to confer medical approval on a family planning method, HHS is manufacturing confusion where none previously existed. *Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 837 (D.C. Cir. 2006)

(finding arbitrary and capricious an agency order that the record revealed to be "a solution in search of a problem").

HHS further feigned ignorance in the Final Rule when it wrote that "[t]he Department also does not understand, and commenters fail to explain, what the addition of 'medically approved' to the definition would mean in practice." 84 Fed. Reg. at 7732. But it later revealed the commenters had explained precisely the import of the "medically approved" language: "Some commenters state the language could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning." *Id.* at 7740. While it recited these concerns, HHS failed to address them. *See Beno v. Shalala*, 30 F.3d 1057, 1074–75 (9th Cir. 1994) ("[A] court should not infer that an agency considered an issue merely because it was raised, where there is no indication that the agency ... refuted the issue."). Thus, the problem is not that commenters neglected their duty to raise the potential problems with removing the "medically approved" requirement; it is the fact that HHS neglected its duty under the law to consider them.

Accordingly, HHS "offered an explanation for its decision" to remove the "medically approved" language from § 59.5(a)(1) "that runs counter to the evidence before the agency," rendering its action arbitrary and capricious. *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856.

f. <u>HHS's Cost-Benefit Analysis is Arbitrary and Capricious</u>

Plaintiffs further contend that the Final Rule as a whole is arbitrary and capricious because HHS conducted and relied upon a deeply flawed cost-benefit analysis. It cited benefits that the Final Rule would confer without any evidentiary basis while disregarding or discounting costs that were supported by the record. *See* California Mot. at 14–18; Essential Mot. at 16–19; *see also* Docket No. 48-1 (amicus brief of the Institute for Policy Integrity at the New York University School of Law).

"As a general rule, the costs of an agency's action are a relevant factor that the agency must consider before deciding whether to act," and "consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act." *Mingo Logan Coal Co. v. Envtl. Prot. Agency*, 829 F.3d 710, 732–33 (D.C. Cir. 2016); *see Michigan v. E.P.A.*, ––– U.S. ––––, 135 S. Ct. 2699, 2707–08, 192 L.Ed.2d 674 (2015) ("Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate."). In promulgating the Final Rule, HHS conducted an economic and regulatory impact analysis as required by "Executive Order 12866 on Regulatory Planning and Review" and "Executive Order 13563 on Improving Regulation and Regulatory Review." 84 Fed. Reg. at 7775. It relied on the cost-benefit analysis in promulgating the Final Rule. *See, e.g., id.* at 7766, 7781–82 (relying on compliance cost estimates to conclude that the new separation requirements will not "have a significant impact on access to services" and to reject commenters' objections that the "requirements will destabilize the network of Title X providers"); *id.* at 7756, 7782–83 (relying on analysis of benefits to assert the

Final Rule will "expand[ ] the type and nature of the Title X providers and ensur[e] the diversity of such providers so as to fill gaps and expand family planning services offered through Title X"). When an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Nat'l Ass'n of Home Builders v. E.P.A.*, 682 F.3d 1032, 1039–40 (D.C. Cir. 2012) (reviewing a cost-benefit analysis conducted pursuant to Executive Order 12866 under the arbitrary and capricious standard); *Council of Parent Attorneys*, 365 F.Supp.3d at at 54 n.11 (same).

HHS's cost-benefit analysis is thus subject to review under the APA. Although such review is deferential, *Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 254 (D.C. Cir. 2013), the analysis conducted by HHS here fails even deferential review. On the one hand, the agency proclaimed that a myriad of benefits would flow from the Final Rule without providing any substantiating basis or analysis. On the other, HHS either ignored or dismissed out of hand evidence of the significant costs the Final Rule is likely to inflict that numerous commenters brought to its attention.

i. HHS Did Not Adequately Consider Costs to Patient and Public Health

In response to the Proposed Rule, commenters submitted ample evidence to HHS that the Final Rule's costs on patients and the public will be substantial.

As previously noted, commenters provided substantial evidence that the Final Rule will drive a significant number of current Title X grantees out of the program. Planned Parenthood, whose health centers serve *over 40%* of all Title X patients, "would be forced

to discontinue [its] participation in Title X if the Proposed Rule takes effect." Rich Decl., Exh. M at 15–16. Further, "a number of state grantees, including Washington, New York, Hawaii, and Oregon have already put the Department on notice that they would be forced to exit the program if the proposed regulations are finalized, along with other direct grantees." *Id.* at 15. These states combined serve 427,000 Title X patients. *Id.* The loss of Title X funding will force providers to significantly scale down their service capacity or shut down altogether. *See id.*, Exh. C at 5–6. Indeed, the Guttmacher Institute recently estimated that the exit of Planned Parenthood could lead to 1.6 million women losing access to the Title X-funded contraceptive care they currently receive. *Id.*; *see also* Part III.A.1., *supra* (detailing how California providers' capacities will be diminished without Title X funding).

In response, HHS proclaims that it "does not anticipate that there will be a decrease in the overall number of facilities offering [Title X] services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule." *Id.* at 7782. As previously discussed, however, this pronouncement is wholly conclusory and unsupported. *See* Part III.A.1., *supra.* HHS provides no evidence to indicate that there are new grantees waiting in the wings to join Title X, much less enough new grantees to fill the vacuum left by the impending exodus.

Commenters also alerted HHS that the decreased access to reproductive health services precipitated by the Final Rule will lead to an increase in the number of unintended pregnancies and births. In particular, an "increase [in] unplanned and mistimed pregnancies" is a "near certainty under the proposed rule." Brindis Decl.,

Exh. B at 11. A 2015 Guttmacher Institute report found that "in California, across all publicly funded contraceptive providers ... it was estimated that, for every seven women who received publicly funded contraceptive services, two pregnancies were averted." *Id.* at 12 n.73. Nationwide, "Title X-funded services helped women avert an estimated 822,300 unintended pregnancies in 2015 alone, thus preventing 387,200 unplanned births and 277,800 abortions." Rich Decl., Exh. L at 31–32. Without the providers of these services, the country's unintended pregnancy rate would have increased by a *whopping 31 percent. Id.* The connection between decreased family planning funding and increased rates of unintended pregnancy is reinforced by two further studies. One documented a 27% increase in births among women (who had been using highly effective, publicly funded contraceptive methods) once Texas "severely restricted public funding for family planning." Brindis Decl., Exh. B at 12; *see also* Rich Decl., Exh. K at 4 (American Public Health Association comment noting that "[i]n states that have eliminated Planned Parenthood from their family planning programs, the public health results have been disastrous"). The other surveyed patients in California's publicly funded family planning program and found that individuals would resort to less effective forms of contraceptive if they were forced to pay for family planning services themselves. Brindis Decl., Exh. B at 11. Billions of dollars in public costs would be "associated with ... unintended pregnancies and outcomes." *Id.* at 12–13.

At three different places in the Final Rule, HHS offers three different, seemingly conflicting responses to this evidence. All three are baseless. First, HHS claims that the Final Rule "is likely to *decrease* unintended pregnancies ... because clients are more likely to visit

clinics that respect their views and beliefs and to use methods that they desire and that fit their individual circumstances." 84 Fed. Reg. at 7743 (emphasis). The agency cites as the basis for this belief § 59.5(a)(1) of the Final Rule, which clarifies that Title X projects need not provide every family planning method or service. But HHS provides no evidence or analysis suggesting a connection between § 59.1(a)(1) and decreased unintended pregnancies. The agency does not, for example, provide any basis for believing that under the current regulations, patients are choosing not to avail themselves of Title X care because their "views and beliefs" are disrespected by clinics providing nondirective counseling.

Second, HHS insists that "[c]ommenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception." 84 Fed. Reg. at 7785. "On the contrary," according to the agency, "more patients could have access to services because of changes to the program." *Id.* No explanation is offered for this conclusion, nor any analysis to support it. To the extent this conclusory assertion stems from the assumption that the Final Rule will prompt large numbers of new grantees to join Title X, that assumption is debunked by record evidence, as detailed above.

