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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

NO. 1:19-cv-3040-SAB

STATE OF WASHINGTON'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND CROSS-MOTION FOR SUMMARY JUDGMENT

NOTED FOR: February 13, 2020
With Oral Argument: 1:15 p.m.
Spokane Courtroom 755

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The State of Washington opposes Defendants' *Motion to Dismiss or, in the Alternative, for Summary Judgment* (ECF No. 112) (MTD) and cross-moves for summary judgment.

I. INTRODUCTION

The Centers for Disease Control and Prevention (CDC), a sub-agency of the Department of Health and Human Services (HHS), recognizes family planning as one of the ten greatest public health achievements of the twentieth century.[1] Congress ensured that those with the least economic resources could share in the benefits of this achievement: in 1970, it enacted Title X of the Public Health Service Act, which established the nation's family planning program dedicated to equalizing access to a broad range of effective contraceptive options and related health care.

Title X has been a public health success story. For nearly 50 years, the program—governed by sound, research-backed guidelines and considered regulations providing for high-quality, patient-centered reproductive health care—has helped low-income patients achieve control over their personal lives

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[1] https://www.cdc.gov/mmwr/preview/mmwrhtml/00056796.htm; *see, e.g.*, AR107973 & n.18 (AAN cmt.). "AR" (followed by the applicable 5- or 6-digit Bates number) refers to the Administrative Record, relevant excerpts of which are submitted as Exhibit 1 to the Declaration of Kristin Beneski.

and economic fortunes, improving public health from generation to generation and saving billions of dollars in preventable health care costs.

In 2019, over the protests of the medical community, Title X grantees, and public health officials, HHS issued the Rule at issue, 84 Fed. Reg. 7714, *codified at* 42 C.F.R. Part 59, which sacrifices women's health and autonomy as it transforms Title X into an ideologically driven program that will serve far fewer patients and offer them lower-quality care. Offering no sound basis for radically departing from prior policies, and ignoring unanimous opposition from the nation's major medical organizations, HHS instituted onerous and unethical new requirements that have already forced out many health care providers, leaving no Title X providers left in the State of Washington. Contrary to the Title X statute and to other statutory limitations on HHS's rulemaking authority, the Rule requires federally funded family planning providers to distort pregnancy counseling, pushing patients toward the agency's preferred outcome regardless of patient wishes or their providers' efforts to comply with HHS's own clinical standards. The Rule also imposes burdensome and counterproductive new requirements with which many experienced and qualified Title X providers cannot comply, forcing them out of the program or imposing exorbitant expenses on them. These changes will deprive many patients of experienced, effective Title X providers—often their only source of health care—while at the same time opening the door to hypothetical new providers with conscience objections to

reproductive health care who will offer more limited services and lower-quality care.

The administrative record, produced after the Ninth Circuit's stay ruling, overwhelmingly shows that Defendants' action was arbitrary and capricious and otherwise contrary to the Administrative Procedure Act (APA), Title X, and other statutory limitations on HHS's rulemaking authority. The Rule is unlawful and should be vacated and set aside.

II. STATEMENT OF FACTS

Title X, the additional statutes that govern its implementation, the challenged rulemaking, and the procedural history of this litigation are briefly summarized here. *See also* ECF No. 9 (WA PI Mot.) at 4–12; ECF No. 18 (NFPRHA PI Mot.) at 2–7.

A. Statutory and Regulatory Background

Title X of the Public Health Service Act, 42 U.S.C. § 300 *et seq.*, is the nation's family planning safety-net program for low-income individuals. Its primary purpose is to equalize access to effective contraception to help women avoid unplanned and unwanted pregnancies. *See* 42 U.S.C § 300; Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970); ECF No. 54 (PI Order) at 7, 15. A bipartisan Congress passed Title X in response to evidence that lack of access to effective contraception prevented low-income women from exercising control over their reproduction, creating poor health and economic outcomes. *See* S. Rep. No. 91-1004 at 9 (1970) (the "medically indigent" should not have to "rely on the

least effective nonmedical techniques for fertility control"); H.R. Rep. No. 91-1472 at 6 (1970).

Through grants to states and other entities, Title X funds regional and local "programs" or "projects" (i.e., a set of federally funded activities) that offer a "broad range of acceptable and effective family planning methods and services[.]" 42 U.S.C. § 300(a). Pursuant to Section 1008 (Prohibition of Abortion), Title X funds may not be used for "abortion as a method of family planning." *Id.* § 300a-6. Under Section 1007 (Voluntary Participation), every patient offered Title X services and information must accept them voluntarily, rather than be subjected to unwanted medical care or advice. *Id.* § 300a-5. Title X programs offer a wide selection of contraceptive options; testing for sexually transmitted infections (STIs) and HIV; cancer screenings; pregnancy testing and counseling; and referrals for out-of-program care. AR406508, 518-19 (Title X Program Requirements); PI Order at 7–9.

Prior to the new Rule, the Washington State Department of Health (DOH) was a Title X grantee—the only grantee in Washington. It ran a statewide program with 16 subrecipient organizations, which in turn operated 85 clinic sites in the state. PI Order at 8; ECF No. 11 (Harris Decl.) ¶ 14; AR278554–55 (Wash. cmt.). The Title X grant to DOH provided $4 million to the program. Harris Decl. ¶ 24. In 2017 alone, Washington's program served over 91,000 patients in need (56% of whom were at or below the federal poverty level), saving over $113 million in health care costs and helping women avoid over 18,000 unintended

pregnancies. *Id.* ¶¶ 26, 33; AR278555 (Wash. cmt.). Title X achieved similar benefits nationwide, where every $1 spent on family planning services resulted in over $7 of cost savings. *See* ECF No. 17-7 (Frost, et al., *Return on Investment: A Fuller Assessment of the Benefits and Costs of the US Publicly Funded Family Planning Program*, The Milbank Quarterly, Vol. 92, No. 4, p.668 (2014)).[2]

HHS is authorized, subject to statutory limitations, to issue regulations implementing Title X. *See* 42 U.S.C. §§ 300–300a-4. Since the 1970s, and with the exception of one anomalous rule that was never fully implemented,[3] HHS regulations and guidance have governed the provision of modern, effective

---

[2] Many public comments in the administrative record cited or referenced this study. *See, e.g.*, AR278576 (Wash. cmt.); AR268837 (ACOG cmt.); AR264433 (Guttmacher Inst. cmt.); AR308042 (NFPRHA cmt.); AR316479 (PPFA cmt.); AR294046 (NACCHO cmt.).

[3] The 1988 "gag rule" prohibited nondirective pregnancy counseling, including referral for abortion, and required physical separation of abortion care. 53 Fed. Reg. 2922 (Feb. 2, 1988). The gag rule was upheld as a permissible agency interpretation of the then-existing Title X statutory landscape in *Rust v. Sullivan*, 500 U.S. 173 (1991), but was never fully implemented due to ongoing litigation, and was formally rescinded in early 1993 amidst public outcry and continued litigation. *See Nat'l Family Planning & Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992); 58 Fed. Reg. 7464 (Feb. 5, 1993).

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contraception and other family planning services, including nondirective pregnancy counseling that incorporates related referrals, while ensuring compliance with the prohibition on funding abortion. *See* 36 Fed. Reg. 18,465 (Sept. 15, 1971), *codified at* 42 C.F.R. Part 59 (1972); 45 Fed. Reg. 37,433 (Jun. 3, 1980), *codified at* 42 C.F.R. Part 59 (1980); 65 Fed. Reg. 41,270 (Jul. 3, 2000), *codified at* 42 C.F.R. Part 59 (2000) ("2000 Regulations"); *see* ECF No. 1 (Wash. Compl.) ¶¶ 29–47.

Since 1996, Congress has explicitly included in its annual appropriations acts a Nondirective Mandate for Title X. *See, e.g.*, Pub. L. No. 115-245 (all Title X pregnancy counseling "shall be nondirective"). HHS long acknowledged that this Congressional "requirement for nondirective options counseling has existed in the Title X program for many years, and, with the exception of the period 1988–1992, it has always been considered to be a necessary and basic health service of Title X projects." 2000 Regulations, 65 Fed. Reg. 41,273. HHS also long recognized that nondirective counseling is consistent with the "prevailing medical standards" of patient-centered care. *Id.*

Section 1554 of the Patient Protection and Affordable Care Act (PPACA), which was enacted in 2010, reinforces the Nondirective Mandate and further restricts HHS's regulatory authority. Section 1554 commands that the agency "shall not promulgate any regulation" that—

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;

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> (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; [or]
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals . . . .

42 U.S.C. § 18114.

HHS's 2000 Regulations complied with these statutory mandates. They required Title X projects to offer neutral, factual information about all pregnancy options—both carrying to term (along with certain postpartum options) and termination of pregnancy—and referral upon request, unless the patient did not want information about a given option. 65 Fed. Reg. 41,279 (former 42 C.F.R. § 59.5(a)(5)). Likewise, HHS's Title X Family Planning Guidelines incorporate a research-backed publication entitled "Providing Quality Family Planning Services" (the QFP), which directs that "[o]ptions counseling should be provided" to pregnant patients as recommended by leading medical institutions. ECF No. 17-3 (QFP) at 14; *see* AR 406508 (Title X Program Requirements) (incorporating the QFP). In late 2017, HHS published an update to the QFP stating that the agency had conducted a review of newly published clinical recommendations from professional medical organizations and concluded that "none . . . marked a substantial shift in how family planning care should be

provided"; therefore, the QFP would continue to govern the provision of Title X family planning services with no change to its standards. ECF No. 17-4.

B. The New Rule

The challenged Rule, 84 Fed. Reg. 7714 (Mar. 4, 2019), *codified at* 42 C.F.R. Part 59 (2019), exceeds statutory limits on HHS's authority, ignores the requirements in the QFP, and reverses HHS's longstanding policies. It disrupts patients' access to medical care and information—whether funded by Title X or otherwise—in numerous ways.

First, the Rule requires Title X-funded medical providers to give their patients coercive and misleading pregnancy counseling (the "counseling distortions"). It broadly prohibits referrals for abortion, striking previous requirements that patients be offered information about all options and referred for out-of-program care upon request and for any "medically indicated" care. *See* 42 C.F.R. §§ 59.5(a)(5), (b)(1), 59.14(a). It requires medical providers to give all pregnant patients directive referrals for prenatal care absent a medical "emergency," regardless of the patient's wishes or the provider's medical judgment. *Id.* § 59.14(b). The Rule also authorizes any clinic staff person to provide directive pregnancy counseling exclusively about carrying to term, while prohibiting any neutral mention of abortion by anyone other than physicians or "advanced practice providers" (APPs). *Id.* §§ 59.14(b), 59.2. Even in the so-called "nondirective counseling" limited to physicians and APPs, those providers *must* discuss continuing the pregnancy, even with patients who have

settled on abortion and regardless of patients' desire not to receive the information. *Id.* § 59.14(b)(1); *see* 84 Fed. Reg. 7747 ("abortion must not be the only option presented"); *see id.* at 7761–62.

Second, as of March 4, 2020, the Rule will require providers to comply with costly, extreme, and unworkable physical separation requirements. Each Title X project, at every site where its activities take place, must physically separate from any non-Title X funded abortion care, abortion referral, expressive or associational activities that support access to safe and legal abortion, or any other activity that might assist any person in accessing abortion care. 42 C.F.R. § 59.15; *see id.* §§ 59.13, 59.14, 59.16. "Factors relevant to" adequate separation include:

- Separate treatment, consultation, examination and waiting rooms;
- Separate office entrances and exits;
- Separate phone numbers and email addresses;
- Separate websites;
- Separate educational services;
- Separate personnel;
- Separate workstations;
- Separate electronic health records (EHRs); and
- The presence or absence of materials "referencing" abortion.

Id. § 59.15(b)–(d). HHS describes all of the above as "physical" aspects of separation. 84 Fed. Reg. 7766–67. Despite the Rule's labeling them simply as

"factors," HHS clarified that employing separate Title X and non-Title X staff in the same facility is insufficient; that collocating Title X activities and abortion care or referral within a single space is impermissible; and that separate EHR systems are mandatory. 84 Fed. Reg. 7764–67, 7769, 7783–84. Substantiated estimates in the administrative record reflect that the costs of separation will be over 20 times HHS's unsupported figure of $30,000 per clinic. 84 Fed. Reg. 7782; *see, e.g.*, AR361429–32 (PPFA cmt.). Clinics that attempt to comply with the Rule will necessarily divert limited resources away from caring for patients to address the unfunded separation mandates and a new infrastructure funding prohibition, thus reducing access to care. *See infra* Section III.B.2.

