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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

EUGENE DIVISION

STATE OF OREGON, et al.,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, et al.,

Defendants.

Case No. 6:19-cv-00317-MC

PLAINTIFF STATES' MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Fed. R. Civ. P. 65 and 5 U.S.C. § 705

Request for Oral Argument

EXPEDITED HEARING REQUESTED

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LOCAL RULE 7-1 CERTIFICATION

Pursuant to LR 7-1(a), undersigned counsel for the State of Oregon and State of New York certify that they, as lead counsel for the plaintiffs, made a good faith effort to confer with counsel for the defendants by telephone conference to resolve the disputed matters addressed in this motion, but were unable to resolve the dispute.

MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Fed. R. Civ. P. 65, Plaintiffs the States of Oregon, New York, Colorado, Connecticut, Delaware, the District of Columbia,[1] Hawai'i, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Pennsylvania, Rhode Island, Vermont, Virginia, and Wisconsin (collectively "States") respectfully move this Court for a preliminary injunction against the implementation of Defendants' Final Rule governing the Title X family planning program, *see* *Compliance with Statutory Program Integrity Requirements*, 84 Fed. Reg. 7714 (Mar. 4, 2019), in order to preserve the status quo until this case is decided on the merits and final judgment is entered. Alternatively, pursuant to 5 U.S.C. § 705, the States move for a stay postponing the effective date of the Final Rule until this case is decided on the merits and final judgment is entered. This motion is supported by the following memorandum of law, the declarations filed herewith (*see* Appendix 1), and the pleadings and papers on file herein.[2]

[1] Plaintiff States as used herein include the District of Columbia.

[2] Plaintiff States also join the Motion for Preliminary Injunction filed by plaintiffs *American Medical Association et al.* in Case No. 6:19-cv-00318-MC ("the *AMA* case").

MEMORANDUM OF LAW

I. Introduction

On March 4, 2019, disregarding hundreds of thousands of comments and decades' worth of evidence and experience, the Department of Health and Human Services ("HHS") adopted a regulation (the "Final Rule") implementing Title X of the Public Health Service Act ("Title X") that should be enjoined as contrary to law and arbitrary and capricious. For decades, federal Title X grants have funded a crucial network of providers that deliver effective and medically appropriate family planning services to low-income individuals. The Final Rule would devastate the program by, among other things: (1) prohibiting health care professionals from providing complete and unbiased information to pregnant patients about their legal options, including abortion, for those who desire it; (2) requiring the unnecessary and arbitrary physical and financial separation of all Title X clinics from any activities relating to abortion, including abortion referral and counseling; and (3) revoking the requirement that family planning information provided under the Title X program be evidence-based.

Title X's current rules, in compliance with federal law and medical ethical standards, protect patients' ability to obtain neutral and comprehensive information about family planning from their health care providers. The Final Rule prohibits this kind of nondirective counseling about abortion and expressly mandates that health care professionals provide information about prenatal care, even if the patient is only interested in terminating the pregnancy. The Final Rule further straightjackets health care professionals by mandating that clinicians obscure the identities of abortion care providers in response to a request for an abortion referral. This *directive counseling* violates the nondirective mandate in the federal appropriations statute that funds HHS, key provisions of the Affordable Care Act ("ACA"), and professional medical codes of ethics. Incredibly, HHS suggests that requiring health care professionals to conceal

information from patients should not be problematic because patients can rely on an Internet search for reliable health care information.

The Final Rule would also implement draconian physical and financial "separation" of abortion-related activities from Title X activities. And it would divert Title X funding from programs offering an array of medically-approved contraceptive methods to programs primarily focused on abstinence or natural family planning.

The Final Rule is invalid under the Administrative Procedure Act and should be enjoined because it is not in accordance with statutory requirements established in Title X itself, the ACA, and every appropriations statute funding HHS since 1996. The Final Rule is also arbitrary and capricious in departing from the statutory text, decades of history, prior practice, and recognized standards of care for health care practitioners. Implementation of the Final Rule will cause irreparable harm to Plaintiff States and their residents. The States will be forced to try to use scarce state public health funds to make up for the loss of Title X funding. Even then, certain residents would not receive services, resulting in unintended pregnancies, an increase in sexually transmitted diseases, and other negative public health outcomes. By contrast, the federal government will not be harmed at all by a preliminary injunction or a stay of the Final Rule. The balance of the equities therefore supports such preliminary relief. Injunctive relief is necessary to protect a vital public health program with nearly fifty years of success from being eviscerated by administrative fiat.