Third, HHS offers an excuse for disregarding the costs associated with higher instances of unintended pregnancies:

> [T]he Department is not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an

> increase in unintended pregnancies, births, or costs associated with either, much less data that could reliably calculate the magnitude of that hypothetical impact. Therefore, the Department concludes that those are not likely or calculable impacts for the purpose of the Executive Order.

84 Fed. Reg. at 7775. This rationale does not withstand even deferential scrutiny.

For one thing, "[t]he mere fact that the ... effect[] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219 (D.C. Cir. 2004) (emphases in original). Yet that is the exact mistake HHS makes here in concluding that unintended pregnancies "are not likely" because it believes the effects of the Final Rule are difficult to quantify. HHS cannot simply disregard costs that are uncertain or difficult to quantify. Its "Guidelines for Regulatory Impact Analysis" set forth in detail how the agency is supposed to "address[] outcomes that cannot be quantified but may have important implications for decisionmaking."[17] HHS Guidelines at 47. Per the Guidelines, "[i]f quantification is not possible, analysts *must* determine how to best provide related information." *Id.* (emphasis added); *see id.* at 47–51 (laying out various approaches for incorporating non-quantified effects into

[17] Notably, the HHS Guidelines specifically list changes in "the type or quality of information available and its dissemination" effectuated by an agency action as a type of cost that is difficult to quantify but that HHS must nevertheless analyze. HHS Guidelines at 48. Absent from the Final Rule, however, is any substantive discussion of how the Final Rule's counseling and referral restrictions might create informational costs.

regulatory impact analysis). "At minimum, analysts should list significant nonquantified effects in a table and discuss them qualitatively." *Id.* at 51. HHS failed to do even that here. In its cost-benefit accounting table, the agency listed the total "Non-quantified Costs" of the Final Rule as, simply, "None." *Id.* at 7777. "None" more aptly describes the extent of HHS's analysis.

Commenters also informed HHS that the exodus of Title X providers will reduce patients' access to health services beyond family planning, and give rise to attendant health costs. "Apart from the delivery of family planning care, Title X providers have come to play an essential and important role in providing any number of other vital health services for low-income Americans," including "screenings for cervical cancer, diabetes, high blood pressures, and sexually transmitted infections (STIs), among a range of other services aimed at primary prevention and referral." Brindis Decl., Exh. B at 3.[18] "[F]or many low-income women, visits to a family planning provider are their only interaction with the health care system at all," so a reduction in the number of Title X sites would "cut off many people" from a critical health resource. *Id.*; *see* Rich Decl., Exh. M at 16 (Planned Parenthood comment explaining that "[f]ifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and may have nowhere else to go to access essential health services without

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[18] HHS itself trumpets these benefits of the current Title X program. *See* Office of Population Affairs, *Title X Family Planning Annual Report 2017 Summary* ES-2, (August 2018) ("Title X-funded cervical and breast cancer screening services are necessary for early detection and treatment," and "Title X-funded STD and HIV services provide testing necessary for preventing disease transmission and adverse health consequences.").

Planned Parenthood"). Commenters cited the case study of a rural Indiana county in which the Planned Parenthood facility closed in 2013 due to cuts to public health funding. Brindis Decl., Exh. B at 6. Without the facility, the county lost free HIV testing services and almost immediately experienced "one of the largest and most rapid HIV outbreaks the country has ever seen." *Id.* at 6–7 (citation omitted).

In response to this evidence, HHS wrote:

> Based on the Department's best estimates, it anticipates that the net impact on those seeking services from current grantees *will be zero*, as any redistribution of the location of facilities will mean that some seeking services will have shorter travel times and others seeking services will have longer travel times to reach a facility. Additionally, as a result of this final rule, the Department anticipates expanded competition that will engender new and/or additional grantees who will serve previously unserved or underserved areas, likely expanding coverage and patient access to services.

84 Fed. Reg. at 7782 (emphasis added).

The agency did not explain how it arrived at its "best estimates,"[19] or how it reached the seemingly speculative conclusion that the Final Rule would result merely in the "redistribution" of services and that be-

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[19] The HHS Guidelines expressly describe "reductions in government payments to hospitals" as a type of "transfer cost" that "should be addressed in the benefit-cost analysis, if significant," because "the affected hospitals may accept fewer patients or use less expensive treatments, in turn affecting health outcomes." HHS Guidelines at 23.

cause of the entrance of new grantees "the net impact on those seeking services from current grantees will be zero." The lack of any evidence or analysis supporting HHS's supposition that everything will even out is particularly conspicuous in the face of evidence that "other types of Title X sites would need to increase their client caseloads by 70 percent" just to compensate for the exit of Planned Parenthood from Title X. Rich Decl., Exh. M at 16. HHS's "naked conclusion ... is not enough." *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 565 (D.C. Cir. 2010).

HHS similarly failed to take account of the costs that will result from its decision to remove the requirement in § 59.5(a)(1) that the family planning methods and services provided under Title X be "medically approved." Commenters notified the agency that this change "could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning." 84 Fed. Reg. at 7740; *see* Rich Decl., Exh. I at 3; *id.*, Exh. Q at 2. Commenters specifically warned HHS that the change "seem[s] to open the door to entities like antiabortion counseling centers (or 'crisis pregnancy centers')" that "commonly do not have any medical staff and are not able or willing to provide many or all modern and FDA-approved methods of contraception." Rich Decl., Exh. E at 15. The agency did not address any of these potential costs to patient health.

ii. HHS Did Not Adequately Consider Compliance Costs

HHS's assessment of the costs to regulated entities of complying with the Final Rule is also inadequate, for the reasons discussed in Part III.C.2.b., *supra.*

iii. The Claimed Benefits are Unsubstantiated and Speculative

On the other side of the cost-benefit equation, HHS contends that the Final Rule is expected to "[e]nhance[] compliance with statutory requirements"; result in an "[e]xpanded number of entities interested in participating in Title X"; and "[e]nhance[ ] patient service and care." 84 Fed. Reg. at 7777, 7782. But HHS provided no evidence in support of any of these claims; nor did it provide any estimates of the expected magnitude of these supposed benefits. Instead, each of these claimed benefits has been shown to "run[ ] counter to the evidence before the agency." *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856. In the absence of any attempt by HHS to quantify or even explain with any substantive analysis the Final Rule's claimed benefits, it cannot be said that there has been a "reasoned determination" that the benefits justify the costs. "[R]easoned decisionmaking requires assessing whether a proposed action would do more good than harm." *Mingo Logan Coal Co. v. Envtl. Prot. Agency*, 829 F.3d 710, 732 (D.C. Cir. 2016).

On the whole, the determination by HHS that the asserted but unsubstantiated, undocumented, and speculative benefits of the Final Rule outweigh its likely substantial costs indicates the agency "put a thumb on the scale by [over]valuing the benefits and [under]valuing the costs." *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172,

1198 (9th Cir. 2008). The cost-benefit analysis is undermined by "serious flaw[s]" that "render the rule unreasonable" in its entirety under the APA. *Nat'l Ass'n of Home Builders*, 682 F.3d at 1039–40; *see State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (holding that agency action was arbitrary and capricious where the agency "only consider[ed] one side of the equation" in its cost-benefit analysis).

3. HHS Did Not Violate Notice and Comment Procedures

Essential Access makes one final claim under the APA. It contends that Defendants did not comply with the APA's notice and comment requirements because the "comprehensive primary care provider" and "physician and APP" requirements in the Final Rule are not logical outgrowths of the proposed rule. *See* Essential Mot. at 19–20.