Third, the Rule makes other changes that distort the provision of family planning services: (a) deemphasizing evidence-based medicine and deleting the requirement that Title X services be "medically approved" (*compare* 42 C.F.R. § 59.5(a)(1) *with* former 42 C.F.R. § 59.5(a)(1)); (b) requiring clinics to offer or be in close proximity to "comprehensive primary health services," which are not Title X services (42 C.F.R. § 59.5(a)(12)); (c) singling out adolescents—especially those with limited means—for even lower-quality care (*id.* §§ 59.2, 59.5(a)(14)); (d) limiting the uses of Title X funds in contravention of the statute (*id.* § 59.18(a)); and (e) adopting grant application criteria that undermine the statute's purpose and vest HHS with unreviewable, non-transparent discretion to arbitrarily deny applications prior to merits review (*id.* § 59.7(b)). *See generally* Wash. Compl. ¶¶ 109–134.

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C. Procedural History

Washington filed suit on March 5, 2019, and its case was consolidated for pretrial proceedings with NFPRHA's. ECF Nos. 1, 8. On April 25, prior to production of the administrative record, the Court held a lengthy hearing and issued a preliminary injunction, ruling that Plaintiffs were likely to succeed on the merits of their claims that the Rule violates the Nondirective Mandate, Section 1554 of the PPACA, Title X, and the APA. PI Order at 14. The Court found the Rule "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," and because HHS "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." *Id.* at 14–16. As the Court observed, "the Department has relied on the record made 30 years ago, but not the record made in 2018–19." *Id.* at 16.

On May 3, Defendants appealed the preliminary injunction and, separately, moved to stay the injunctions issued by this Court and district courts in Oregon and California. ECF Nos. 57, 58. On June 20, a Ninth Circuit motions panel granted Defendants' request to stay the preliminary injunctions. ECF No. 87. On July 3, the Ninth Circuit granted rehearing en banc, ruling that the motions panel's stay order "shall not be cited as precedent by or to any court of the Ninth Circuit." ECF No. 92. However, the Ninth Circuit allowed the stay to remain in effect, ECF No. 93—enabling HHS to make the Rule effective and begin

implementing it (as described in the following section). Merits briefing on the appeal of the preliminary injunction was completed on July 19, and the en banc panel held oral argument on September 23.

Meanwhile, on June 24—*after* the motions panel stayed the preliminary injunctions—Defendants produced the administrative record to Plaintiffs, *see* ECF No. 88, and on September 26, they certified its completeness. Declaration of Kristin Beneski ¶ 4 & Ex. 2 (AR Certification). The certified administrative record contains over 500,000 public comments, along with copies of approximately 108 legal, academic, and other materials that the agency apparently referenced. *See* 84 Fed. Reg. 7722; Beneski Decl. Ex. 2 (AR Index). Materials in the certified administrative record include the Office of Population Affairs' *Title X Family Planning Annual Reports* for 2016 and 2017; seven reports by the Guttmacher Institute, a leading reproductive healthcare research and policy organization; a copy of the entire PPACA, including Section 1554 (42 U.S.C. § 18114); and a number of other items that discuss Title X and/or family planning (although many do not). *See* Beneski Ex. 2 (AR Index). In addition, major medical associations submitted comments consistently opposing the rule, including the American Medical Association (AMA); the American College of Obstetricians and Gynecologists (ACOG); the American Academy of Pediatrics; the American College of Physicians; the American Psychological Association; the Association of American Medical Colleges; various medical organizations representing the nation's specialists in family medicine, obstetrics

and gynecology, reproductive health, adolescent health, and neonatal health; various nationwide organizations representing nurses, nurse-midwives, physicians' assistants, and social workers; public health research and policy organizations; and many others. *See generally* Beneski Decl. Ex. 1 (Administrative Record Excerpts, including over 50 examples of significant opposing comments).

D. Implementation of the New Rule

On July 20, HHS issued guidance to Title X grantees requiring them to submit, by August 19, 2019, an "action plan describing the steps that they will take to come into compliance with all aspects of the Final Rule," and by September 18, a "written statement" indicating "that the grant project is in compliance" with the Rule (except for the physical separation requirements that would go into effect in March 2020). *See* Beneski Decl. Ex. 3.

This action forced Washington on August 22 to terminate its participation in Title X, as it was unable to comply with the Rule's unlawful and harmful counseling distortions and other now-effective provisions. Declaration of Lacy Ferenbach, Ex. 1. (Washington also would be unable to satisfy the Rule's pending separation requirements.) As a direct consequence of the Rule, there are now no Title X providers left in Washington, according to the most recent available data

from the Office of Population Affairs.[4] The State thus is funding its family planning program with no federal support for the first time since Title X was established nearly 50 years ago, and future funding is uncertain.

III. ARGUMENT

A. Legal Standard

Under the APA, courts "shall . . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," basing their review on the administrative record. 5 U.S.C. § 706. "[I]n APA cases, the Court's role is to determine whether, as a matter of law, evidence in the administrative record supports the agency's decision." *King County. v. Azar*, 320 F. Supp. 3d 1167, 1171 (W.D. Wash. 2018) (citing *Occidental Eng'rg Co. v. INS*, 753 F.2d 766, 769 (9th Cir. 1985); *accord Naiker v. U.S. Citizenship & Immigration Servs.*, 352 F. Supp. 3d 1067, 1072 (W.D. Wash. 2018) ("[T]he district court's function is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did."). Because a district court does not resolve factual questions when reviewing administrative proceedings, summary judgment "is an appropriate mechanism for deciding the legal question" of

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[4] https://www.hhs.gov/opa/sites/default/files/Title-X-Family-Planning-Directory-October2019.pdf (no service sites in Washington (Region 10) as of October 2019).

whether the agency acted in accordance with law and with a reasoned basis grounded in the record. *Boyang, Ltd. v. INS*, 67 F.3d 305 (9th Cir. 1995)).

Defendants correctly recite legal standards applicable to a Rule 12(b)(6) motion, MTD at 12, which plainly have no merit here. The allegations in Washington's 86-page Complaint are hardly "threadbare" or "conclusory" and included "enough facts" to support a preliminary injunction—far more than is needed to "state a claim on which relief can be granted." Fed. R. Civ. P. 12(b)(6); *see* PI Order at 14–16. Accordingly, the Motion to Dismiss should be denied.

B. The New Rule Is Arbitrary and Capricious

Count IV of Washington's Complaint challenges the Rule as arbitrary and capricious. Because this claim is grounded in the administrative record—which was not produced and certified as complete until well after Defendants appealed the preliminary injunction—it has not been fully briefed or reviewed by any court. The Rule is arbitrary and capricious for all the reasons discussed in NFPRHA's brief, which sections Washington adopts and incorporates herein by reference in their entirety. The discussion below highlights aspects of the Rule that have particular salience for Washington and its residents.

1. HHS' failure to consider grantee reliance on the prior regulations demonstrates that the rulemaking was arbitrary and capricious

It is "a central principle of administrative law . . . that, when an agency decides to depart from decades-long practices," it "must at a minimum acknowledge the change and offer a reasoned explanation for it." *State of New*

York v. U.S. Dep't of Health & Human Servs., --- F. Supp. 3d ----, 2019 WL 5781789, at *52 (S.D.N.Y. Nov. 6, 2019) (quoting *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017)). In such circumstances, an agency must "be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account," and provide a "reasoned explanation" for upending "decades of industry reliance on the Department's prior policy." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)) ("when [an agency's] prior policy has engendered serious reliance interests that must be taken into account" . . . "[i]t would be arbitrary or capricious to ignore such matters"). Washington's inability to comply with the new Rule absent massive economic cost or state government reorganization highlights HHS's arbitrary and capricious failure to fully consider and address the reliance interests of Title X grantees.

For nearly 50 consecutive years, DOH was Washington's sole Title X grantee, administering a network of providers who offered family planning services to low-income individuals throughout the state. Over these decades, Washington was able to administer its program in compliance with all federal requirements without having to curtail other state government functions or acquire physically separate facilities for Title X-related activities. In adopting the new Rule, HHS completely ignored Washington's reliance interests and the sudden burdens the Rule imposes on all Title X grantees and subrecipients.

For example, the Rule's "physical separation" requirements are uniquely burdensome on states like Washington because they apply not only to direct abortion care, but to all (non-Title X) activities that might "increase the availability or accessibility of abortion for family planning purposes." 42 C.F.R. §§ 59.15, 59.16; *see, e.g.*, AR256448–49 (AccessMatters cmt.) (discussing impact on "health departments, and other large comprehensive health systems," of having to physically separate a "long and nebulous list" of abortion-related activities "undertaken **outside Title X projects and with non-Title X funds**"). Washington has robust policy and legal protections for individual health care decisions,[5] and some of DOH's activities relate to abortion access, care, or policy—such as seeking appropriations for and administering state-funded health care programs independent of Title X that include abortion; supporting, providing

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[5] Patients of any age have the right to choose or refuse birth control services, prenatal care, and abortion-related services under Washington law. RCW 9.02.100(1)–(2); RCW 9.02.110; *State v. Koome*, 530 P.2d 260 (Wash. 1975). It is the public policy of the state of Washington that every woman has the fundamental right to choose or refuse abortion, and the State cannot discriminate against the exercise of these rights. RCW 9.02.100. If a State program provides maternity care benefits to women, it must also provide "substantially equivalent benefits, services, or information to permit them to voluntarily terminate their pregnancies." RCW 9.02.160.

information, and testifying before the legislature on matters such as the Reproductive Parity Act; supporting reproductive health education and outreach; developing public-facing content and materials that may include information about abortion; paying dues to organizations that provide public health support, such as NFPRHA; and other activities consistent with Washington's public policy and commitment to protecting the health and welfare of its residents. Harris Decl. ¶ 82.

DOH administers its health-related programs and performs myriad other state governmental functions from its headquarters in a single government building in Olympia. Under the new Rule, Washington would have to *physically* separate the administration of its Title X program from all of its other work on unrelated health-related programs or government functions that touch on abortion. *See* 42 C.F.R. §§ 59.15, 59.16. As a practical matter, this would require physical and programmatic reorganization of one of the largest agencies of state government, siloing one component of Washington's public health work (Title X) from all other parts of the agency. This is impossibly burdensome, disruptive, and costly. *See* Harris Decl. ¶¶ 72–79, 82.

Further, like most states with cabinet-level agency personnel, Washington would be unable to comply with the Rule's "separate personnel" requirement, 42 C.F.R. § 59.15(c), because the Secretary of Health and other high-level DOH personnel necessarily oversee multiple programs. Harris Decl. ¶ 82. The requirements for separate "phone numbers, email addresses, educational services,

and websites," 42 C.F.R. § 59.15(b), are also not feasible for any state government. These requirements are completely attenuated from any reasonable HHS goal: notwithstanding the obvious burdens imposed on state health departments (and other grantees), HHS was unable to articulate any rationale for requiring physical separation of family planning program administration from other state government activities having nothing to do with Title X, or for requiring employment of completely separate state personnel for the sole purpose of Title X participation.

Independent of the counseling distortions (which have already forced Washington out of the program), the separation requirements are so onerous that they unreasonably disqualify Washington from Title X despite 50 years of successful participation and compliance, simply because Washington is separately engaged in non-Title X activities inconsistent with HHS's current ideological direction. *See City of L.A. v. Barr*, 929 F.3d 1163, 1192 (9th Cir. 2019) (agency should make grant allocations "based on factors solely related to the goal of implementing the stated statutory purposes in a reasonable fashion, rather than taking irrelevant . . . factors into account"); *cf. Rust*, 500 U.S. at 197 ("effectively prohibiting the [grant] recipient from engaging in . . . protected conduct outside the scope of the federally funded program" may violate the Constitution).