II. Background

A. Statutory and regulatory framework

1. The Title X statute. Title X is a landmark federal safety-net program that since 1970 has funded grants to states and other entities to provide high-quality reproductive health care to low-income individuals. *See* 42 U.S.C. § 300(a). Key provisions of Title X and its

implementation history are described in Plaintiffs' Complaint, ¶¶ 41-57 (Docket No. 1).

2. The nondirective appropriations mandate. Beginning in 1996, and following the Supreme Court's decision in *Rust v. Sullivan*, 500 U.S. 173 (1991), Congress's Title X appropriation statutes have required that "all pregnancy counseling" in Title X programs "shall be nondirective." Omnibus Consolidated Rescissions and Appropriations Act ("Consolidated Rescissions and Appropriations Act"), 1996, Pub. L. No. 104-134, Title II, 110 Stat. 1321, 1321-22 (1996). This statutory mandate ("Nondirective Mandate") has appeared in every subsequent Title X appropriations statute since 1996. *See, e.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 ("2019 Health and Human Servs. Appropriations Act"), Pub. L. No. 115-245, Title II, 132 Stat. 2981, 3070-71 (Sept. 28, 2018).

3. The 2000 Title X regulation currently in effect. In 2000, HHS issued a final rule (the "2000 regulation") that is still largely in effect today. 65 Fed. Reg. 41270 (July 3, 2000). Implementing the Nondirective Mandate, the 2000 regulation provided that each Title X project must "[n]ot provide abortion [as] a method of family planning," and must:

> (i) Offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: (A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination.
> (ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.

Id. at 41279 (codified at 42 C.F.R. § 59.5(a)(5)). The 2000 regulation is described in more detail in Plaintiffs' Complaint, ¶¶ 52-57 (Docket No. 1).

4. The Affordable Care Act. In 2010, Congress restricted HHS's ability to interfere with the provision of medical care by enacting Section 1554 of the ACA, which provides:

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

42 U.S.C. § 18114.

B. The challenged rulemaking

1. *The Department's 2018 proposal.* The 2018 proposed rule, 83 Fed. Reg. 25502 (June 1, 2018), and the strenuous opposition HHS received in response, are described in detail in Plaintiffs' Complaint, ¶¶ 261-73 (Docket No. 1).[3]

[3] *See* Letter from the Attorneys General of Washington, Oregon, Vermont, and Massachusetts to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("WA Ltr."); Letter from the Attorneys General of California, Connecticut, Delaware, Hawai'i, Illinois, Iowa, Maine, Maryland, Minnesota, New Jersey, New Mexico, North Carolina, and the District of Columbia to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 30, 2018) ("CA Ltr."); Letter from the New York Attorney General to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("NY Ltr."); Letter from New York State Dep't of Health to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 27, 2018) ("NY DOH Ltr."); Letter from James L. Madara, CEO & Exec. Vice President, Am. Med. Ass'n, to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("AMA Ltr."); Letter from Danielle M. Salhany, Chair, Me. Section of the Am. Coll. of Obstetricians & Gynecologists, to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("ACOG Ltr."); Letter from Karen S. Cox, President, Am. Acad. of Nursing, to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 26, 2018) ("AAN Ltr."); Letter from Colleen A. Kraft, President, Am. Acad. of Pediatrics to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("AAP Ltr.); Letter from Dana Singiser, Vice President of Pub. Policy & Gov't Relations, Planned Parenthood Action Fund, to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("PPFA Ltr."); Letter from Rachel Benson Gold, Vice President for Pub. Policy, Guttmacher Inst., to Office of Population Affairs, U.S. Dep't of Health & Human Servs. (July 31, 2018) ("Guttmacher Ltr."); Letter from John Meigs, Jr., Board Chair, Am. Acad. of Family Physicians to Alex Azar, Sec'y, U.S. Dep't of Health & Human Servs. (July 25, 2018) ("AAFP Ltr."); Letter from Catherine Thomasson, Senior Population Campaigner, Center for Biological

2. The Final Rule. On March 4, 2019, HHS published the Final Rule in the Federal Register. 84 Fed. Reg. 7714. The Final Rule adopted a provision (the "gag requirement") that both restricts information health care providers may share with their patients and forces them to provide certain information to patients, whether or not that information is desired. While not included in the proposed rule, the Final Rule adds a proviso that only physicians or "advanced practice providers" ("APP")—providers with a graduate degree and license to diagnose, treat, and counsel patients—may provide what HHS calls "nondirective pregnancy counseling." But actual nondirective pregnancy counseling is no longer required, and, when counseling on patient options is permitted, HHS directs providers not to discuss abortion as "the only option" and to "discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented." *Id.* at 7747.