The APA generally requires an agency to engage in notice and comment as part of its rulemaking process. *See* 5 U.S.C. § 553(b). The agency must publish a notice of proposed rulemaking in the Federal Register and notify the public of, *inter alia*, "the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b)(3). "Agencies are free—indeed, they are encouraged—to modify proposed rules as a result of the comments they receive." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004). However, "an agency's proposed rule and its final rule may differ only insofar as the latter is a 'logical outgrowth' of the former." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (citation omitted). A final rule is considered a logical outgrowth of a proposed rule "only if interested parties

'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (quoting *Ne. Md. Waste Disposal Auth.*, 358 F.3d at 952); *Envtl. Def. Ctr., Inc. v. U.S. E.P.A.*, 344 F.3d 832, 851 (9th Cir. 2003).

a. The "Comprehensive Primary Care Provider" Requirement is a Logical Outgrowth of the Proposed Rule

According to Essential Access, the requirement in § 59.14(b)(1)(ii) of the Final Rule that Title X projects can only refer patients to "licensed, qualified, comprehensive primary health care providers" is not a logical outgrowth of the Proposed Rule, which permitted referrals to "licensed, qualified, comprehensive health service providers." 83 Fed. Reg. at 25531. That is, Essential Access objects that the Proposed Rule did not specify that "comprehensive health service providers" must provide "primary care services." Essential Mot. at 20.

Essential Access has not cited any authority for the proposition that "comprehensive primary care" is meaningfully different from "comprehensive care," such that interested parties could not have anticipated that the Final Rule would incorporate the former term. Essential Access insists that language in the Final Rule "contemplates that 'comprehensive' health care services can be 'primary' or 'prenatal.'" Essential Reply at 8 (citing 84 Fed. Reg. at 7761). But the actual language in the Final Rule does not draw a distinction between "primary" comprehensive care and "prenatal" comprehensive care; it merely indicates that "comprehensive

primary care" can include prenatal care. *See* 84 Fed. Reg. at 7761 ("The Department is finalizing § 59.14(b)(1)(ii) to allow Title X providers to give a single list of providers to any pregnant woman. This list will contain licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)."). Essential Access has not shown a likelihood of success on its claim that § 59.14(b)(1)(ii) of the Final Rule is not a logical outgrowth of the Proposed Rule.

b. <u>The "Physician or APP" Requirement is a Logical Outgrowth of the Proposed Rule</u>

Essential Access also argues the requirement in § 59.14(b)(1) of the Final Rule that any nondirective pregnancy counseling under Title X can only be "provided by physicians or advanced practice providers" is not a logical outgrowth of the Proposed Rule. Essential Mot. at 20. It is true, as Essential Access points out, that the term "advanced practice provider" does not appear anywhere in the Proposed Rule. But that is because the Proposed Rule was more restrictive than the Final Rule; under the former, only physicians were permitted to provide pregnancy counseling:

> [A] doctor, though not required to do so, would be permitted to provide nondirective counseling on abortion. Such nondirective counseling would not be considered encouragement, promotion, or advocacy of abortion as a method of family planning, as prohibited under section 59.16 of this proposed rule. Moreover, a doctor would also be permitted to provide a list of licensed, qualified, comprehensive health service providers, some (but not all) of which provide abortion in addition to comprehensive prenatal care.

83 Fed. Reg. at 25518. In summarizing the changes between the Proposed Rule and the Final Rule, HHS wrote, "as a result of comments on the type of medical professional who could provide nondirective counseling and referrals under the proposed rule, ... the Department has determined that, in addition to medical doctors, advanced practice providers (APPs) may provide nondirective counseling and referrals." 84 Fed. Reg. at 7727–28.

The Proposed Rule signaled that the agency was considering limiting counseling responsibilities to individuals with advanced medical degrees, so it cannot be said that the Final Rule "finds no roots in the agency's proposal." *Envtl. Integrity Project v. E.P.A.*, 425 F.3d 992, 996 (D.C. Cir. 2005); *see Hodge v. Dalton*, 107 F.3d 705, 712 (9th Cir. 1997) (holding that a final rule "in character with the original proposal" is a logical outgrowth). Moreover, the Final Rule indicates that the Proposed Rule engendered "comments on the type of medical professional who could provide nondirective counseling and referrals." 84 Fed. Reg. at 7727–28. Essential Access argues that "[h]ad HHS provided proper notice, the public may have expressed concerns ... [that] the definition of APP is much too narrow, and excludes professionals who currently provide the bulk of pregnancy options counseling at Title X centers." Essential Mot. at 20. However, any such comments about the ability of certain categories of professionals to provide counseling could equally have been submitted to the Proposed Rule because those professionals were already excluded under the Proposed Rule.

Accordingly, Essential Access has not shown that a likelihood that § 59.14(b)(1) of the Final Rule is not a logical outgrowth of the Proposed Rule.

4. Plaintiffs' Remaining Claims

Because the Court finds that Plaintiffs have established that they are likely to succeed on the merits of their "not in accordance with law" and "arbitrary and capricious" claims under the APA, the Court will not reach their constitutional claims at this time.

D. Scope of Injunction

Plaintiffs have made a strong showing on each of the *Winter* factors, and accordingly are entitled to preliminary relief. They ask the Court to grant a nationwide injunction. California Mot. at 25; Essential Mot. at 33–35. Defendants respond that any injunctive relief should be limited to Plaintiffs, *i.e.*, to the state of California. Opp. at 46–50.

The recent Ninth Circuit ruling in *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) provides guidance on how a district court should exercise its discretion in crafting an injunction. *Azar* emphasized that while "'there is no bar against ... nationwide relief in federal district court or circuit court,' such broad relief must be 'necessary to give prevailing parties the relief to which they are entitled.'" *Id.* at 582 (quoting *Bresgal v. Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987)). The Ninth Circuit determined that the nationwide injunction it was reviewing was overbroad because "while the record before the district court was voluminous on the harm to the plaintiffs, it was not developed as to the economic impact on other states." *Id.* at 584. The court instructed that "[d]istrict judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts." 911 F.3d at 584.

Plaintiffs have supplied ample evidence of the Final Rule's anticipated impact within California. *See* Part III.A., *supra*. They offer three reasons why a nationwide injunction is necessary to afford them adequate relief. First, they assert that any violation of the APA "compel[s]" a nationwide injunction. Essential Reply at 14. Notably, however, *Azar* found that the plaintiffs there had shown a likelihood of success on their APA claims, and nonetheless ruled that a nationwide injunction was overbroad. *See* 911 F.3d at 575–81. This suggests that, notwithstanding an APA violation, this Court still must assess whether "[t]he circumstances of this case dictate a narrower scope" of relief. *Id.* at 584.

Plaintiffs' second argument is that they *have* provided sufficient evidence of the Final Rule's nationwide impact to support a broad injunction, and in particular cite to the Kost and Brindis declarations. *See* Essential Reply at 15 (citing Kost Decl. ¶¶ 76–78; Brindis Decl. ¶¶ 80–93). While the portions of the declaration on which Plaintiffs rely address the many Title X providers around the country will leave the program because of the Final Rule, the record does not indicate that preserving the current Title X network in other states is "necessary to redress the injury shown by the *[P]laintiff[s]*." *Azar*, 911 F.3d at 584 (emphasis added). Both Plaintiffs are from California. Neither Plaintiff has offices or operations outside of California. And nearly all the harms they document are focused on California. *See, e.g.*, Cantwell Decl. ¶ 32; Tosh Decl. ¶ 52. It is difficult to conduct a balance of hardship as to effects outside of California on this record.

Third, Plaintiffs argue that "Title X funding recipients draw from a single pool of funding, such that '[t]he conditions imposed on one can impact the amounts received by others.'" California Reply at 15 (quoting *City*

of Chicago v. Sessions, 888 F.3d 272, 292 (7th Cir. 2018)). According to Plaintiffs, recipients of Title X funding are "interconnected" because if Title X grantees in some areas claim less funding, grantees in other areas would receive commensurately more. Even so, however, an injunction limited to California would allow grantees within the state to maintain and deploy their regular allotment of Title X funds; grantees in other states would not be able to take away California's funds. It is difficult to discern on this record how a preliminary injunction limited to California will affect other states in a way that will harm Plaintiffs and their clients in California. In short, Plaintiffs have not shown at this juncture that a nationwide injunction is necessary to protect their interests. The Court cannot find, on this record, that Plaintiffs have made "a showing of nationwide impact" to warrant nationwide relief. *Azar*, 911 F.3d at 583.

Accordingly, Plaintiffs' motions for preliminary injunction are **GRANTED** and the Final Rule is **ENJOINED** as to enforcement in the state of California.

This order disposes of *California* Docket No. 26 and *Essential Access* Docket No. 25.