HHS wholly failed to consider the serious reliance interests of large health departments, such as Washington's DOH, in being able to administer Title X in

compliance with federal requirements without having to acquire separate facilities and new senior personnel, as well as duplicative administrative systems. The Rule's new physical separation requirements are arbitrary and capricious for this reason, in addition to all the reasons NFPRHA discusses.

2. HHS failed to consider the Rule's devastating public health impacts

HHS's assertion that the providers forced out of the Title X program by the Rule will be replaced by others, with no impact on patients, is pure sophistry and warrants no deference for the reasons NFPRHA discusses at length. Removing qualified providers from the Title X network, by definition, "will undermine the quality and standard of care upon which millions of women depend," AR269333 (AMA cmt.) and "puts at risk access to quality family planning services," AR268846–48 (ACOG cmt.). Numerous comments in the record document that patients will bear the "brunt of the impact" of the Rule's requirements, "with nowhere to turn for high-quality, unbiased, comprehensive family planning information and care." AR256454 (AccessMatters cmt.); *see also* AR54193–95 (Ctr. for Biological Diversity (CBD) cmt.); AR102349 (Nat'l Council of Jewish Women (NCJW) cmt.); AR106457 (Nat'l Inst. for Reprod. Health (NIRH) cmt.); AR106800–01 (Miliken Inst. cmt.); AR107973 (Am. Academy of Nursing (AAN) cmt.); AR2239147–50 (Jacobs Inst. cmt.); AR239897 (Am. Pub. Health Ass'n (APHA) cmt.); AR245693 (Cal. AG, et al. cmt.); AR264423–24, 433–34 (Guttmacher Inst. cmt.); AR278573 (Wash. cmt.);

AR280767–68 (Nat'l Women's Law Ctr. (NWLC) cmt.); AR294047 (Nat'l Ass'n of County & City Health Officials (NACCHO) cmt.); AR308042–45 (NFPRHA cmt.) (rule will "radically change the makeup of the Title X network, leaving patients without access to critical care in many instances and requiring subpar, ineffective care in others"); AR316419 (PPFA cmt.) (describing the "negative effects on the quality of patient care at Title X-funded sites that attempt to adhere" to the rule); AR317926 (Physicians for Reprod. Health (PRH) cmt.); AR385033–34 (Fam. Planning Councils of Am. (FPCA) cmt.).

In contrast with these detailed and substantiated comments in the administrative record, HHS offers the bald assertion that it "does not believe" the Rule will impact patients' access to care. 84 Fed. Reg. 7725; *see also id.* at 7769, 7781. This is a "generalized conclusion" that does not satisfy the agency's obligation to consider "important aspect[s] of the problem." *AEP Texas N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010); *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

The separation requirements will disrupt care coordination and continuity. Pregnancy testing, information, discussion, and referral are part of a single integrated, patient-centered process not amenable to physical separation. *See* 2000 Regulations, 65 Fed. Reg. 41,275 (highlighting comment that "'women's reproductive health needs are not artificially separated between services'"). Pregnancy testing is "part of core family planning services" and is "a common reason for a client to visit a provider of family planning services," according to

HHS's current Program Requirements. QFP at 13. "The test results should be presented to the client, followed by a discussion of options and appropriate referrals." *Id.* at 14. Pregnant patients should be referred to "appropriate providers of follow-up care" upon request; if "pregnancy abnormalities or problems are suspected," the provider should either "manage the condition or refer the client for immediate diagnosis and management." *Id.* If a pregnancy test is negative and the patient does not wish to become pregnant, she "should be offered contraceptive services"—namely, presenting the "full range of FDA-approved contraceptive methods," with the information "tailored and presented to ensure a client-centered approach." *Id.* at 7, 8, 14. If the patient does wish to become pregnant, she should be offered appropriate services in line with her intentions. *Id.* at 14.

Artificially separating aspects of this process jeopardizes patients' health and safety and imposes needless costs on patients whose financial resources are already limited. *See* AR316425 (PPFA cmt.) (physical separation "works against [Congress's] goal of providing coordinated family-planning services and counseling"); *id.*, AR316432–33, 482 (requiring "two separate visits to two separate facilities" entails "unnecessary costs to patients . . . and interferes with the integration of care"); AR106464 (NIRH cmt.) (separation requirements "go against the growing movement toward coordinating health care to ensure positive patient experience and outcomes"). Physically separating abortion care in particular also makes it virtually impossible to provide same-day post-abortion

contraception funded by Title X, needlessly increasing the risk of unintended pregnancy among abortion patients. AR316432–33 (PPFA cmt.).

For the reasons NFPRHA addresses, the Rule forces qualified providers out of the Title X program, reduces access to care, and lowers the quality of Title X care. The inevitable result will be more unintended pregnancies, as well as higher rates of mortality, disease, poverty, and other health and economic problems—especially among our society's most marginalized and vulnerable populations. *See* AR239895 (APHA cmt.) ("Limiting support for comprehensive reproductive health services takes us back to failed policies that harm women's health," including "an increase in maternal deaths and encouraging unsafe abortions"); AR 107972 (AAN cmt.) (citing evidence that removing specialized reproductive health care providers from family planning networks "is linked with increased pregnancy rates that differ substantially from rates of unaffected populations"); AR264433 (Guttmacher Inst. cmt.) (rule will cause significant numbers of patients to "los[e] access to the comprehensive, high-quality services they need to avoid unintended pregnancies, STIs, cervical cancer, and other negative and potentially costly health outcomes"); AR308573 (Inst. for Policy Integrity cmt.) (citing research showing that "when Title X recipient programs close, almost half the patients dependent on those services lose their only access to health care"); AR264536, 538 (Ass'n of Am. Med. Colleges (AAMC) cmt.) (rule will "reverse" Title X's contribution to the "dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low" and "harm

lower income Americans and patients in rural areas"); AR278750 (Ass'n of Women's Health, Obstetric & Neonatal Nurses (AWHONN) cmt.), AR308089 (Int'l Women's Health Coalition (IWHC) cmt.), AR285353 (Johns Hopkins Med. Depts. cmt.), AR107240 (Nat'l Ass'n of Social Workers (NASW) cmt.), AR102351 (NCJW cmt.), AR317926–27 (PRH cmt.) (similar); AR245691, 702-03 (Cal. cmt.) ("less access to critical preventive care" leads to "increased unintended pregnancies" and "increased maternal mortality outcomes," which are already higher in the U.S. than any developed nation); AR268847–48 (ACOG cmt.); AR294047–48 (NACCHO cmt.); AR280773 (NWLC cmt.); AR316418, 454 (PPFA cmt.); AR278576–77 (Wash. cmt.) (patients will lose access to contraception and other critical health services like STI and HIV testing and cancer screening, which can be lifesaving).

Many comments in the administrative record point to recent real-world examples in which policies like the new Rule led to adverse health outcomes. *See* AR102349–50 (NCJW cmt.), AR107239 (NASW cmt.), AR239148 (Jacobs Inst. cmt.), AR269333 (AMA cmt.), AR281210 (Am. Coll. of Physicians cmt.), AR295491 (Ass'n of Maternal & Child Health Progs. cmt.), AR307784 (Am. Ass'n of Univ. Women (AAUW) cmt.), AR308086–87 (IWHC cmt.), AR316419 (PPFA cmt.), AR317925 (PRH cmt.) (each citing a study published in the New England Journal of Medicine showing that 2013 Texas regulations excluding Planned Parenthood from its state-funded network caused a 35% decline in the use of the most effective methods of contraception, and a corresponding increase

in unintended pregnancy which led to a 27% increase in childbirth covered by Medicaid); AR106796–97, 801 (Miliken Inst. cmt.) (citing additional studies on the Texas rule); AR277794–95 (Am. Acad. of Pediatrics (AAP) and Soc'y for Adolescent Health & Medicine (SAHM) cmt.) ("When qualified providers are excluded from publicly funded programs serving low-income patients, other providers are unable to fill the gap" and patients lose access to care (citing examples in Texas and Indiana)); AR264538 (AAMC cmt.) (citing research showing that community health center participants in Title X lack capacity to accept new patients when other providers leave the network); AR308088 (IWHC cmt.) (discussing clinic closure caused by global gag rule, which deprived patients of "access to essential services well beyond abortion care, including cervical cancer screenings, STI testing, HIV testing and treatment, and pre-natal and postpartum care"); *id.*, AR308091–92 (citing "clear and compelling evidence from years of research" that "gag rule" policies like this Rule "have not led to a decrease in abortions globally; in fact, the policy has been associated with increased abortion rates" due to increases in unintended pregnancy).

Commenters also pointed out the well-documented "health and social consequences" arising from policies that demonstrably increase unintended pregnancy rates, including "infant mortality, maternal mortality, lifelong childhood disability, and family impoverishment and its related effects." AR106801 (Miliken Inst. cmt.); *see also* AR246647 (Dr. Steinauer cmt.) (citing research showing that carrying a pregnancy to term "is more dangerous to a

woman's health than abortion, especially for patients with conditions that increase the health risks of pregnancy"); AR239150–51 (Jacobs Inst. cmt.) (increase in unintended pregnancy will result in more abortions, adverse infant health outcomes, intimate partner violence, and generational poverty); AR269333 (AMA cmt.) (rule will "reverse decades of progress in reducing unintended and teen pregnancy"); AR54197 (CBD cmt.) (less access to long-acting contraceptives results in more unplanned teen pregnancies, which are associated with "a higher school dropout rate, less and later prenatal care, less economic advancement in life and engagement in more risk behaviors," while children of teen mothers have "higher rates of premature birth, infant mortality, low birth weight on delivery and delayed or problems with normal childhood development").

Because of the nature of Title X, these documented harms will disproportionately impact already-vulnerable and underserved populations—the very people whom Title X was designed to serve. *See* AR281210–11 (Am. Coll. of Physicians cmt.), AR277795 (AAP & SAHM cmt.) (rule would "exacerbate racial and socioeconomic disparities in access to care by leaving Title X patients, who are disproportionately black and Latinx, without alternate sources of care"); AR308089 (IWHC cmt.) (rule will "deny people who already face health disparities access to care," including people of color and people with language barriers); AR248191 (Black Women for Wellness cmt.) ("Women of color will be disproportionately impacted" by the rule and "stand to lose the most."");

AR305328–29 (Nat'l Council of Asian Pacific Americans cmt.) (rule will disproportionately impact Asian American Pacific Islander women, who experience higher cervical cancer rates and are more at risk for unintended pregnancy than other racial groups); AR308420–21 (Nat'l Health Care for the Homeless Council) (reduced access "worsens homelessness and poverty"); AR280243–44 (Am. Psychol. Ass'n cmt.) (rule "endangers a patient population that has an unmet need for services and high risk for mental health problems"); *see also* AR102351–52 (NCJW cmt.); AR107240–41 (NASW cmt.); AR263514–15 (Sexuality Info. & Health Educ. Council of U.S. cmt.); AR305735–36 (ACLU cmt.); AR307453–54 (Nat'l Latina Inst. for Reprod. Health cmt.); AR316432–33, 454 (PPFA cmt.); AR317927 (PRH cmt.); AR372640 (Nat'l Women's Health Network (NWHN) cmt.).

These public health consequences are devastating to individual patients and carry exorbitant public economic costs. *See* AR106801 (Miliken Inst. cmt.) (Medicaid covers almost half of U.S. births; a "spike in unintended pregnancy and childbearing" caused by the rule will raise Medicaid spending nationwide); AR316419 (PPFA cmt.) (childbirth covered by Medicaid increased by 27% after enactment of similar regulations in Texas); AR256454 (AccessMatters cmt.) (predicting taxpayer cost of $80 million per year based on conservative estimate of only 10,000 more Medicaid-funded births resulting from loss of access to Title X services); AR102349 (NCJW cmt.) (in 2010, Title X-funded health centers saved state and federal governments $7 billion); AAFP cmt. at 2

("Universal coverage of contraceptives is cost effective and reduces unintended pregnancy and abortion rates."); AR294046 (NACCHO cmt.) ("Ultimately, increased taxpayer contributions will be required" to address the "long-term cyclical impacts of this rule."). These costs, "in terms of both public health outcomes and taxpayer dollars," are "exactly the costs that Congress sought to avoid when creating the Title X program in the first instance[.]" AR308044–45 (NFPRHA cmt.).