The gag requirement permits health care providers to provide only "information about maintaining the health of the mother and unborn child during pregnancy" without providing any other information about pregnancy options. *Id.* at 7789. This is true even if the patient requests information only about abortion care. In response to such a request, the provider may give the patient a list of providers, but this list need not contain any providers who offer abortion care, regardless of patient request, and if it does, the abortion care providers must be fewer than half the providers on the list and must not be identified in any way as providers of abortion care.

Moreover, the gag requirement prohibits direct referrals for abortion care: "A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion." *Id.* at 7788-

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Diversity to Office of the Asst. Sec'y for Health, U.S. Dep't of Health & Human Servs. (July 10, 2018) ("CBD Ltr.").

89. Though it *prohibits* abortion care referrals, the gag requirement *requires* prenatal care referrals, regardless of patient request. The Final Rule provides, "[b]ecause Title X funds are intended only for family planning, once a client served by a Title X project is medically verified as pregnant, *she shall be referred to a health care provider for medically necessary prenatal health care*." *Id.* at 7789 (emphasis added).

The Final Rule also imposes onerous physical separation requirements on providers. Prior to adoption of the Final Rule, HHS required financial but not physical separation of Title X-funded care from abortion care. 65 Fed. Reg. 41281, 41282 (June 28, 2000). Under the Final Rule, a Title X project "must be organized so that it is physically and financially separate . . . from activities which are prohibited . . . from inclusion in the Title X program." 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15). In order to comply, a project "must have an objective integrity and independence from prohibited activities." *Id.* The rule identifies nonexclusive factors relevant to the Secretary's determination of whether such objective integrity and independence exist, including separate health care records, workstations, personnel, and signs. *Id.* Title X project activities must be separated not only from abortion care but also any other restricted activity under the Final Rule, including referrals for abortion care.

In addition, the Final Rule weakens the quality and scope of care that must be provided in Title X-funded projects. The Final Rule removes the regulatory requirement that family planning methods and services be "medically approved." *Id.* And it encourages less effective contraceptive care by emphasizing "natural" fertility awareness methods and allowing projects not to include "every acceptable and effective family planning method or service." *Id.*

C. Harms to the States

The Final Rule harms the States in multiple ways. First, the Rule would impair and delay access to high quality contraceptive care and abortion care and place women at greater risk of

harm from abortions at later gestational ages or from unwanted pregnancies.[4] These consequences would cause damage to women's physical, emotional, and economic well-being as well as that of any future children born in a financially unstable or unprepared household.[5] Second, the Rule would force many providers, including Planned Parenthood, and also, for example, community hospitals and clinics, to withdraw from the program and leave the States' residents at risk of losing access to health care altogether.[6] This reduction of and disruption in service would lead to negative public health outcomes, even outside the reproductive health context.[7] Finally, these public health impacts will have fiscal implications for States because State funds will be needed to restructure existing programs and to pay for medical care that would not have been incurred absent the Final Rule.[8]

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[4] Darney Decl. ¶¶ 13, 16; Kost Decl. ¶¶ 65, 93-94, 96-101 (The Kost declaration is filed in the *AMA* case. The States request the Court to consider the Kost declaration as support for their motion and, if this case is not consolidated with the *AMA* case, reserve the right to file the identical declaration in this case if necessary to complete their record on appeal); Byrd Decl. (DC) ¶ 4; Gallagher Decl. (VT) ¶¶ 20, 22, 26; Gillespie Decl. (WI) ¶¶ 29-30; Handler Decl. (NV) ¶ 9; Holmes Decl. (VT) ¶ 18; Kunkel Decl. (NM) ¶¶ 22-25; Reece Decl. (CO) ¶ 13.

[5] Darney Decl. ¶ 23; Kost Decl. ¶¶ 49-59, 65; Zoll Decl. (MA) ¶ 13.

[6] PPFA Ltr., 15; CA Ltr.,10-11; WA Ltr., 23-24; NY Ltr., 8; Tobias Decl. (NY) ¶¶ 45-46; Alifante Decl. (NJ) ¶ 32; Gallagher Decl. (VT) ¶ 23; Gillespie Decl. (WI) ¶ 27; Holmes Decl. (VT) ¶¶ 18-19; Keenan Decl. (CT) ¶¶ 5-6; Lytle-Barnaby Decl. (DE) ¶¶ 27-29; Brandt Decl. (MN) ¶ 9; Charest Decl. (MI) ¶¶ 7-10; Cooke Decl. (MA) ¶ 10; Childs-Roshak Decl. (MA) ¶ 16; Drew Decl. (MA) ¶ 18; MacNaughton Decl. (MA) ¶¶ 11-12; Preiss Decl. (MA) ¶ 11; Nelson Decl. (MD) ¶ 16; Skinner Decl. (CT) ¶¶ 24-25.