IT IS SO ORDERED.

APPENDIX E

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 19-15974
D.C. No. 3:19-cv-01184-EMC

STATE OF CALIFORNIA, by and
through Attorney General Xavier Becerra,
Plaintiff-Appellee,

v.

ALEX M. AZAR II, in his Official Capacity as
Secretary of the U.S. Department of Health & Human
Services; U.S. DEPARTMENT OF HEALTH
& HUMAN SERVICES,
Defendants-Appellants.

No. 19-15979
D.C. No. 3:19-cv-01195-EMC

ESSENTIAL ACCESS HEALTH, INC.;
MELISSA MARSHALL, M.D.,
Plaintiffs-Appellees,

v.

ALEX M. AZAR II, Secretary
of U.S. Department of Health & Human Services;
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES,
Defendants-Appellants.

No. 19-35386
D.C. Nos.
6:19-cv-00317-MC
6:19-cv-00318-MC

STATE OF OREGON; STATE OF NEW YORK; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NORTH CAROLINA; COMMONWEALTH OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; STATE OF WISCONSIN; AMERICAN MEDICAL ASSOCIATION; OREGON MEDICAL ASSOCIATION; PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.; PLANNED PARENTHOOD OF SOUTHWESTERN OREGON; PLANNED PARENTHOOD COLUMBIA WILLAMETTE; THOMAS N. EWING, M.D.; MICHELE P. MEGREGIAN, C.N.M.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DIANE FOLEY; OFFICE OF POPULATION AFFAIRS,

Defendants-Appellants.

No. 19-35394
D.C. Nos.
1:19-cv-03040-SAB
1:19-cv-03045-SAB

STATE OF WASHINGTON; NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION; FEMINIST WOMEN'S HEALTH CENTER; DEBORAH OYER, M.D.; TERESA GALL,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; DIANE FOLEY, MD, in her official capacity as Deputy Assistant Secretary for Population Affairs; OFFICE OF POPULATION AFFAIRS,

Defendants-Appellants.

Filed June 20, 2019

Before: Edward Leavy, Consuelo M. Callahan, and Carlos T. Bea, Circuit Judges.

Per Curiam Order

ORDER ON MOTIONS FOR STAY PENDING APPEAL

*   *   *

ORDER

PER CURIAM:

BACKGROUND

In 1970, Congress enacted Title X of the Public Health Service Act ("Title X") to create a limited grant program for certain types of pre-pregnancy family planning services. *See* Pub. L. No. 91-572, 84 Stat. 1504 (1970). Section 1008 of Title X, which has remained unchanged since its enactment, is titled "Prohibition of Abortion," and provides:

> None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.

42 U.S.C. § 300a-6.

In 1988, the Department of Health and Human Services ("HHS") explained that it "interpreted [§] 1008 … as prohibiting Title X projects from in any way promoting or encouraging abortion as a method of family planning," and "as requiring that the Title X program be 'separate and distinct' from any abortion activities of a grantee." 53 Fed. Reg. at 2923. Accordingly, HHS promulgated regulations forbidding Title X grantees from providing counseling or referrals for, or otherwise encouraging, promoting, or advocating abortion as a method of family planning. *Id.* at 2945. To prevent grantees from evading these restrictions, the regulations placed limitations on the list of medical providers that a program must offer patients as part of a required referral for prenatal care. *See id.* Such a list was required to exclude providers whose principal business is the provision of abortions, had to include providers who do not provide abortions, and could not

weigh in favor of providers who perform abortions. *Id.* at 2945. The regulations also required grantees to keep their Title X funded projects "physically and financially separate" from all abortion-related services that the grantee might also provide (the "physical-separation" requirement). *Id.*

In 1991, the Supreme Court upheld the 1988 regulations against a challenge in *Rust v. Sullivan*, 500 U.S. 173 (1991). *Rust* held that § 1008 of Title X was ambiguous as to whether grantees could counsel abortion as a family planning option and make referrals to abortion providers. *Id.* at 184. Applying deference under *Chevron, USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984), the Supreme Court found that the 1988 regulations were a permissible interpretation of § 1008. *Id.* at 184–85. The Supreme Court also held that the 1988 regulations were not arbitrary or capricious because the regulations were justified by "reasoned analysis," that the regulations were consistent with the plain language of Title X, and that they did not violate the First or Fifth Amendments. *Id.* at 198–201.

Several years later (and under a new presidential administration), HHS suspended the 1988 regulations. 58 Fed. Reg. 7455 (1993). HHS finally promulgated new Title X regulations in 2000, which re–interpreted § 1008 as requiring Title X grantees to provide "nondirective"[1] abortion counseling and abortion referrals upon request. 65 Fed. Reg. 41270–79. The 2000 regula-

[1] Under the 2000 regulations, "nondirective" counseling meant the provision of "factual, neutral information about any option, including abortion, as [medical providers] consider warranted by the circumstances, … [without] steer[ing] or direct[ing] clients toward selecting any option." 65 Fed. Reg. 41270–01.

tions also eliminated the 1988 regulations' physical–separation requirement. *Id.*

In 2019, HHS once again revised its Title X regulations, promulgating regulatory language (the "Final Rule") that substantially reverts back to the 1988 regulations. 84 Fed. Reg. 7714. Under the Final Rule, Title X grantees are prohibited from providing referrals for, and from engaging in activities that otherwise encourage or promote, abortion as a method of family planning. *Id.* at 7788–90. Providers are required to refer pregnant women to a non-abortion pre- natal care provider, and may also provide women with a list of other providers (which may not be composed of more abortion providers than non-abortion providers). *See id.* at 7789. Notably, however, the Final Rule is less restrictive than the 1988 regulations: it allows (but does not require) the neutral presentation of abortion information during nondirective pregnancy counseling in Title X programs. *Id.* The Final Rule also revives the 1988 regulations' physical–separation requirement, imposes limits on which medical professionals can provide pregnancy counseling, clarifies the previous requirement that family planning methods be "medically approved," and creates a requirement that providers encourage family participation in decisions. *Id.* at 7789.

The Final Rule was scheduled to take effect on May 3, 2019, although grantees would have until March 4, 2020, to comply with the physical-separation requirement. *Id.* at 7714. But a group of state governments and existing Title X grantees ("Plaintiffs") challenged the Final Rule in federal court in three states (California, Washington, and Oregon), and sought preliminary injunctive relief. The district courts in all three states granted Plaintiffs' preliminary injunction motions on nearly identical grounds. *See Washington v. Azar*,

19–cv–3040, 2019 WL 1868632 (E.D. Wash. Apr. 25, 2019); *Oregon v. Azar*, 19-cv-317, 2019 WL 1897475 (D. Oregon Apr. 29, 2019); *California v. Azar*, 19–cv–1184, 19–cv–1195, 2019 WL 1877392 (N.D. Cal. Apr. 26, 2019). As a result of the three preliminary injunctions, the Final Rule has not gone into effect.

HHS appealed all three preliminary injunction orders to this court, and filed motions to stay the injunctions pending a decision on the merits of its appeals. Because the three motions for a stay pending appeal present nearly identical issues, we consider all three motions jointly.

ANALYSIS

In ruling on a stay motion, we are guided by four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (internal quotation marks omitted). Although review of a district court's grant of a preliminary injunction is for abuse of discretion, *Southwest Voter Registration Education Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003), "[a] district court by definition abuses its discretion when it makes an error of law," *Koon v. United States*, 518 U.S. 81, 100 (1996).

I.

We conclude that the Government is likely to prevail on its challenge to the district courts' preliminary injunctions based on their findings that the Final Rule

is likely invalid as both contrary to law and arbitrary and capricious under 5 U.S.C. § 706(2)(A).