HHS ignored the Rule's public health costs entirely, basing its estimate solely on the (lowballed) initial economic cost to some clinics of complying with the physical separation requirements. *See* 84 Fed. Reg. 7718, 7782 (estimating $36.08 million total cost of separation requirements, based exclusively on estimate of $30,000 per site for just 15% of sites). Simply ignoring those costs that the agency finds inconvenient is arbitrary and capricious. *See Michigan v. EPA*, 135 S. Ct. 2699, 2706 (2015) ("Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions."); *see also Am. Wild Horse Pres. Campaign*, 873 F.3d at 932 (agency may not "brush[] aside critical facts" when making regulatory decisions).

3. HHS ignored patients' reliance interests in access to high-quality care and effective contraception

As discussed in NFPRHA's brief, the Rule's counseling distortions and endorsement of offering limited or non-medically-approved contraceptive

options, including to address providers' (rather than patients') preferences, radically alters the nature of Title X care. In making these changes, HHS failed to consider patients' legitimate expectations that medical care providers—regardless of their funding source—will offer complete, medically accurate, ethical, options-based care that puts the patient first. Converting Title X to a program that steers pregnant patients toward childbirth and offers the least effective forms of contraception to patients who wish to avoid pregnancy, in service of providers' conscience concerns, directly undermines trust in the health care system, discourages patients from seeking services, and negatively impacts their health.

In addition to the counseling distortions discussed by NFPRHA and in Section III.D.2 below, the Rule distorts Title X care by prioritizing providers who emphasize fertility awareness-based methods (FABMs) and who object to the more effective methods that most Americans rely on. It does so by removing the requirement that family planning methods be "medically approved," by prohibiting clinics from using Title X funds to purchase contraceptives in bulk (with no similar limitations on funding the provision of fertility-awareness information), and by giving funding priority to "diverse" providers (who in reality offer a more limited range of family planning services). Indeed, many commenters pointed out that the Rule opens the door to providers who will not offer patients the "full range" of contraceptive choices the QFP deems necessary to ensure "effectiveness" consistent with Title X and principles of high-quality,

evidence-based, patient-centered care. QFP at 1, 2, 7, 24; *see* AR294043–44 (NACCHO cmt.) (rule permits clinics to provide "calendar-based methods relying on abstinence during fertile windows" that "have not been regulated, approved, or certified by any particular agency or accreditation body"); AR54196 (CBD cmt.); AR102351 (NCJW cmt.); AR106459–60 (NIRH cmt.); AR107240 (NASW cmt.); AR245691, 704–05 (Cal. cmt.); AR256446–47 (AccessMatters cmt.); AR264416–18 (Guttmacher Inst. cmt.); AR264537 (AAMC cmt.); AR268686 (Missouri FHC cmt.); AR268843–44 (ACOG cmt.); AR269332–33 (AMA cmt.); AR277793–94 (AAP & SAHM cmt.); AR278564 (Wash. cmt.); AR278750 (AWHONN cmt.); AR280771–72 (NWLC cmt.); AR281205–06 (Am. Coll. of Physicians cmt.); AR305734–35 (ACLU cmt.); AR307785 (AAUW cmt.); AR308013–14 (NFPRHA cmt.); AR315936–37 (Am. Coll. of Nurse-Midwives (ACNM) cmt.); AR316466–67 (PPFA cmt.); AR372637–38 (NWHN cmt.); AR385033 (FPCA cmt.).

Indisputably, FABMs are among the "least effective" contraceptive methods. QFP at 10; *see also* AR406218 (Family Planning Annual Report, 2017). FABMs have "incredibly high failure rates," AR315937 (ACNM cmt.): approximately 24% of women who rely on a FABM experience an unintended pregnancy within the first year. QFP at 10; *see also* AR269332 (AMA cmt.); AR268845 (ACOG cmt.); WA 14 n.53. It is no surprise, then, that "less than 0.5% of female Title X contraceptive users rely on some type of FABM, including natural family planning, as their primary method." AR264418

(Guttmacher Inst. cmt.).[6] Moreover, FABMs are not an appropriate option for many patients, including women whose menstrual cycles are less than 26 or more than 32 days, and women living with intimate partner violence who require a contraceptive method that cannot be detected or interfered with. AR280771–72 (NWLC cmt.).

Filling the Title X network with providers who offer curtailed services and emphasize FABMs rather than more effective forms of birth control deprives poorer women of meaningful choices and the control over their own lives that Title X promised. *See, e.g.*, AR248198 (Black Women for Wellness cmt.) ("Our communities do not need watered down sex education and sparse medical

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[6] HHS claims the percentage of women using FABMs "doubled" from 2008 to 2014, citing a nationwide Guttmacher study. 84 Fed. Reg. 7731 n.49. True, but according to the cited study, the increase was from 1% to 2% of all users, whereas the use of long-acting reversible methods (IUDs and implants) increased from 6% to 14% in the same period—likely contributing to the lower unintended pregnancy rate. AR406163–64; *see Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 69 (D.D.C. 2016) (agency may not "cherry-pick[]" evidence and "ignore[] critical context"). The Guttmacher Institute commented that HHS's use of its work to justify the Rule was "disingenuous," "inaccurate," and "misleading." AR264425 (Guttmacher Inst. cmt.).

information; we demand HHS uphold the integrity of the Title X program and provide comprehensive, medically-accurate, evidence-based, culturally- and linguistically-appropriate care to communities of color living with low-incomes."); AR102346 (NCJW cmt.) (National Council of Jewish Women opposes the rule because "our reproductive freedoms are integrally bound to our religious liberty"); *see also* AR268845 (ACOG cmt.) ("Encouraging more single-method or limited method service providers within a Title X project will threaten access to comprehensive information about the full range of contraception methods," leaving "large populations without access to the most effective methods of family planning"). Even HHS's own sources are in accord. *See* AR407162–64 (ACOG's Women's Preventive Services Initiative "recommends that adolescent and adult women have access to the *full range* of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes") (emphasis added) and AR406635 (same) (both cited in the Rule's preamble, 84 Fed. Reg. 7741 n.70).

FABMs are already available to Title X patients who choose them. 42 U.S.C. § 300(a) (family planning services include "natural family planning"). As these least effective methods become the *only* ones available to many Title X patients, however, those who have long relied on Title X for the most effective methods of preventing unintended pregnancies will be significantly harmed. *See, e.g.*, QFP at 10 (noting first-year failure rate of 24% for FABMs versus 9% for the pill, 0.2% for hormonal IUDs, and 0.05% for contraceptive implants). HHS

arbitrarily "gave no consideration to the disruption" the Rule will cause to patients' lives. *Regents of Univ. of Cal. v. U.S. Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1045 (N.D. Cal.), *aff'd*, 908 F.3d 476 (9th Cir. 2018), *cert. granted sub nom. Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 139 S. Ct. 2779 (2019). HHS's complete failure to meaningfully grapple with these patient harms is arbitrary and capricious.

4. HHS's enforcement rationale for the separation requirements is pure speculation

As NFPRHA points out, the Rule is a solution in search of a problem. Disregarding the demonstrable harm that will result, HHS imposed the onerous separation requirements to address nonexistent compliance problems with Title X's financial separation requirement. *See* 84 Fed. Reg. 7765 (asserting that the physical separation requirement "assists with statutory compliance" by "ensuring" there is no "commingling"). This enforcement rationale is based on pure speculation. *See Choice Care Health Plan, Inc. v. Azar*, 315 F. Supp. 3d 440, 443 (D.D.C. 2018) ("the facts on which the agency purports to have relied must have some basis in the record"); *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (agency action based on "speculative evidence" was arbitrary and capricious).

The record is devoid of evidence that *any* grantee used Title X funds contrary to Section 1008 while the 2000 Regulations were in effect. In fact, HHS failed to consider its own "regular, extensive, and comprehensive audits" of

Title X funding recipients under the 2000 Regulations, 84 Fed. Reg. 7763, which are absent from the record. *See Thompson v. U.S. Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989) (administrative record must include "all documents and materials directly or *indirectly* considered by the agency decision-makers"). Many commenters pointed out that HHS used these audits effectively to monitor financial separation under the 2000 Regulations (which themselves note that "Title X grantees are subject to rigorous financial audits," 65 Fed. Reg. 41,275). *See* AR245706–07 (Cal. cmt.); AR256446 (AccessMatters cmt.); AR278566 (Wash. cmt.); AR293834 (Drexel Coll. of Med. Women's Care Ctr. cmt.); AR308024-25 (NFPRHA cmt.); *see also* Harris Decl. ¶¶ 41–49 (describing DOH monitoring of subrecipients), Ex. 1 (grant award subject to auditing requirements). HHS even admits in the Rule's preamble that "demonstrated abuses of Medicaid funds"—its lone example of federal funding abuse—"do not necessarily mean that Title X grants are being abused[.]" 84 Fed. Reg. 7725. HHS's purported concerns about "risks" ring hollow; the absence of any supporting evidence in the record is dispositive.

* * *

For these and all of the other reasons set forth in NFPRHA's brief, the Rule is arbitrary and capricious and should be set aside.

C. The New Rule Is Procedurally Flawed Under the APA

In addition to being arbitrary and capricious under Section 706, the Rule is also procedurally flawed under Section 553 of the APA, which requires a

notice-and-comment process for any substantive rulemaking. 5 U.S.C. § 553. While a proposed rule need not be "identical" to the final version, "a final rule which departs from the proposed rule must be a logical outgrowth of the proposed rule." *Nat'l Res. Def. Council v. U.S. EPA*, 279 F.3d 1180, 1186 (9th Cir. 2002) (citation omitted). Relatedly, the public is entitled to notice of any issues that are "on the table" as part of the contemplated rulemaking. *Id.* at 1180 (citing *Am. Med. Ass'n v. United States*, 887 F.2d 760, 768 (7th Cir. 1989)). "The object, in short, is one of fair notice." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174–76 (2007); *accord Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019) (Gorsuch, J.) ("Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes . . . ."). Here, several provisions of the Rule are not a logical outgrowth of the rulemaking process, and HHS's failure to provide the public with sufficient notice of these provisions provides independent grounds to set them aside.

First, HHS deprived the public of an opportunity to evaluate and comment on its baseless pronouncement that referrals for prenatal care are "medically necessary" for *all* pregnant patients, even when the pregnancy will be terminated. 84 Fed. Reg. 7728, 7730, 7747 & n.75, 7748, 7759, 7761, 7762; MTD at 20. HHS omitted this erroneous claim from the proposed rule, belatedly adding it to the final version after the comment period closed. *See generally* Proposed Rule, 83 Fed. Reg. 25,502; Wash. Compl. ¶ 73. If medical organizations and professionals had received notice that HHS intended to deem prenatal care

"medically necessary" for all pregnant patients receiving Title X services, they would have opposed it precisely because that claim is demonstrably false. *See* ECF No. 34-1 (ACOG *Amicus* Br.) at 13–15 ("Prenatal care is not medically indicated for patients who wish to terminate their pregnancies."); ECF No. 13 (Kimelman Decl.) ¶ 10 ("Prenatal care is not a medically indicated or appropriate course of care for a patient who intends to terminate her pregnancy."); ECF No. 16 (Zerzan-Thul Decl.) ¶ 11 ("[I]f a patient . . . elects to terminate the pregnancy, pre-natal care would not be medically necessary."); *cf.* MTD at 20 (erroneously conflating "prenatal care" with "primary health care").[7] Obligating Title X providers to refer pregnant patients for prenatal care on the false grounds of medical necessity "requires [the provider] to represent as his own an[] opinion that he does not in fact hold"—an outcome *Rust* directly cautioned against. 500 U.S. at 200; *contra* MTD at 16 (asserting, without support or explanation, that the Rule does not require providers to misrepresent their medical opinions).

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[7] In the Rule's preamble, HHS sought to back up its false assertion by noting that prenatal care is deemed a "medically necessary" service for purposes of Medicaid reimbursement. 84 Fed. Reg. 7762. But this has no bearing on whether such care is indicated or appropriate for every patient. *See* Zerzan-Thul Decl. ¶ 11 (Medicare reimbursement eligibility "is not a standard a provider uses to determine whether a patient must as a medical matter receive a particular service").