[7] Kost Decl. ¶ 66; Tobias Decl. (NY) ¶¶ 19, 26, 43, 44-45; David Decl. (NY) ¶ 22; Schaler-Haynes Decl. (NJ) ¶¶ 27-37; Alifante Decl. (NJ) ¶¶ 31, 32; Alexander-Scott Decl. (RI) ¶ 11; Walker Harris Decl. (VA) ¶ 4; Gillespie Decl. (WI) ¶¶ 27, 29-30; Handler Decl. (NV) ¶¶ 7-9; Holmes Decl. (VT) ¶ 18; Wilson Decl. (NC) ¶ 12; Anderson Decl. (HI) ¶ 19; Stephens Decl. (DE) ¶¶ 19-20, 23; Drew Decl. (MA) ¶ 19; Reece Decl. (CO) ¶ 16.

[8] Rimberg Decl. (OR) ¶¶ 40-43, 48; Byrd Decl. (DC) ¶¶ 6-7, 9; Gallagher Decl. (VT) ¶¶ 24-25; Gillespie Decl. (WI) ¶ 30; Handler Decl. (NV) ¶ 9; Holmes Decl. (VT) ¶ 18; Keenan Decl (CT) ¶¶ 8, 10-11; Rattay Decl. (DE) ¶¶ 20-21, 23-25; Brandt Decl. (MN) ¶¶11-12; Charest Decl. (MI) ¶ 7; Cooke Decl. (MA) ¶ 13; Lightner Decl. (IL) ¶ 32.

III. Argument

To obtain a preliminary injunction, Plaintiffs must establish that "(1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of the equities tips in their favor; and (4) an injunction is in the public interest." *Short v. Brown*, 893 F.3d 671, 675 (9th Cir. 2018) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). When the federal government is a party, the last two factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). The Ninth Circuit weighs these factors on a sliding scale, such that where there are only "serious questions going to the merits" a preliminary injunction may still issue so long as "the balance of hardships tips *sharply* in the plaintiff's favor" and the other two factors are satisfied. *Shell Offshore, Inc. v. Greenpeace, Inc.*, 709 F.3d 1281, 1291 (9th Cir. 2013) (citation omitted).

Alternatively, the Administrative Procedures Act ("APA") empowers courts "to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. Courts have concluded that the standard for such a stay is the same as the standard for a preliminary injunction. *See, e.g.*, *Bauer v. DeVos*, 325 F. Supp. 3d 74, 104-05 (D.D.C. 2018) (citing cases).

A. Plaintiffs are likely to succeed on the merits.

The APA provides that courts must "hold unlawful and set aside" agency action that is "not in accordance with law"; "in excess of statutory jurisdiction, authority, or limitations"; "arbitrary, capricious, [or] an abuse of discretion"; or "without observance of procedure required by law." 5 U.S.C. §§ 706(2)(A), (C), (D). The APA requires this Court to conduct "plenary review of the Secretary's decision," which is to be "thorough, probing, [and] in-depth." *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 415, 420 (1971). Plaintiffs are likely to succeed on the merits of their claims because the Final Rule fails to meet both the substantive and the

procedural requirements of the APA.

1. The Final Rule is not in accordance with law.

The Final Rule is "not in accordance with law" and is "in excess of statutory jurisdiction, authority, or limitations," 5 U.S.C. §§ 706(2)(A), (C), because (a) the gag requirement contravenes the Nondirective Mandate that has been included in every appropriations statute funding HHS since 1996; and (b) the gag and separation requirements both violate a core provision of the Affordable Care Act that forbids HHS interference in the provision of medical care and in communications between medical providers and their patients.

This Court may preliminarily enjoin the Final Rule if the Rule is contrary to law. *See E. Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1248, 1256 (9th Cir. 2018) (denying government's motion for stay of temporary restraining order prohibiting enforcement of agency rule pending appeal); *E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094 (N.D. Cal. Dec. 19, 2018) (granting preliminary injunction against implementation of rule). As the Supreme Court made clear in *Chevron, U.S.A., Inc. v. NRDC*, "if Congress has directly spoken to the precise question at issue . . . that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." 467 U.S. 837, 842-43 (1984); *see also City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013) (in determining whether an agency action is in excess of statutory authority, "the question . . . is always whether the agency has gone beyond what Congress has permitted it to do").

a. The gag requirement is contrary to the Nondirective Mandate.