As a threshold matter, we note that the Final Rule is a reasonable interpretation of § 1008. Congress enacted § 1008 to ensure that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. If a program promotes, encourages, or advocates abortion as a method of family planning, or if the program refers patients to abortion providers for family planning purposes, then that program is logically one "where abortion is a method of family planning." Accordingly, the Final Rule's prohibitions on advocating, encouraging, or promoting abortion, as well as on referring patients for abortions, are reasonable and in accord with § 1008. Indeed, the Supreme Court has held that § 1008 "plainly allows" such a construction of the statute. Rust, 500 U.S. at 184 (upholding as a reasonable interpretation of § 1008 regulations that (1) prohibited abortion referrals and counseling, (2) required referrals for prenatal care, (3) placed restrictions on referral lists, (4) prohibited promoting, encouraging, or advocating abortion, and (5) mandated financial and physical separation of Title X projects from abortion-related activities). The text of § 1008 has not changed.

II.

Because *Rust* largely forecloses any attempt to argue that the Final Rule is not a reasonable interpretation of the text of § 1008, the district courts instead relied on two purportedly intervening laws that they say likely render the Final Rule "not in accordance with law." 5 U.S.C. § 706(2)(A). The first is an "appropria-

tions rider" that Congress has included in every HHS appropriations act since 1996. The 2018 version states:

> For carrying out the program under [T]itle X of the PHS Act to provide for voluntary family planning projects, $286,479,000: Provided, [t]hat amounts provided to said projects under such title shall not be expended for abortions, *that all pregnancy counseling shall be non-directive*, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

132 Stat 2981, 3070–71 (2018) (emphasis added). The second is an ancillary provision of the Affordable Care Act (ACA), located within a subchapter of the law entitled "Miscellaneous Provisions," which reads:

> Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
>
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant in-

formation to patients making health care decisions;

(5) violates the principles of informed consent and the ethical standards of health care professionals; or

(6) limits the availability of health care treatment for the full duration of a patient's medical needs.

Pub. L. No. 111–148, title I, § 1554 (42 U.S.C. § 18114) ("§ 1554").

These two provisions could render the Final Rule "not in accordance with law" only by impliedly repealing or amending § 1008, or by directly contravening the Final Rule's regulatory provisions.

First, we conclude that neither law impliedly repealed or amended § 1008. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 663 (2007) ("[E]very amendment of a statute effects a partial repeal to the extent that the new statutory command displaces earlier, inconsistent commands."). "[R]epeals by implication are not favored and will not be presumed unless the intention of the legislature to repeal is clear and manifest." *Id.* at 662 (internal quotation marks and alterations omitted); *United States v. Madigan*, 300 U.S. 500, 506 (1937) ("[T]he modification by implication of the settled construction of an earlier and different section is not favored."). Indeed, "[w]e will not infer a statutory repeal unless the later statute expressly contradict[s] the original act or unless such a construction is absolutely necessary … in order that [the] words [of the later statute] shall have any meaning at all." *Nat'l Ass'n of Home Builders*, 551 U.S. at 662.

Plaintiffs admit that there is no irreconcilable conflict between § 1008 and either the appropriations rider or § 1554 of the ACA. *E.g.*, California State Opposition to Motion for Stay at p. 14; Essential Access Opposition to Motion for Stay at p.14. And we discern no "clear and manifest" intent by Congress to amend or repeal § 1008 via either of these laws—indeed, neither law even refers to § 1008. The appropriations rider mentions abortion only to prohibit appropriated funds from being expended for abortions; and § 1554 of the ACA does not even *mention* abortion.

As neither statute impliedly amended or repealed § 1008, the question is therefore whether the Final Rule is nonetheless "not in accordance with law" because its provisions are incompatible with the appropriations rider or § 1554 of the ACA. 5 U.S.C. § 706(2)(A). We think that HHS is likely to succeed on its challenge to the district courts' preliminary injunctions because the Final Rule is not contrary to either provision.

The appropriations rider conditions HHS funding on a requirement that no Title X funds be expended on abortion, and that "all pregnancy counseling shall be nondirective." Pub. L. No. 115–245, div. B, tit. II, 132 Stat 2981, 3070–71 (2018). (The plain text of the rider actually seems to *reinforce* § 1008's restrictions on funding abortion-related activities.)

The district courts held that the Final Rule's counseling and referral requirements directly conflicted with the appropriations rider's "nondirective" mandate. But its mandate is *not* that nondirective counseling be given in every case. It is that such counseling as is given shall be nondirective. The Final Rule similarly does not require that any pregnancy counseling be given, only that if given, such counseling shall be nondirective

(and may include neutrally-presented information about abortion). 84 Fed. Reg. 7716 ("Under the [F]inal [R]ule, the Title X regulations no longer require pregnancy counseling, but permits the use of Title X funds in programs that provide pregnancy counseling, so long as it is nondirective."). The Final Rule is therefore not in conflict with the appropriations rider's nondirective pregnancy counseling mandate.

Although the Final Rule *does* require the provision of referrals to non-abortion providers, *id.* at 7788–90, such referrals do not constitute "pregnancy counseling." First, providing a referral is not "counseling." HHS has defined "nondirective counseling" as "the meaningful presentation of options where the [medical professional] is not suggesting or advising one option over another," 84 Fed. Reg. at 7716, whereas a "referral" involves linking a patient to another provider who can give further counseling or treatment, *id.* at 7748. The Final Rule treats referral and counseling as distinct terms, as has Congress and HHS under previous administrations. *See, e.g.*, 42 U.S.C. § 300z-10; 53 Fed. Reg. at 2923; 2928–38 (1988); 65 Fed. Reg. 41272–75 (2000). We therefore conclude that the Final Rule's referral requirement is not contrary to the appropriations rider's nondirective pregnancy counseling mandate.[2]

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[2] But to the extent there is any ambiguity, "when reviewing an agency's statutory interpretation under the APA's 'not in accordance with law' standard, … [we] adhere to the familiar two-step test of *Chevron*." *Nw. Envtl. Advocates v. U.S. E.P.A.*, 537 F.3d 1006, 1014 (9th Cir. 2008). Applying *Chevron* deference, we would conclude that HHS's treatment of counseling and referral as distinct concepts is a reasonable interpretation of the applicable statutes.

But even if referrals are included under the rubric of "pregnancy counseling," it is not clear that referring a patient to a non-abortion doctor is necessarily "directive." Nondirective counseling does not require equal treatment of all pregnancy options—rather, it just requires that a provider not affirmatively endorse one option over another. 84 Fed. Reg. at 7716. When Congress wants specific pregnancy options to be given equal treatment, it knows how to say so *explicitly*. For example, Congress has mandated that "adoption information and referrals" shall be provided "on an *equal basis* with all other courses of action included in nondirective counseling." 42 U.S.C. § 254c-6(a)(1) (emphasis added). If "nondirective" already meant that all pregnancy options (including adoption) shall be given equal treatment, it would render meaningless Congress's explicit instruction that adoption be treated on an equal basis with other pregnancy options. "[C]ourts avoid a reading that renders some words altogether redundant." Scalia, Antonin, and Garner, Bryan A., Reading Law: The Interpretation of Legal Texts (2012) 176. Congress has enacted no such statutory provision explicitly requiring the equal treatment of abortion in pregnancy counseling and referrals.[3]

We next consider § 1554 of the ACA. As a threshold matter, it seems likely that any challenge to the Final Rule relying on § 1554 is waived because Plaintiffs concede that HHS was not put on notice of this specific

[3] But as discussed above, to the extent there is any ambiguity as to whether the appropriation rider's nondirective mandate means that Title X grantees must be allowed to provide referrals to abortion providers on an equal basis with non-abortion providers, we would defer to HHS's reasonable interpretation under *Chevron* that referral to non-abortion providers is consistent with the provision of nondirective pregnancy counseling.

challenge during the public comment period, such that HHS did not have an "opportunity to consider the issue." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007) ("The waiver rule protects the agency's prerogative to apply its expertise, to correct its own errors, and to create a record for our review."). Although some commenters stated that the proposed Final Rule was contrary to the ACA *generally*, and still others used generic language similar to that contained in § 1554, preservation of a challenge requires that the "specific argument" must "be raised before the agency, not merely the same general legal issue." *Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (per curiam). Although "agencies are required to ensure that they have authority to issue a particular regulation," they "have no obligation to anticipate every conceivable argument about why they might lack such statutory authority." *Id.* at 398.