Second, HHS failed to provide notice that Section 59.14(b)'s obscured list of referral sources (in which abortion providers cannot be identified) must include *only* "comprehensive primary health care providers." 42 C.F.R. § 59.14(b). If commenters had had notice of this provision, they could have pointed out that limiting referrals to such providers diminishes the ability to include any abortion providers on the list. *See* NFPRHA Compl. ¶ 111. Indeed, Washington could have advised HHS that there are *no known providers in the state* who would qualify. *See* Harris Decl. ¶ 54. "[O]ne of the salient questions" in determining whether a provision is a logical outgrowth is "whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments." *Nat'l Res. Def. Council*, 279 F.3d at 1186. That is undoubtedly the case here.

Third, Defendants appear to concede that HHS failed to provide notice and an opportunity to comment on the change to Section 59.5(b)(1) limiting out-of-program referrals to "medically necessary" as opposed to "medically indicated" care; they argue only that the change was immaterial. MTD at 41. Even if one were to accept Defendants' definition of "indicated" as the correct one,[8] it does not support their position: treatment that a provider may "suggest"

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[8] Defendants rely on a generic dictionary definition of "indicate," but ignore their own source's "medical definition" of the same term: i.e., "to call for especially as treatment for a particular condition." *See Merriam-Webster*, https://

is "advisable," *id.*, is plainly broader than treatment that is "necessary." The Rule makes a material change by removing the referral requirement for any type of medically indicated care—and it needlessly endangers patients by outright prohibiting referrals for medically indicated abortion short of an "emergency medical situation" (the only example HHS identified as permissible under the Rule). 84 Fed. Reg. 7762; *see* NFPRHA Compl. ¶ 110; Wash. Compl. ¶ 78. Again, if medical professionals had received notice of this change, they would have had an opportunity to explain that clinical standards require referrals for medically indicated care—including medically indicated abortion—regardless of whether there is an acute "emergency." *See* QFP at 14 (if "pregnancy abnormalities or problems are suspected," a family planning provider should provide treatment or appropriate referral); AR406518 (Title X Program Requirements) ("All projects must provide . . . referrals to other medical facilities when medically indicated," which "includes, but is not limited to emergencies").

Fourth, the requirement that only physicians and "APPs" may deliver non-directive pregnancy counseling fails the logical outgrowth test as well. *See* NFPRHA Compl. ¶ 107. In its Motion, HHS completely ignores that the term "advanced practice provider" appears nowhere in the proposed rule, while it is elaborately defined in the final version. *See* MTD at 40-41. HHS's failure to

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www.merriam-webster.com/dictionary/indicate (scroll to "More Definitions for *indicate*": "Medical Definition of *indicate*").

provide notice on this issue prevented the public from commenting on the Rule's definition of APP, and from explaining how that definition excludes many qualified professionals who have long provided pregnancy counseling at Title X centers, including registered nurses, clinical social workers, and health educators.

In sum, because HHS failed to comply with the APA's notice and comment requirements in significant respects, the Rule is unlawful for this reason as well.

D. The New Rule Violates Three Controlling Statutes

Agency action in violation of a statute is unlawful and must be set aside. 5 U.S.C. § 706(2). Here, the Court correctly found Plaintiffs were likely to succeed on the merits of their claims that the Rule violates the Nondirective Mandate, Section 1554 of the PPACA, and Title X itself. PI Order at 15. It should confirm that again here, with the benefit of the administrative record.

1. *Rust v. Sullivan* is inapposite

Defendants rely almost entirely on *Rust v. Sullivan* to excuse their unlawful rulemaking. But *Rust* was decided before Congress enacted the Nondirective Mandate and the PPACA; addressed an earlier, more limited rulemaking based on a different record; and held that said rulemaking did not violate certain constitutional rights—not that it was consistent with the later-enacted limitations on HHS's authority. *See* PI Order at 10 n.4. *Rust* did not somehow foreclose judicial review of any future rulemaking, and it cannot speak to whether the Rule at issue violates later-enacted statutes.

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HHS nevertheless argues that it can ignore the Nondirective Mandate because the *Rust* Court approved of similar regulations in 1991 and the Nondirective Mandate cannot nullify *Rust*. HHS further claims that Title X contains a "statutory delegation of authority" to promulgate the regulations at issue. MTD at 19, 27. But as HHS elsewhere acknowledges, the *Rust* Court simply held that the 1988 regulations adopted what was then a "permissible construction" of Section 1008. Indeed, the Court held that Section 1008 was ambiguous and "does not speak directly to the issues of counseling, referral, advocacy, or program integrity." 500 U.S. at 184. Thus, the Court was "unable to say" that the 1988 rule was "impermissible." 500 U.S. at 184.

At that time, the Court accepted HHS's position that "Title X is limited to preconceptional services" and must only be used for "*preventive* family planning services." *Id.* at 179; MTD at 13, 14, 17. The Court reasoned that, because pregnancy counseling is a "post conception" service, "a doctor's silence with regard to abortion" pursuant to the gag rule is not misleading in the context of a "preconceptional" program. *Rust*, 500 U.S. at 179, 200; MTD at 16. Later, in 1996, Congress foreclosed that rationale when it clarified that "pregnancy counseling" *can and does* occur within Title X programs, and mandated that "all" Title X pregnancy counseling "shall be nondirective." Pub. L. No. 115-245. HHS concedes that it "must enforce" and "projects must comply" with the Nondirective Mandate. 84 Fed. Reg. 7747. Defendants' *post hoc* litigation strategy of questioning the Nondirective Mandate's legal effect (MTD at 18, 19)

is meritless: this enactment is plainly part of the Title X *corpus juris*, is not defeated by a presumption against "implied repeals," and is binding on the agency. *Infra* Section III.D.2.

Moreover, *Rust* did not address Section 1554 of the PPACA, which was enacted in 2010. Under this statute, Congress removed any authority to enact regulations that interfere with patient–provider communications or restrict patients' access to information and care. That an ambiguity in Title X formerly permitted such regulations does not somehow exempt HHS from Section 1554's clear commands. *See* 5 U.S.C. § 706(2)(C) (agency action in excess of statutory authority must be set aside); *see Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014) ("an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate"). Section 1554 renders the counseling distortions, the separation requirements, and other aspects of the Rule impermissible and *ultra vires*, independently of *Rust*. *Infra* Section III.D.3.

Defendants' discussion of *Rust*'s constitutional holdings is a red herring. MTD at 15–17. The agency's policy preferences—constitutional or not—cannot conflict with congressional directives. *See City of Arlington, Tex. v. FCC*, 569 U.S. 290, 296–97 (2013) (agency discretion is cabined by scope of authority as delegated by Congress). Whether a government action is unconstitutional and whether an agency regulation is *ultra vires* are distinct questions. Here, the Rule's violations of the Nondirective Mandate, Section 1554, Title X, and the APA are dispositive. Agencies cannot override policies enacted by Congress, which "is

both qualified and constitutionally entitled to weigh the costs and benefits of different approaches and make the necessary policy judgment." *Azar*, 139 S. Ct. at 1816. "If the [agency] doesn't like Congress's . . . policy choices, it must take its complaints there." *Id.* at 1815; *accord SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) ("It is Congress's job to enact policy and it is this Court's job to follow the policy Congress has prescribed."); *cf. also In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013) (executive branch lacks authority to refuse to spend Congressional appropriations). Here, Congress decided that all Title X pregnancy counseling "shall be nondirective"; that HHS "shall not promulgate" regulations interfering with patients' access to information and care; that Title X services "shall be voluntary"; and that agencies must adhere to the APA's requirements. In the face of these statutory commands, the *Secretary's* policy preference of directing patients toward "conception and childbirth" rather than taking a neutral stance (MTD at 16) is irrelevant and not entitled to any deference.

2. The New Rule violates the Nondirective Mandate

a. The presumption against implied repeals is not implicated

Defendants' attempt to cast doubt on the Nondirective Mandate's applicability is a nonstarter. MTD at 19, 23, 25–28. HHS itself recognized that the Nondirective Mandate clarified the law with respect to Title X care and is binding. 84 Fed. Reg. 7747 (acknowledging that "projects must comply with Congress's requirement that pregnancy counseling be nondirective, and the Department must enforce that requirement"). Defendants' *post hoc* argument to

the contrary is not entitled to any weight. *Price v. Stevedoring Serv. of Am., Inc.*, 697 F.3d 820, 830 (9th Cir. 2012) ("'deference to . . . an agency's convenient litigating position would be entirely inappropriate'") (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988)).

The argument fails on its merits, too. Because there is no statutory "authorization" for the challenged regulations, Defendants' implied repeal (or "implied amendment") arguments are irrelevant. Courts only consider implied repeal if "statutes are in 'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute.'" *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 663 (2007). Neither applies here. Instead, the Nondirective Mandate harmonizes with Section 1008. Congress's requirement that "all pregnancy counseling" be nondirective is consistent with Section 1008's condition that "[n]one 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. Referring patients who request abortion care to a provider operating *outside the Title X program* does not make abortion part of the Title X program—in the same way that prenatal care does not become part of the program if such a referral is given.[9] Indeed, HHS has never disputed that the

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[9] HHS also speculates about Congress's reasons for first enacting the Nondirective Mandate to attempt to support its argument that *Rust* somehow controls. MTD at 26-27. But the annually reenacted nondirective

2000 Regulations properly implemented the Nondirective Mandate[10]—nor could it, since Congress reenacted the Mandate every year in which those regulations were in effect, as the Court previously recognized. Beneski Decl. Ex. 4 (Verbatim Rpt.) at 53:19-23, 55:10–13; *see Forest Grove Sch. Dist. v. T.A.*, 557 U.S. 230, 239–40 (2009) ("Congress is presumed to be aware of an administrative . . . interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."). "[W]here two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1018 (1984) (internal quotation marks and citations omitted). The Court should decline Defendants' invitation to find that the Nondirective Mandate has no legal effect.

Defendants previously argued, erroneously, that the Supreme Court *did* adopt an "authoritative judicial interpretation" of Section 1008 in *Rust*, Verbatim Rpt. at 60:1–3—an untenable reading this Court correctly rejected. *See* PI Order at 10 n.4 (citing 500 U.S. at 184–203). Having abandoned that position, Defendants nevertheless claim a statutory conflict between Congress's "implicit"

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requirement—which clearly means nondirective in any direction—must be enforced as written.

[10] In fact, HHS awarded grant funds subject to the 2000 Regulations as recently as April 1, 2019. *See* ECF No. 60-1 (Johnson Decl.) at 3.

delegation of authority to interpret the "ambiguity" in Section 1008, and the Nondirective Mandate's foreclosure of HHS's current interpretation. MTD at 27-28. But Defendants cite no case in which a court found an "irreconcilable conflict" where Congress merely narrowed the range of permissible agency interpretations of another, ambiguous statutory provision. *See id.* In fact, "the power of a provision of law to give meaning to a previously enacted ambiguity comes to an end once the ambiguity has been authoritatively resolved." *J.EM. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 146 (2001) (Scalia, J., concurring); *accord United States v. Fausto*, 484 U.S. 439, 453 (1988) (the "classic judicial task of reconciling many laws enacted over time . . . necessarily assumes that the implications of a statute may be altered by the implications of a later statute"). The Nondirective Mandate simply adds to the body of law pertaining to Title X services, clarifying what was once ambiguous. *See Branch v. Smith*, 538 U.S. 254, 281 (2003) (plurality op.) ("courts do not interpret statutes in isolation, but in the context of the *corpus juris* of which they are a part, including later-enacted statutes").

Even if the Nondirective Mandate could be read as an "amendment" that implicates the presumption against implied repeals, MTD at 28, the presumption still would not apply for several reasons. First, the presumption does not apply where the later-enacted statute "*expressly*" addresses the relevant issue. *Republic of Iraq v. Beaty*, 556 U.S. 848, 861 (2009) (emphasis original). Here, it could not be clearer that the Nondirective Mandate applies to Title X. *See* Pub. L. No.