But even if this challenge were preserved, it seems likely that § 1554 does not affect § 1008's prohibition on *funding* programs where abortion is a method of family planning. Section 1554 prohibits "creat[ing] any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "imped[ing] timely access to health care services," "interfer[ing] with communications regarding a full range of treatment options between the patient and the provider," "restrict[ing] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," "violat[ing] the principles of informed consent and the ethical standards of health care professionals," and "limit[ing] the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114. But as the Supreme Court noted in *Rust*, there is a clear distinction be-

tween affirmatively impeding or interfering with something, and refusing to subsidize it. *Rust*, 500 U.S. at 200–01. In holding that the 1988 regulations did not violate the Fifth Amendment, the Supreme Court reasoned that "[t]he Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected," and that the Government "may validly choose to fund childbirth over abortion and implement that judgment by the allocation of public funds for medical services relating to childbirth but not to those relating to abortion." *Id.* at 201. The Government's "decision to fund childbirth but not abortion places no governmental obstacle in the path of a woman who chooses to terminate her pregnancy, but rather, by means of unequal subsidization of abortion and other medical services, encourages alternative activity deemed in the public interest." *Id.* (internal quotations and citations omitted). Indeed, the Supreme Court has recognized that "[t]he difficulty that a woman encounters when a Title X project does not provide abortion counseling or referral leaves her in no different position than she would have been if the Government had not enacted Title X." *Id.* at 202. *Rust's* reasoning is equally applicable to counter the district courts' conclusions that the Final Rule is invalidated by § 1554. Title X is a limited grant program focused on providing pre-pregnancy family planning services—it does not fund medical care for pregnant women. The Final Rule can reasonably be viewed as a choice to subsidize certain medical services and not others.[4]

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[4] The preamble to § 1554 also suggests that this section was not intended to restrict HHS interpretations of provisions outside the ACA. If Congress intended § 1554 to have sweeping effects on all HHS regulations, even those unrelated to the ACA, it would have stated that § 1554 applies "notwithstanding any other provi-

III.

The district courts also held that the Final Rule likely violates the Administrative Procedure Act (APA)'s prohibition on "arbitrary and capricious" regulations. 5 U.S.C. § 706(2)(A). "'Arbitrary and capricious' review under the APA focuses on the reasonableness of an agency's decision-making process." *CHW W. Bay v. Thompson*, 246 F. 3d 1218, 1223 (9th Cir. 2001) (emphasis in original). But "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). We think that is precisely what the district courts did.

To find that the Final Rule's enactment was arbitrary and capricious, the district courts generally ignored HHS's explanations, reasoning, and predictions whenever they disagreed with the policy conclusions that flowed therefrom.

For example, with respect to the physical separation requirement, the district courts ignored HHS's reasoning for its re-imposition of that requirement (which was approved by *Rust*): that physical separation would ensure that Title X funds are not used to subsidize abortions via co-location of Title X programs in abortion clinics. *See* 84 Fed. Reg. at 7763–68. HHS's reasoning included citation to data suggesting "that abortions are increasingly performed at sites that focus primarily on contraceptive and family planning ser-

sion *of law*," rather than "[n]otwithstanding any other provision *of this Act*." *See, e.g.*, *Andreiu v. Ashcroft*, 253 F.3d 477, 482 (9th Cir. 2001) (holding that the phrase "notwithstanding any other provision of law" in 8 U.S.C. § 1252(f)(2) meant that the provision "trumps any contrary provision elsewhere in the law").

vices—sites that could be recipients of Title X funds." *Id*. at 7765. Similarly, the district courts ignored HHS's primary reasoning for prohibiting abortion counseling and referrals: that such restrictions are required by HHS's reasonable reading of § 1008 (again, approved by Rust). *Id*. at 7746–47. Further, the district courts ignored HHS's consideration of the effects that the Final Rule would likely have on the number of Title X providers, and credited Plaintiffs' speculation that the Final Rule would "decimate" the Title X provider network, rather than HHS's prediction—based on evidence cited in the administrative record—"that honoring statutory protections of conscience in Title X may increase the number of providers in the program," by attracting new providers who were previously deterred from participating in the program by the former requirement to provide abortion referrals. *See id*. at 7780. Such predictive judgments "are entitled to particularly deferential review." *Trout Unlimited v. Lohn*, 559 F.3d 946, 959 (9th Cir. 2009). With respect to the Final Rule's definition of "advanced practice provider," and its provision on whether family planning methods must be "medically approved," HHS reasoned that these provisions would clarify subjects that had caused confusion in the past. 84 Fed. Reg. at 7727–28, 32. Although the district courts insist that HHS failed to consider that the Final Rule requires providers to violate medical ethics, HHS did consider and respond to comments arguing just that. *See id*. at 7724, 7748. HHS similarly considered the costs of compliance with the Final Rule. *Id*. at 7780.

In light of the narrow permissible scope of the district court's review of HHS's reasoning under the arbitrary and capricious standard, we conclude that HHS is likely to prevail on its argument that the district court

erred in concluding that the Final Rule's enactment violated the APA.[5]

IV.

The remaining factors also favor a stay pending appeal. HHS and the public at large are likely to suffer irreparable harm in the absence of a stay, which are comparatively greater than the harms Plaintiffs are likely to suffer.

Absent a stay, HHS will be forced to allow taxpayer dollars to be spent in a manner that it has concluded violates the law, as well as the Government's important policy interest (recognized by Congress in § 1008) in ensuring that taxpayer dollars do not go to fund or subsidize abortions. As the Supreme Court held in Rust, "the government may 'make a value judgment favoring childbirth over abortion, and … implement that judgment by the allocation of public funds," and by "declining to 'promote or encourage abortion.'" *Rust*, 500 U.S. at 193. Additionally, forcing HHS to wait until the conclusion of a potentially lengthy appeals process to implement the Final Rule will necessarily result in predictable administrative costs, and will beget significant uncertainty in the Title X program.

The harms that Plaintiffs would likely suffer if a stay is granted are comparatively minor. The main potential harms that Plaintiffs identify are based on their

[5] The district court in Washington also briefly stated that the Final Rule was likely invalid because it "violates the central purpose of Title X, which is to equalize access to comprehensive, evidence-based, and voluntary family planning." Washington Preliminary Injunction Order at 15. But this conclusion is foreclosed by the existence of § 1008, and by the Supreme Court's contrary finding in *Rust*.

prediction that implementation of the Final Rule will cause an immediate and steep decline in the number of Title X providers. But these potential harms obviously rely on crediting Plaintiffs' predictions about the effect of implementing the Final Rule, over HHS's predictions that implementation of the final rule will have the *opposite* effect. As described above, we think that HHS's predictions—supported by reasoning and evidence in the record (84 Fed. Reg. at 7780)—is entitled to more deference than Plaintiffs' contrary predictions. While some Title X grantees will certainly incur financial costs associated with complying with the Final Rule if the preliminary injunctions are stayed, we think that harm is minor relative to the harms to the Government described above.

V.

Because HHS and the public interest would be irreparably harmed absent a stay, harms to Plaintiffs from a stay will be comparatively minor, and HHS is likely to prevail in its challenge of the preliminary injunction orders before a merits panel of this court (which is set to hear the cases on an expedited basis), we conclude that a stay of the district courts' preliminary injunction orders pending appeal is proper.

The motion for a stay pending appeal is **GRANTED**.

APPENDIX F

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 19-15974
D.C. No. 3:19-cv-01184-EMC
Northern District of California, San Francisco

STATE OF CALIFORNIA, by and through
Attorney General Xavier Becerra,
Plaintiff-Appellee,
v.

ALEX M. AZAR II, in his Official Capacity as
Secretary of the U.S. Department of
Health & Human Services; U.S. DEPARTMENT
OF HEALTH & HUMAN SERVICES,
Defendants-Appellants.

No. 19-15979
D.C. No. 3:19-cv-01195-EMC
Northern District of California, San Francisco

ESSENTIAL ACCESS HEALTH, INC.;
MELISSA MARSHALL, M.D.,
Plaintiffs-Appellees,
v.

ALEX M. AZAR II, Secretary of U.S. Department of
Health and Human Services; UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellants.

No. 19-35386
D.C. Nos. 6:19-cv-00317-MC, 6:19-cv-00318-MC
District of Oregon, Eugene

STATE OF OREGON; ET AL.,
Plaintiffs-Appellees,
v.

ALEX M. AZAR II; ET AL.,
Defendants-Appellants.

No. 19-35394
D.C. Nos. 1:19-cv-03040-SAB, 1:19-cv-03045-SAB
Eastern District of Washington, Yakima

STATE OF WASHINGTON; ET AL.,
Plaintiffs-Appellees,
v.

ALEX M. AZAR II, in his official capacity as
Secretary of the United States Department
of Health and Human Services; et al.,
Defendants-Appellants.

Filed May 8, 2020

Before:
THOMAS, Chief Judge, and LEAVY, WARDLAW,
W. FLETCHER, PAEZ, BYBEE, CALLAHAN,
M. SMITH, IKUTA, MILLER and LEE,
Circuit Judges.

ORDER

A majority of the panel has voted to deny the Petition of Plaintiffs-Appellees Essential Access Health, Inc. and Melissa Marshall, M.D. for Full Court or Limited En Banc Court Rehearing (Case No. 19-15974, ECF No. 139; Case No. 19-15979, ECF No. 135); the Petition of the State of California et al. for En Banc or Full Court Rehearing (Case No. 19-15974, ECF No. 139; Case No. 19-15979, ECF No. 131; Case No. 19-35386, ECF No. 180); the Petition of Plaintiffs-Appellees National Family Planning & Reproductive Health Association et al. for Full Court or Limited En Banc Court Rehearing (Case No. 19-35394, ECF No. 139); the Petition of Plaintiffs-Appellees American Medical Association et al. for Full Court or Limited En Banc Court Rehearing (Case No. 19-35386, ECF No. 179) (collectively, the "Petitions").

Judges Leavy, Bybee, Callahan, M. Smith, Ikuta, Miller, and Lee voted to deny the Petitions. Judge Paez voted to grant the Petitions.

The full court has been advised of the Petitions, and no Judge has requested a vote on whether to rehear the matter as a full court. Fed. R. App. P. 35.

The Petitions are DENIED.

APPENDIX G

STATUTES AND REGULATIONS INVOLVED

5 U.S.C. § 706

§706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

42 U.S.C. § 300a-6

§ 300a-6. Prohibition against funding programs using abortion as family planning method

None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.

42 U.S.C. § 18114

§ 18114. Access to therapies

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;

(2) impedes timely access to health care services;

(3) interferes with communications regarding a full range of treatment options between the patient and the provider;

(4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;

(5) violates the principles of informed consent and the ethical standards of health care professionals; or

(6) limits the availability of health care treatment for the full duration of a patient's medical needs.

Pub. L. No. 116-94, div. A, tit. II, 133 Stat. 2534, 2558 (2019) (Excerpt)

* * *

FAMILY PLANNING

For carrying out the program under title X of the PHS Act to provide for voluntary family planning projects, $286,479,000: Provided, That amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be non-directive, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.

* * *

42 C.F.R. §§ 59.1-59.19

§ 59.1 To what programs do these regulations apply?

(a) The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children. Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and subrecipients, and grantees shall require and ensure that subrecipients (and the subrecipients of subrecipients) comply with the requirements contained in these regulations pursuant to their written contracts with such subrecipients.

(b) Except for §§ 59.4, 59.8, and 59.10, the regulations of this subpart are also applicable to the execution of contracts under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects, and will be applied in accordance with the applicable statutes, procedures and regulations that generally govern Federal contracts. To this extent, the use of the terms "grant", "award", "grantee", and "subrecipient" in applicable regulations of this subpart will apply similarly to contracts, contractors and subcontractors, and the use of the term "project" or "program" will also apply to a project or program established by means of a contract.

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Advanced Practice Provider means a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM).

Family means a social unit composed of one person, or two or more persons living together, as a household.

Family planning means the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. These means include a broad range of acceptable and effective family planning methods and services, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility, including information about or referrals for adoption. Family planning services include preconception counseling, education, and general reproductive and fertility health care, in order to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. Family planning methods and services are never to be coercive and must always be strictly voluntary. Family planning does not include postconception care (includ-

ing obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.

Grantee means the entity that receives Federal financial assistance by means of a grant, and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.

Low income family means a family whose total income does not exceed 100% of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). The project director may find that low income family also includes members of families whose annual income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example:

(1) Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:

(i) That it suspects the minor to be the victim of child abuse or incest; and

(ii) That it has, consistent with, and if permitted or required by, applicable State or local

law, reported the situation to the relevant authorities.

(2) For the purpose of considering payment for contraceptive services only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage, the project director may consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services. In making that determination, the project director must also consider other circumstances affecting her ability to pay, such as her total income. The project director may, for the purpose of considering whether the woman is from a low income family or is eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5, consider her annual income as being reduced by the total annual out-of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs, or estimate them at $600.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Program and project are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by, a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services

that satisfy the requirements of the grant within a service area.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands (Midway, Wake, et al.), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

Subrecipient means any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be referred to as "delegates" or "contract agencies."

§ 59.3 Who is eligible to apply for a family planning services grant or contract?

Any public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents). Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequi-

site to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.1

(3) Provide services in a manner which protects the dignity of the individual.

(4) Provide services without regard to religion, race, color, national origin, handicapping condition, age, sex, number of pregnancies, or marital status.

(5) Not provide, promote, refer for, or support abortion as a method of family planning.

(6) Provide that priority in the provision of services will be given to persons from low-income families.

(7) Provide that no charge will be made for services provided to any persons from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to persons other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(9) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reim-

bursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX or XXI agency is required.

(10) Provide an opportunity for maximum participation by existing or potential subgrantees in the ongoing policy decisionmaking of the project.

(11) Provide for an Advisory Committee as required by § 59.6.

(12) Should offer either 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, in order to promote holistic health and provide seamless care.

(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:

(i) Subrecipients and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided;

(ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and

(iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(14) Encourage 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).

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for informational and educational programs designed to—

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by persons to whom family planning services may be beneficial.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Except as provided in § 59.14(a), provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the grantee. The grantee must be prepared to substantiate, that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by oth-

ers in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) Size. The Committee shall consist of no fewer than five but not more than nine members, except that this provision may be waived by the Secretary for good cause shown.

(2) Composition. The Committee shall include individuals broadly representative (in terms of demographic factors such as race, color, national origin, handicapped condition, sex, and age) of the population or community for which the materials are intended.

(3) Function. In reviewing materials, the Advisory Committee shall:

(i) Consider the educational and cultural backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(iii) Review the content of the material to assure that the information is factually correct;

(iv) Determine whether the material is suitable for the population or community to which is to be made available; and

(v) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will, in the Department's judgment, best promote the purposes of statutory provisions applicable to the Title X program, and ensure that no Title X funds are used where abortion is a method of family planning.

(b) Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process, but shall be deemed ineligible for funding. The Department will explicitly summarize each requirement of the Title X regulations or include the Title X regulations in their entirety within the Funding Announcement, and shall require each applicant to describe its plans for affirmative compliance with each requirement.

(c) If the proposal is deemed compliant with this regulation, then applicants will be subject to criteria for se-

lection within the competitive grant review process, including:

(1) The degree to which the applicant's project plan adheres to the Title X statutory purpose and goals for the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents), while meeting all of the statutory and regulatory requirements and restrictions, including that none of the funds shall be used in programs where abortion is a method of family planning.

(2) The degree to which the relative need of the applicant for Federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.

(3) The degree to which the applicant takes into account the number of patients, particularly low-income patients, to be served while also targeting areas that are more sparsely populated and/or places in which there are not adequate family planning services available.

(4) The extent to which family planning services are needed locally and the applicant proposes innovative ways to provide services to unserved or underserved communities.

(d) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(e) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75, subpart E.

§ 59.10 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following HHS Department-wide regulations which apply to grants under this subpart. These include:

37 CFR Part 401—Rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 59.12 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to or at the time of any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

§ 59.13 Standards of compliance with prohibition on abortion.