115-245 (appropriating funds for carrying out "title X of the PHS Act," provided that "all pregnancy counseling shall be nondirective"). Second, the presumption does not apply unless the earlier-enacted statute is "narrow, precise, and specific" whereas the later-enacted statute "cover[s] a more generalized spectrum." *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976). Here, the reverse is true: the later-enacted Nondirective Mandate narrowly and precisely specifies that Title X programs provide "nondirective" pregnancy counseling,[11] whereas Section 1008 "does not speak directly" (or at all) to that issue. *Rust*, 500 U.S. at 184. The Nondirective Mandate is binding law and HHS must follow it.

b. The required counseling distortions violate the Nondirective Mandate

HHS's argument that the Rule *complies* with the Nondirective Mandate fares no better. *See* MTD at 20–25. The Nondirective Mandate supports pregnant patients in freely determining the course of their own medical care, and protects them from directive counseling that steers them toward unwanted or unneeded medical treatment (consistent with Title X's requirement that all of its services and information be "voluntary," *see infra* Section III.D.4). In contrast, the Rule impermissibly *requires* Title X providers to deprive their patients of those rights

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[11] Defendants' assertion that the Nondirective Mandate is "silent" on this point is plainly incorrect. MTD at 2, 19; *see also id.* at 26 (erroneously asserting that the Nondirective Mandate does not mention "pregnancy" or Title X).

by concealing information related to abortion and pushing all pregnant patients toward carrying to term—and moreover, *permits* providers to distort pregnancy counseling even further if they wish. This untenable interpretation warrants no deference, *see U.S. Dep't of Navy v. Fed. Labor Relations Auth.*, 665 F.3d 1339, 1348 (D.C. Cir. 2012) (no deference owed to agency interpretation of appropriations statute)—and HHS does not claim otherwise.

A patient with a confirmed pregnancy has two options: carry the pregnancy to term or terminate the pregnancy. As HHS has acknowledged, "nondirective counseling is the provision of information on all available options *without promoting, advocating, or encouraging one option over another*." 83 Fed. Reg. 25,512 n.41 (Jun. 1, 2018) (emphasis added). Indeed, the only other statute in which Congress refers to nondirective pregnancy counseling—the Infant Adoption Awareness Act (IAAA)—makes clear that such counseling entails offering information and referral about "all" options on an "equal basis," flatly contradicting HHS's current position. 42 U.S.C. § 254c–6 ("adoption information and referrals" must be provided "on an *equal basis with all other courses of action included in nondirective counseling* to pregnant women") (emphasis added). Despite the clear meaning Congress ascribes to nondirective pregnancy counseling, Defendants admit that the Rule *does not* treat all pregnancy options on an "equal basis." MTD at 24–25. They also concede that "push[ing]" clients toward one option is an "abuse" of nondirective pregnancy counseling. MTD at 26. Directing patients toward HHS's preferred option and denying referrals for

the other option, as the Rule requires, cannot be reconciled with the Nondirective Mandate. If Congress had wanted providers to steer patients away from abortion and withhold complete information about that option, MTD at 24–25, it would have said so instead of requiring, neutrally, that all pregnancy counseling be "nondirective." Just as an "agency's preference for symmetry cannot trump an asymmetrical statute," *Michigan*, 135 S. Ct. at 2710, here HHS's preference for asymmetrical pregnancy counseling cannot trump the symmetrical Nondirective Mandate.

As a backstop to their argument that the Nondirective Mandate has no legal effect, *see supra* Section III.D.2.a, Defendants attempt to limit its import by claiming that referrals are not part of counseling. MTD at 21. Once again, the IAAA forecloses Defendants' position: it requires the "provision of 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). Accordingly, to the extent there is any doubt, "Congress' use of the identical term 'nondirective counseling' should be read consistently across" the IAAA and the Nondirective Mandate "to include referrals as part of counseling." *California v. Azar*, 385 F. Supp. 3d 960, 991 (N.D. Cal. 2019) (citing *Dir., OWCP v. Newport News Shipbldg. & Dry Dock Co.*, 514 U.S. 122, 130 (1995)); *accord Azar*, 139 S. Ct. at 1812 (courts should "not lightly assume that Congress silently attaches different meanings to the same term in the same or related statutes").

HHS's identification of statutes, regulations, guidance, and proposed legislation that use the terms "counseling" and "referral" either disjunctively or conjunctively in other contexts does not establish that the terms are unrelated—far from it. MTD at 21–23. As the Supreme Court recently explained, Congress sometimes lists items separately in a statute even when they "have substantial overlap." *Azar*, 139 S. Ct. at 1814 n.1. Here, Congress's inclusion of "referrals" *within* "nondirective counseling" in the IAAA dictates *in pari materia* application. *See Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972). Because Congress has made it quite clear that related referrals are "included in" the counseling process, 42 U.S.C. § 254c-6(a)(1), it is also irrelevant that "referrals" were listed separately in the never-passed Family Planning Amendments Act. MTD at 22; *see City of Milwaukee v. Illinois*, 451 U.S. 304, 332 n.24 (1981) (courts should not look to "unsuccessful attempts at legislation" to discern Congress's intent).

The notion that referrals are not part of counseling is just another convenient *post hoc* litigating position. In the Rule's preamble, HHS itself described "counseling, information, and referral" as being "part of nondirective postconception counseling" within Title X. 84 Fed. Reg. 7733–34; *see also id.* at 7747 (acknowledging that referrals are made "during" counseling); *id.* at 7730

(referring to counseling and "corresponding referrals").[12] That is consistent with the administrative record, which shows that as a matter of clinical practice and prevailing medical standards, counseling and referral are intertwined and complementary aspects of the same patient-centered services—as HHS's own QFP establishes. *Supra* at 21-22; *see* ECF No. 17-3 (QFP) at 14 (in describing "Pregnancy Testing and Counseling," the QFP specifies that pregnancy test results "should be presented to the client, followed by a discussion of options and appropriate referrals"); Verbatim Rpt. at 23:16–25:3; *see also* AR107973 (AAN cmt.); AR315936 (ACNM cmt.); AR268840–41 (ACOG cmt.); AR269331–32 (AMA cmt.); AR239894 (APHA cmt.); AR245694–95 (Cal. cmt.); AR246646–47 (Dr. Steinauer cmt.); AR264420–22 (Guttmacher Inst. cmt.);

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[12] Defendants' assertion that HHS did not view the Nondirective Mandate as applying to referrals when it adopted the 2000 Regulations, MTD at 23, is difficult to understand. The cited page states 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. 41,275. Likewise, it proves nothing that HHS previously acknowledged the 1988 gag rule was "permissible" under *Rust*. MTD at 23 (quoting 65 Fed. Reg. 41,277). The 1988 rule *preceded* the Nondirective Mandate, and "the agency's view" does not override statutory directives. *Supra* Section III.D.1.

AR106798–99 (Miliken Inst. cmt.); AR239149 (Jacobs Inst. cmt.); AR268687 (Missouri Fam. Health Council cmt.); AR308013–19 (NFPRHA cmt.); AR106458–59 (NIRH cmt.); AR280766 (NWLC cmt.); AR316402–06, 409–13, 419 (PPFA cmt.); AR278560–61 (Wash. cmt.). Most patients would rightly be astonished by a referral inconsistent with the course of treatment selected during the counseling process. *See Oregon v. Azar*, 389 F. Supp. 3d 898, 913 n.5 (D. Or. 2019) ("I cannot imagine visiting my urologist's office to request a vasectomy, only to be given a list of fertility clinics. I would think my doctor had gone mad.").

c. The optional counseling distortions unlawfully permit directive counseling

Even if one sets aside the bar on abortion referrals and the mandatory prenatal care referral, the Rule's counseling scheme still fails to comply with the Nondirective Mandate. It makes its so-called "nondirective" counseling optional, and injects direction even there to ensure that abortion is not the only option discussed, even if that is the only option the patient specifies. 84 Fed. Reg. 7747 ("abortion must not only be the only option presented").[13] Moreover, the Rule permits providers and clinic staff to give directive counseling that only discusses

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[13] When discussing the pregnancy counseling requirements in place in 1981, Defendants repeatedly cite a misleading excerpt of a secondary source rather than citing the applicable regulation. MTD at 24, 25 (citing a GAO report).

"maintaining the health of the mother and unborn child during pregnancy"—again, regardless of whether the patient wants that information. 42 C.F.R. § 59.14(b)(1)(iv)). Defendants erroneously claim that the "provision *allowing* Title X projects to provide 'nondirective pregnancy counseling'" (as one of several optional types of counseling) is "entirely consistent" with the Nondirective Mandate. MTD at 23. This facially illogical assertion fails; the statute makes it *mandatory*, not optional, that any Title X pregnancy counseling be nondirective. Selecting one of the other three types of pregnancy counseling permitted by the Rule, *see* 42 C.F.R. § 59.14(b)(1)(i)–(iv), betrays the statutory guarantee *to patients* that they will not be pushed into medical treatment or steered down a particular path. Yet the Rule allows providers to do just that.

d. The New Rule's counseling distortions are not severable

"Whether the offending portion of a regulation is severable depends upon the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). HHS's assertion that the "prenatal-referral requirement is severable from the abortion-referral prohibition," MTD at 20, is untenable because it would require this Court to excise half a sentence in Section 59.14(b), leaving an incomplete sentence and unclear remainder of the provision behind. In addition, HHS's central intent in adopting Section 59.14(b) was the mandatory prenatal referral, which it begins with and which is the only information that it affirmatively requires providers to

give during pregnancy counseling. Moreover, severing one aspect of the counseling distortions would not solve the contrary-to-law problem, because none of the counseling distortions can "function" consistent with the Nondirective Mandate for the reasons discussed above.[14]

3. The Rule violates Section 1554's limits on HHS rulemaking

The Rule is also contrary to law because it violates the specific limits on HHS regulatory authority that Congress enshrined in the PPACA. Section 1554 of that statute explicitly prohibits HHS from promulgating "any regulation" that, among other things, creates barriers to a patient's receipt of appropriate health care or interferes with a provider's ability to communicate about the "full range of treatment options" or "to provide full disclosure of all relevant information to patients making health care decisions." 42 U.S.C. § 18114. The Rule plainly violates all five relevant subsections of Section 1554,[15] which explains why HHS focuses its defense on its misplaced waiver argument.

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[14] The 1989 dissent on which HHS relies is inapposite because, like *Rust*, it preceded the Nondirective Mandate, and dealt with a different rulemaking. *See* MTD at 20.

[15] The Rule's restrictions on counseling "violate the principles of informed consent and the ethical standards of health care professionals," *id.* § 18114(5), for example, by interposing coercive requirements on Title X providers to provide unnecessary and unwelcome prenatal treatment referrals over the express

a. Defendants' waiver argument fails

Defendants contend that Plaintiffs "waived any challenge to the Rule under § 1554" because no public comment filed in the rulemaking process specifically cited the statutory subsection. MTD at 29. This argument is woefully misguided.

First and foremost, there can be no waiver because HHS undisputedly considered Section 1554 and its limits as part of the rulemaking. The entire PPACA, including Section 1554, is in the certified administrative record, belying any suggestion that the agency was unaware of its applicability here.

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wishes of patients, as described above; NFPRHA also discusses the Rule's medical ethics violations at length. The Rule's counseling prohibitions are *designed* to prevent Title X clinicians from fully disclosing "all relevant information to patients making health care decisions" about pregnancy, thus "interfere[ing] with communications" about the "full range of treatment options," *id.* § 18114(3)-(4). The Rule creates "unreasonable barriers" and "impedes [patients'] timely access" (*id.* § 18114(1)-(2)) to abortion care by, e.g., referring patients seeking an abortion to prenatal care instead and requiring clinics to establish separate facilities, personnel and separate health care records for abortion-related activity. Sections 59.14-59.16. The Rule creates new and unnecessary obstacles to a patient's timely access to contraceptive care, for example by barring the provision of Title X care immediately following an abortion (which must occur in a separate physical location).

AR397742-43 (copy of Section 1554); *see Thompson*, 885 F.2d at 555 (administrative record includes "all documents and materials directly or indirectly considered by the agency decision-makers"). Dispelling any doubt, HHS confirmed during this litigation that the agency was aware of Section 1554 and the substantive considerations it enumerates. Verbatim Rpt. at 67:24–68:8. The Ninth Circuit "will not invoke the waiver rule . . . if an agency has had an opportunity to consider the issue . . . even if the issue was considered sua sponte by the agency . . . ." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007). Here, the record confirms that the conflicts between the Rule and Section 1554's prohibitions were "adequately before the agency for consideration." *Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1060 (N.D. Cal. 2018).