A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.

§ 59.14 Requirements and limitations with respect to post-conception activities.

(a) Prohibition on referral for abortion. A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.

(b) Information about prenatal care.

(1) Because Title X funds are intended only for family planning, once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care. The Title X provider may also choose to provide the following counseling and/or information to her:

(i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;

(ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);

(iii) Referral to social services or adoption agencies; and/or

(iv) Information about maintaining the health of the mother and unborn child during pregnancy.

(2) In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency.

(c) Use of permitted lists or referrals to encourage abortion.

(1) A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

(2) The list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in paragraph (b)(1)(ii) of this section may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortion.

(d) Provision of medically necessary information. Nothing in this subpart shall be construed as prohibiting the

provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not promote abortion as a method of family planning.

(e) Examples.

(1) A pregnant client of a Title X project requests prenatal health care services. Because the provision of such services is outside the scope of family planning supported by Title X, the client is referred for prenatal care and may be provided a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). Provision of a referral for prenatal health care is consistent with this part because prenatal care is a medically necessary service.

(2) A Title X project discovers an ectopic pregnancy in the course of conducting a physical examination of a client. Referral arrangements for emergency medical care are immediately provided. Such action complies with the requirements of paragraph (b) of this section.

(3) After receiving nondirective counseling at a Title X provider, a pregnant woman decides to have an abortion, is concerned about her safety during the procedure, and asks the Title X project to provide her with a referral to an abortion provider. The Title X project tells her that it does not refer for abortion, but provides the following: A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), which is not presented as a referral for abortion, but as a list of comprehensive primary care

and prenatal care providers that does not identify which providers perform abortion, and the project staff member does not identify such providers on the list; and information about maintaining her health and the health of her unborn child during pregnancy. Such actions comply with paragraphs (a) through (c) of this section.

(4) A pregnant woman asks the Title X project to provide her with a list of abortion providers in the area. The project tells her that it does not refer for abortion, and provides her a list that consists of hospitals and clinics and other providers, all of which provide comprehensive primary health care (including prenatal care), as well as abortion as a method of family planning. Although there are several licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in the area that do not provide abortion as a method of family planning, none of these providers is included on the list. Provision of the list is inconsistent with paragraphs (a) and (c) of this section.

(5) A pregnant woman requests information on abortion and asks the Title X project to refer her for an abortion. The counselor tells her that the project does not consider abortion a method of family planning and, therefore, does not refer for abortion. The counselor offers her nondirective pregnancy counseling, which may discuss abortion, but the counselor neither refers for, nor encourages, abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services and offers her the list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal

care), assistance, and information for pregnant women described in paragraph (b) of this section. None of the providers on the list provide abortions. Such actions are consistent with paragraphs (a) through (c) of this section.

(6) Title X project staff provide contraceptive counseling to a client in order to assist her in selecting a contraceptive method. In discussing oral contraceptives, the project counselor provides the client with information contained in the patient package insert accompanying a brand of oral contraceptives, referring to abortion only in the context of a discussion of the relative safety of various contraceptive methods and in no way promoting abortion as a method of family planning. The provision of this information is consistent with paragraph (d) of this section and this section generally and does not constitute an abortion referral.

§ 59.15 Maintenance of physical and financial separation.

A Title X project must be organized so that it is physically and financially separate, as determined in accordance with the review established in this section, from activities which are prohibited under section 1008 of the Public Health Service Act and §§ 59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program. In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities. Mere bookkeeping separation of Title X funds from other monies is not sufficient. The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances. Factors relevant to this determination shall include:

(a) The existence of separate, accurate accounting records;

(b) The degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;

(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

(d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

§ 59.16 Prohibition on activities that encourage, promote, or advocate for abortion.

(a) Prohibition on activities that encourage abortion.

(1) A Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions in the funded project that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion for family planning purposes.

(2) Prohibited actions include the use of Title X project funds for the following:

(i) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning;

(ii) Providing speakers or educators who promote the use of abortion as a method of family planning;

(iii) Attending events or conferences during which the grantee or subrecipient engages in lobbying;

(iv) Paying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes;

(v) Using legal action to make abortion available in any way as a method of family planning; and

(vi) Developing or disseminating in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning.

(b) Examples.

(1) Clients at a Title X project are given brochures advertising a clinic that provides abortions, or such brochures are available in any fashion at a Title X clinic (sitting on a table or available or visible within the same space where Title X services are provided). Provision or availability of the brochure violates paragraph (a)(2)(vi) of this section.

(2) A Title X project makes an appointment for a pregnant client for an abortion for family planning purposes. The Title X project has violated paragraph (a)(1) of this section.

(3) A Title X project pays dues with project funds to a State association that, among other activities, lobbies at State and local levels for the passage of legislation to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annu-

al budget on such activity and does not separately collect and segregate the funds for such purposes. Payment of dues to the association violates paragraph (a)(2)(iv) of this section.

(4) An organization conducts a number of activities, including operating a Title X project. The organization uses non-project funds to pay dues to an association that, among other activities, engages in lobbying to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity. Payment of dues to the association by the organization does not violate paragraph (a)(2)(iv) of this section.

(5) An organization that operates a Title X project engages in lobbying to increase the legal availability of abortion as a method of family planning. The project itself engages in no such activities, and the facilities and funds of the project are kept separate from prohibited activities. The project is not in violation of paragraph (a)(2)(i) of this section.

(6) Employees of a Title X project write their legislative representatives in support of legislation seeking to expand the legal availability of abortion, in their personal capacities and using no project funds to do so. The Title X project has not violated paragraph (a)(2)(i) of this section.

(7) On her own time and at her own expense, a Title X project employee speaks before a legislative body in support of abortion as a method of family planning. The Title X project has not violated paragraph (a)(2)(i) of this section.

(8) A Title X project uses Title X funds for sex education classes in a local high school. During the course of the class, information is distributed to students that includes abortion as a method of family planning. The Title X project has violated paragraph (a)(2)(vi) of this section.

§ 59.17 Compliance with reporting requirements.

(a) Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, "State notification laws").

(b) A project may not receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:

(1) Has in place and implements a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:

(i) A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client's sexual partner(s);

(ii) Timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or provider with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws.

(iii) Protocols to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and

(iv) Commitment to conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STDs.

(2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section, including which:

(i) Indicate the age of minor clients;

(ii) Indicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required; and

(iii) Document each notification or report made pursuant to such State notification laws.

(c) Continuation of grantee or subrecipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.

(d) The Secretary may review records maintained by a grantee or subrecipient for the purpose of ensuring compliance with the requirements of this section, the requirement to encourage family participation in family planning decisions, or any other section of this rule.

§ 59.18 Appropriate use of funds.

(a) Title X funds shall not be used to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient. Funds shall only be used for the pur-

poses, and in direct implementation of, the funded project, expressly permitted by this regulation and authorized within section 1001 of the Public Health Service Act, that is, to offer family planning methods and services. Grantees must use the majority of grant funds to provide direct services to clients, and each grantee shall provide a detailed plan or accounting for the use of grant dollars, both in their applications for funding, and in any annually required reporting. Any significant change in the use of grant funds within the grant cycle shall not be undertaken without the approval of the Office of Population Affairs.

(b) Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for office.

(c) Each project supported under Title X shall fully account for, and justify, charges against the Title X grant. The Department shall put additional protections in place to prevent possible misuse of Title X funds through misbilling or overbilling, or any other unallowable expense.

§ 59.19 Transition provisions; compliance.

(a) Compliance date concerning physical and financial separation. The date by which covered entities must comply with the physical separation requirements contained in § 59.15 is March 4, 2020. The date by which covered entities must comply with the financial separation requirements contained in § 59.15 is July 2, 2019.

(b) Compliance date concerning applications. The date by which covered entities must comply with § 59.7 and 59.5(a)(13) (as it applies to grant applications) is the

date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.

(c) Compliance date concerning reporting, assurance, and provision of service requirements. The date by which covered entities must comply with §§ 59.5(a)(12), 59.5(a)(13) (as it applies to all required reports), 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18 is July 2, 2019.