Even if HHS had not considered Section 1554—which it plainly did—the agency still has an independent obligation not to exceed statutory limitations on its rulemaking authority. "[T]he waiver rule does not apply . . . where the scope of the agency's power to act is concerned," because it is the *agency's* "obligation to examine its own authority and not to promulgate implementing regulations in a way that exceeds its scope." *Pruitt*, 293 F. Supp. 3d at 1061; *Nat. Res. Def. Council v. EPA*, 755 F.3d 1010, 1023 (D.C. Cir. 2014) (rejecting waiver argument because agency must justify its exercise of authority "even if no one objects to it during the comment period"). Here, despite its obligation to examine the limits of its authority when propounding new regulations and its admitted

knowledge of the limits established by Section 1554, HHS failed to discuss those limits *at all* in the proposed rule or the final version.[16]

Further, even if the scope of review here were circumscribed by the rulemaking comments (and if the portion of the record that actually contains a copy of the statute were disregarded for some reason), commenters need only raise an issue "with sufficient clarity to allow the decision maker to understand and rule on the issue raised." *Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010); *Pruitt*, 293 F. Supp. 3d 1060 (no waiver where record was "replete with comments" opposing EPA's extension of compliance deadline, though comments did not challenge EPA's *authority* to do so). Here, critical stakeholders objected that the Rule would create unreasonable barriers to care, impede timely access to services, interfere with patient–provider communications, and violate principles of informed consent and medical ethics. *See, e.g.*, AR269330–34 (AMA cmt.), AR2785561–63, 573–76 (Wash. cmt.) (discussing medical ethics violations, interference in patient–provider relationship, and impacts on access to care); *see generally*

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[16] *Koretoff v. Vilsack*, 707 F.3d 394 (D.C. Cir. 2013), is distinguishable because there, the agency satisfied its obligation to "ensure that [it has] legal authority to issue a particular regulation" by "expressly" citing the authorizing statute, and was not required to anticipate plaintiffs' argument that the *same statute* did not provide authority for the challenged action.

NFPRHA Br. at _ (citing comments); *see also Oregon v. Azar*, 389 F. Supp. 3d at 914 (citing American Medical Association brief "meticulously matching specific comments to each prong of 42 U.S.C. § 18114"); *California v. Azar*, 385 F. Supp. 3d at 993–95 (collecting comments).

Finally, even if waiver could present a viable defense under other circumstances, with the Rule's implementation, Washington has been subject to enforcement and is not limited to a "facial review" of the Rule's provisions. *Cf.* MTD at 29 (arguing that "'the price for a ticket to facial review is to raise objections in the rulemaking'"). As HHS concedes, "[a] plaintiff can raise such 'statutory arguments if and when the Secretary applies the rule' to them." MTD at 29 (quoting *Koretoff*, 707 F.3d at 398 (per curiam)). Washington was forced to end its participation in the Title X program because it was unable to comply with the Rule's unlawful and harmful counseling restrictions and other currently-effective provisions that violate Section 1554. Because the Rule has been applied to Washington (and the entire Title X network) through its nationwide implementation, there is no question that Washington may challenge the Rule's violation of the protections afforded by Section 1554 of the PPACA, irrespective of what arguments were raised during the notice-and-comment process (or in the pre-enforcement phase of this litigation).

b. The Rule violates Section 1554's plain text

The Rule is contrary to law because it directly conflicts with Section 1554. HHS cannot rely on its general grant of authority to enact regulations under

Title X to evade the explicit Congressional limits on *the same authority to regulate* contained in Section 1554. Title X can, and should, be read in harmony with Section 1554, and since the Rule is contrary to the plain text of Section 1554, it must be set aside.

Section 1554 unequivocally states that HHS "shall not promulgate *any* regulation" violating various patient protections. 42 U.S.C. § 18114 (emphasis added). As written, this Congressional directive applies to the Rule just as it would to any other HHS regulation: the word "any" "bespeaks breadth." *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134 (2018); *see, e.g.*, *id.* (FLSA overtime exception for "any salesman" included service advisors); *Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 219 (2008) (noting the "expansive meaning" of the word "any" in statutory interpretation, and holding that reference to "any other law enforcement officer" was not limited to those with customs enforcement duties); *United States v. Gonzales*, 520 U.S. 1, 5 (1997) (statutory term "any other term of imprisonment" left "no basis in the text for limiting" the phrase to federal sentences); *Harrison v. PPG Industries, Inc.*, 446 U.S. 578, 588–89 (1980) (statutory phrase "any other final action" in Clean Air Act "offer[ed] no indication whatever that Congress intended" to limit the phrase to final actions similar to those in specifically enumerated sections).

HHS first suggests that its Rule does not come within the scope of Section 1554 because the regulation "simply limits what the government chooses to fund through the Title X grant program" rather than purporting to regulate healthcare

directly. MTD at 30. Characterizing the Rule as a simple grant limitation is disingenuous: the Rule directly addresses the provision of specific health care services.[17] Its subject matter is plainly encompassed within Section 1554's restrictions on HHS for regulations concerning "medical care," "health care services," "communications . . . between the patient and the provider," and "principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114. Nothing suggests that Congress intended to exempt reproductive health care from Section 1554's purview *sub silentio*. *See Seed Co. Ltd. v. Westerman*, 266 F. Supp. 3d 143, 148 (D.D.C. 2017) ("general terms should be accorded 'their full and fair scope' and not be 'arbitrarily limited'").

Next, HHS attempts to cabin Section 1554's application to the PPACA statutory scheme, relying on its "notwithstanding" clause. MTD at 31. However, the Supreme Court has rejected that very argument, holding that "[n]otwithstanding subsection (a)(1)" does not limit what follows to (a)(1) because, *inter alia*, the "ordinary meaning of 'notwithstanding' is 'in spite of,' or 'without prevention or obstruction from or by.'" *NLRB v. SW Gen., Inc.*, 137

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[17] *See, e.g., supra* n.15 (listing significant examples of the Rule's intrusion into health care). Indeed, if Section 1006 is read as simply authority to promulgate grant-making regulations, as HHS implies, the Rule clearly exceeds such authority. *See id.*

S. Ct. 929, 940 (2017). Moreover, where Congress wanted to limit a provision to the PPACA alone, it said so explicitly, *see California v. Azar*, 385 F. Supp. 3d at 995–96 (discussing Sections 1553 and 1555 of the PPACA),[18] whereas Congress did not use such limiting language in Section 1554. These attempts to side shuffle are meritless: Section 1554 applies to "any" HHS regulation, and the statute's plain language demonstrates that the Rule exceeded HHS's regulatory authority.

The statutory interpretation inquiry should end there, with the plain language of Section 1554. Instead, Defendants turn to "settled rules of statutory construction" to argue that "[i]f Title X's specific delegation of authority to the Secretary to adopt the Rule somehow conflicted with the general directives in § 1554, '[i]t is a commonplace of statutory construction that the specific governs the general.'" MTD at 31 (citation omitted); *cf. id.* at 30 ("nothing in § 1554 abrogates Title X's authorization for the Rule."). This argument does not aid

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[18] Section 1553 provides 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). Section 1555 states 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).

Defendants at all. HHS cannot identify a statutory conflict—Title X and the PPACA are harmonious—and the maxim does not apply. Indeed, to the extent that the canon could apply here, it supports Plaintiffs.

The "general/specific" interpretive canon governs where one statutory permission is *contradicted* by a more specific prohibition or permission, or where one statute renders another superfluous. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). To clarify, again, nothing in Title X provides a "specific delegation of authority" for the Rule. *Supra* at 43; *cf.* MTD at 30. Rather, HHS's Title X regulatory authority is set out in Section 1006 of the statute.[19] Comparing that provision with Section 1554 demonstrates that Section 1554 is a far more specific limitation on HHS's rulemaking powers than the general rulemaking grant in Section 1006. Thus, to the extent there is any conflict between the general permission to regulate and the specific prohibition on particular regulations, Section 1554 controls under the very canon of interpretation on which HHS relies.

To the extent Defendants are suggesting that there is a statutory conflict between the specific limits in Section 1554 and Section 1008—the abortion funding prohibition that applies generally to implementation of Title X by HHS

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[19] Section 1006 of Title X provides: "Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate." 42 U.S.C. § 300a-4.

and grantees—they utterly fail to explain it. Section 1008 provides that Title X funds cannot be used for abortion, and Section 1554 provides that HHS cannot promulgate regulations that violate medical ethics or interfere with medical care. There is no evidence that these directives conflict, and HHS may only regulate within the boundaries established by these statutes.[20] Finally, to the extent Defendants imply that the Rule is a "specific" interpretation of Section 1008 that can override the plain statutory language of Section 1554, that argument should be soundly rejected. *See supra* at 40-41; *Utility Air Regulatory Grp.*, 573 U.S. at 328.

Failing to find a statutory conflict, HHS next protests that Section 1554 doesn't demonstrate clear Congressional intent to "erase the Secretary's pre-existing authority to adopt regulations [for Title X]" in Section 1006. MTD at 28–29. This is a strange argument: the PPACA wrought a massive overhaul of the health care system, and through Section 1554, Congress explicitly chose to limit HHS's rulemaking authority in specific contexts. The plain language of Section 1554 manifestly demonstrates Congressional intent, and as Justice Thomas explained in *Encino Motorcars*: "Even if Congress did not foresee all of the applications of the statute, that is no reason not to give the statutory text a fair

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[20] HHS does not argue that the Rule is the only regulatory means of implementing Section 1008—nor could it in light of its decades of prior regulation.

reading." 138 S. Ct. at 1143 (citing *Union Bank v. Wolas*, 502 U.S. 151, 158 (1991)).

At base, HHS suggests that Section 1554's limitations cannot apply to the new Rule because it could have issued the Rule prior to Section 1554's adoption—in other words, that Title X cannot be read in light of subsequent legislation without raising the specter of implied repeal. But this argument again fails for lack of statutory conflict. *See Fausto*, 484 U.S. at 453 (where statutes can be harmonized, there is no implied repeal issue). To the contrary, it is axiomatic that the judicial interpretation of a statute is affected by other legislation on the same subject, particularly where Congress speaks subsequently and more specifically to the topic at hand. *Supra* at 44-45; *see, e.g.*, *Fausto*, 484 U.S. at 453 (legislative overhaul of civil service system impacted legal interpretation of prior enacted statute); *United States v. Romani*, 523 U.S. 517, 530–31 (1998) ("a specific policy embodied in a later federal statute should control our construction of the priority statute even though it had not been expressly amended").

HHS argues that the Section 1554 claim "is substantively the same as the constitutional arguments rejected in *Rust*." MTD at 30. This is plainly wrong: *Rust* did not address the statutory limits of HHS's authority under Section 1554

or the Nondirective Mandate, as neither existed at the time *Rust* was decided.[21] Since at least 1996, Congress has required Title X care to be consistent with modern, ethical, patient-centered principles per the Nondirective Mandate. Section 1554 continues that trend, giving these principles the force of law and prohibiting government intrusion into the exam room for all types of medical care. Defendants' wild suggestion that Section 1554 as written "would effectively halt HHS from making even minor changes to the Title X program," MTD at 31, is baseless. HHS may continue to regulate Title X and all of its other programs as long as the agency does not improperly interfere with the provision of health care when doing so—just as it did for many years prior to the Rule.

Section 1554 sets clear limits on HHS regulatory authority that must be read in conjunction with the grant in Section 1006 to issue regulations related to Section 1008, and HHS must comply with the limits of all of these statutory provisions. Because the Rule violates Section 1554, it must be set aside.

4. The New Rule violates the Title X statute

"'In order to be valid regulations must be consistent with the statute under which they are promulgated.'" *E. Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1248 (9th Cir. 2018) (brackets omitted) (quoting *United States v. Larionoff*,

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[21] The related argument that Congress needed to explicitly abrogate *Rust* (which addressed a rule rescinded in 1993), during the passage of the PPACA decades later is simply nonsensical. MTD at 40.

431 U.S. 864, 873 (1977)). Courts will not "rubber-stamp" rules "inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *A.T.F. v. Fed. Labor Relations Auth.*, 464 U.S. 89, 97 (1983); *accord FEC v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981).

This Court correctly found that the Rule likely violates Title X's central purpose: to equalize access to comprehensive, evidence-based, voluntary family planning services. PI Order at 15. The Court should make the same finding on the merits. By forcing qualified providers out of the program and replacing them (if at all) with providers who do not support access to biomedical contraceptives or complete medical information, the Rule impedes access to the "comprehensive" and "effective" services Title X was meant to fund, sacrificing the statute's overall purpose to HHS's broad, impermissible new interpretation of Section 1008. This "allow[s] the exception to swallow the rule, thereby undermining the purpose of the statute itself." *Nat'l Fed'n of Fed. Emps. v. McDonald*, 128 F. Supp. 3d 159, 172 (D.D.C. 2015); *see also Stewart v. Azar*, 366 F. Supp. 3d 125, 138 (D.D.C. 2019) (rejecting HHS regulation that was not "reasonably approximated toward enhancing the provision" of medical services per statute's "central objective"). *Rust* does not speak to these matters, as it did not address Title X's overall purpose, nor did it confront a statewide loss of all

Title X providers, as has occurred in Washington and elsewhere, and a national map riddled with new Title X gaps.

The Rule violates individual statutory requirements as well, though Defendants fail to address them with any seriousness. *First*, the counseling distortions violate Title X's requirement that acceptance of both "services" and "information" "shall be voluntary." 42 U.S.C. § 300a-5; *see id.* § 300(a) (Title X's first sentence provides that federal funding will support "voluntary" family planning services). Under the Rule, however, patients *must* participate in counseling about continuing their pregnancy, including both information and referral, even when they seek information about abortion alone and voice their lack of consent to discussing prenatal options or referral. 42 C.F.R. § 59.14(b); *see also* 84 Fed. Reg. 7747 ("abortion must not only be the only option presented," even if it is the only option the patient is considering); *see also id.* (if the provider chooses to discuss abortion, they must present "the possible risks and side effects to . . . the unborn child" of that procedure, even if the patient objects).

HHS claims that Section 59.5(a)(2), which continues unchanged from the 2000 regulations, ensures that the Rule complies with the statute's voluntary participation requirement. MTD at 33. But that continuing, general regulation does not override the specific pregnancy counseling requirements and violations of the statutory voluntariness requirement adopted in this Rule. Section 59.14(b)(1)'s forced prenatal referral, for example, and providers' required

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discussion of prenatal options whenever abortion is discussed during pregnancy counseling, must now occur as a result of this Rule and must take place even without patients' consent and contrary to their explicit directions. *See* 42 C.F.R. § 59.14(b)(1); 84 Fed. Reg. 7747.

Defendants' selective reading of the "voluntary" requirement is likewise unavailing. MTD at 33. It completely ignores the first clause's imperative statement: "The acceptance by any individual of family planning services or . . . information . . . *shall be voluntary and* shall not be a prerequisite to eligibility for [other programs]." 42 U.S.C. § 300a-5 (emphasis added). Congress requires that Title X information and services be voluntary *and* not a prerequisite; it did not define the former as coextensive with the latter. *See Nat'l Ass'n of Mfrs. v. Dep't of Defense*, 138 S. Ct. 617, 632 (2018) (courts must "give effect, if possible, to every word Congress used"); *Brusewitz v. Wyeth LLC*, 562 U.S. 223, 236 (2011) ("and" is a coordinating junction that "link[s] independent ideas"). Moreover, by seeking to redefine "voluntary" in this manner, HHS asks this Court to disregard the word's plain meaning, contrary to a basic principle of statutory interpretation. *See Cal. Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1067 (9th Cir. 2019) (courts look to the "ordinary meaning"); *United States v. Price*, 921 F.3d 777, 784 (9th Cir. 2019) (ordinary meaning is used "unless the statute clearly expresses an intention to the contrary"). HHS's narrow and atypical reading of "voluntary" also disregards legislative history that comports with the plain meaning. *See* S. Rep. No. 91-1004, at 12 (Congress included

"explicit safeguards" in the statute "to insure that the acceptance of family planning services and information relating thereto must be on a purely voluntary basis by the individuals involved").

Second, the Rule inexplicably limits the use of Title X funds for core functions such as "bulk purchasing of contraceptives," "clinical training for staff," and distribution of "educational materials." 42 C.F.R. § 59.18; *see* 84 Fed. Reg. 7773–74. This contradicts the statute's text, which says Title X funds should be used to "offer . . . effective family planning methods" and that projects will make available "educational materials," 42 U.S.C. §§ 300(a), 300a-4(d)(1), and its declaration of purpose, which includes assisting in "providing trained manpower needed to effectively carry out . . . family planning services," Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970). HHS fails to reconcile the Rule's funding restrictions with the statute's plain language. *Rust* is again unavailing, as it did not analyze, apply, or base its holding on any portion of Title X other than Section 1008, and the 1988 rule did not restrict the use of Title X funds in the same way. Section 59.18 is unprecedented.

Third, the Rule requires Title X clinics to offer or be in "close physical proximity" to "comprehensive primary health services." 42 C.F.R. § 59.5(a)(12). Such services fall outside the scope of Title X, which specifically and exclusively

concerns "family planning" services.[22] 42 U.S.C. § 300 *et seq.* Thus, the requirement exceeds the scope of HHS's Title X rulemaking authority. *See California v. U.S. Dep't of Health & Human Servs.*, 941 F.3d 410, 425 (9th Cir. 2019) ("An agency literally has no power to act unless and until Congress confers power upon it. . . . [T]he question is always whether the agency has gone beyond what Congress has permitted it to do.") (cleaned up; citations omitted); *see Portland Gen. Elec. Co.*, 501 F.3d at 1026 ("[R]egardless of how serious the problem an administrative agency seeks to address, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law, because an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.") (cleaned up; citations omitted).

HHS cannot meaningfully defend the Rule's violations of Title X's text, overall purpose, and individual provisions, which are dispositive as to multiple provisions of the Rule.

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[22] HHS effectively acknowledged as much: its rationale for this requirement was "to help minimize the difficulty of patients receiving needed health care *outside of Title X services*," and it conceded that primary health services are not billable to the Title X program. 84 Fed. Reg. 7749 (emphasis added).

E. The Constitutional Claims Reinforce the Important Interests at Stake, but Need Not Be Reached Because the Statutory Violations Are So Pervasive

The Court need not reach Plaintiffs' constitutional claims now. *See, e.g.*, *Iturribarria v. INS*, 321 F.3d 889, 895 (9th Cir. 2003) ("We decline to decide cases on constitutional grounds when other grounds on which to base our decision are available."). Indeed, it should not do so because the contrary-to-law claims and the arbitrary and capricious claims each afford Plaintiffs complete relief, i.e., vacatur of the entire Rule. *See Jean v. Nelson*, 472 U.S. 846, 854–55 (1985) (holding that the court below should not have addressed a constitutional issue because the relief sought could be obtained under statutes and regulations).

In the event the Court does review these claims, however, Defendants are wrong to declare that all First Amendment claims are foreclosed by *Rust.* MTD at 42–43. That decision left open the argument that "traditional relationships such as that between doctor and patient should enjoy protection under the First Amendment" in the context of a government-subsidized health care program.500 U.S. at 200. In 1991, the *Rust* Court viewed Title X as not encompassing any medical counseling about pregnancy—but now, under the Nondirective Mandate and this Rule, it is clear that patients do look to Title X providers for unbiased clinical pregnancy counseling. *See supra* at 40. The Nondirective Mandate was designed to facilitate unbiased professional speech. Yet, after underscoring the professional medical nature of pregnancy counseling within Title X today (e.g., by restricting the provision of so-called "nondirective" pregnancy counseling to

physicians and APPs), the Rule interferes with clinician–patient communications in a way that the Supreme Court recently warned against. *See Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2374 (2018) (discussing the "dangers associated with content-based regulations," including government manipulation of the "content of doctor-patient discourse").

As discussed, the Rule's pregnancy counseling provisions require clinicians to portray prenatal care as "medically necessary" and to therefore send all pregnant patients to that care. They require clinicians to offer non sequiturs in response to patient questions, and to steer patients toward health care options they do not seek. "By compelling individuals to speak a particular message," the 2019 counseling requirements "alter the content of [physicians and other Title X clinicians'] speech," impose a particulate viewpoint, and damage the clinician–patient relationship without the compelling justification that the First Amendment requires. *Id.* at 2371 (internal quotations and brackets omitted).

The Rule also clashes with the First Amendment because it interferes with Title X recipients' activities outside the Title X program. Clinicians' ability to explain that prenatal care is not, in fact, medically necessary for all pregnant patients— or even to inform patients that those same clinicians offer more expansive care (including abortion referral information) at some other, non-Title-X funded location—are harmed by the messages that the Rule compels them to convey within its pregnancy counseling distortions and its prohibition on even indicating indirect routes to information. Conditions that prevent

government-funded providers from "participating in [constitutionally protected] activities on [their] own time and dime" are unconstitutional. *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 218 (2013).

Similarly, the vagueness upon vagueness built into the Rule, as discussed in NFPRHA's brief, presents independent constitutional issues. *See County of Santa Clara v. Trump*, 275 F. Supp. 3d 1196, 1217 (N.D. Cal. 2017) (finding defunding provision for "sanctuary cities" unconstitutionally vague), *aff'd in part, vacated in part*, 897 F.3d 1225 (9th Circ. 2018); *Bella Lewitzky Dance Found. v. Frohmayer*, 754 F. Supp. 774, 784-85 (C.D. Cal. 1991) (rejecting vague advance certification requirement in connection with government funding). Those cannot be swept aside by mere reference to a *lack* of any vagueness ruling in *Rust* or the fact that this case challenges the Rule as promulgated, rather than in one particular application. *Cf.* MTD at 44-45. Unlike any of the cases that Defendants cite, Section 59.7(b) of this Rule imposes an all-encompassing, uncertain eligibility requirement for future Title X funding (which also incorporates all the other vagueness of the Rule), empowers the Secretary to reject an application without explanation in enforcing that threshold requirement, and provides no visibility into or recourse from that decisionmaking. *See County of Santa Clara*, 275 F. Supp. 3d at 1217 (Secretary's discretion to apply vague defunding terms invites arbitrary and discriminatory enforcement). Because this wholly opaque cutoff occurs before a grant is funded,

the procedures "to obtain clarity" that HHS suggests do not apply. *Cf.* MTD at 45 n.5.

The utterly arbitrary, capricious, and unlawful nature of the Rule is more than enough to warrant vacatur in full. *See* 5 U.S.C. § 706(2) (courts "shall . . . set aside" unlawful agency action); *Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("If [the agency's action] is not sustainable on the administrative record made, then the [agency's] decision must be vacated."). Rather than reaching the constitutional claims, the Court can rest on those bases for granting Plaintiffs relief. Importantly, while the Rule's legal defects are many, Plaintiffs need only prevail on one of their APA claims to warrant vacatur in full. *See* 5 U.S.C. § 706(2) (courts must set aside agency action that is "arbitrary, capricious, an abuse of discretion, *or* otherwise not in accordance with law" *or* "in excess of statutory jurisdiction, authority, or limitations," *or* "without observance of procedure required by law"). Each major provision of the Rule, and the Rule as a whole, is arbitrary and capricious for multiple reasons, any of which is sufficient to require setting it aside. Independently, the major provisions of the Rule violate one or more of the limitations established by Section 1554—and independent of that, multiple provisions violate the Nondirective Mandate, Title X, and/or the APA's notice-and-comment requirements, as discussed above.

IV. CONCLUSION

For the reasons above and those in NFPRHA's brief, the State of Washington respectfully requests that the Court deny Defendants' Motion to

Dismiss and alternative Motion for Summary Judgment in full and enter summary judgment in its favor as to Counts I–IV of the Complaint.

DATED this 20th day of November, 2019.

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 20th day of November, 2019, at Seattle, Washington.

/s/ Kristin Beneski
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