Plaintiffs are likely to succeed on the merits of their APA claim because the gag requirement contravenes express statutory language that has constrained the Department's administration of the Title X program from 1996 to the present. The appropriations statute that funds HHS requires, in connection with the Title X program, that "all pregnancy counseling be

nondirective." 2019 Health & Human Servs. Appropriations Act, 132 Stat. at 3070-71. Congress included this Nondirective Mandate in each preceding appropriations statute dating to 1996. *See supra* Part II.A.2; Complaint ¶ 51. Since 1981, HHS has defined nondirective counseling to mean a neutral presentation of all pregnancy options, including information on prenatal care, adoption, and abortion, as well as referrals on request. *See* Complaint ¶¶ 44-51; *see also* 42 C.F.R. § 59.5(a)(5). It is this well-established definition of nondirective counseling that Congress incorporated in 1996. *See* Consolidated Rescissions and Appropriations Act of 1996. And since the 2000 regulations were promulgated, Congress has repeatedly reenacted the Nondirective Mandate, ratifying the Department's construction of that mandate as codified by the 2000 Rule.

This construction is consistent with clinical guidance and codes of ethics in the relevant medical professions. Leading medical organizations have adopted both clinical and ethical guidelines that require unbiased and complete pregnancy options counseling and appropriate referrals upon request.[9] Additionally, clinical guidelines issued in 2014 by the Centers for Disease Control and HHS's Office of Population Affairs ("OPA")—the office charged with administering Title X—recommend comprehensive nondirective counseling by endorsing the ethical and clinical standards of leading medical organizations.[10] The 2014 guidelines also urge providers that "[e]very effort should be made to expedite and follow through on all referrals."[11]

[9] *See, e.g.*, AMA Ltr. 2; ACOG Ltr. 6; AAN Ltr. 4; Guttmacher Ltr. 7-8.

[10] Loretta Gavin, Susan Moskosky, et al., Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs, Morbidity and Mortality Weekly Report, 63 Recommendations and Reports No. 4, 13 (April 25, 2014) ("QFP").

[11] *Id.* at 14.

The Final Rule contravenes the statutory Nondirective Mandate in multiple ways. The Final Rule does not require nondirective pregnancy counseling, but rather purports to make it optional. *See* 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)). Further, the "nondirective counseling" in the Final Rule is actually directive counseling slanted in favor of pregnancy continuation. Numerous provisions of the Final Rule make that clear.

First, the Final Rule mandates directive counseling towards carrying a pregnancy to term and away from abortion care by prohibiting referral for abortion care and *requiring*—in every case—referral of a pregnant patient for prenatal care. *Id.* at 7788-89 (to be codified at 42 C.F.R. § 59.14(a), (b)(1)). *This is true regardless of the patient's request*. The Final Rule in this respect is plainly inconsistent with the statutory Nondirective Mandate. The Final Rule does not satisfy the Nondirective Mandate by allowing providers to provide a list of "comprehensive primary health care providers" to pregnant patients that may, but is not required to, contain abortion care providers. As noted above, any list given to the patient need not contain any providers that offer abortion care and, if the list does include abortion providers, these providers must comprise less than half the providers on the list and must not be identified in any way as providers of abortion care. The list must, in other words, conceal from patients seeking abortion care the identity of providers actually offering that care. *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(c)(2)). This is inconsistent with the Nondirective Mandate.

Second, the Final Rule affirmatively permits directive counseling towards pregnancy continuation. It would allow providers *not* to provide what HHS now calls "nondirective pregnancy counseling" and instead to provide only a list of prenatal care providers, "referral to social services or adoption agencies," and "information about maintaining the health of the mother and unborn child during pregnancy," even when the pregnant patient has decided to

pursue abortion care and requests a referral. *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)(ii)-(iv)). It also limits all manner of activities relating to abortion, including "counseling . . . as an indirect means of encouraging or promoting abortion as a method of family planning." *Id.* at 7789 (to be codified at 42 C.F.R. § 59.16(a)). Even making a brochure available about a clinic that provides abortion care would violate this provision. *Id.* at 7790 (to be codified at 42 C.F.R. § 5.16(b)(1)). This is plainly inconsistent with the Nondirective Mandate.

Third, to the extent pregnancy options counseling is permitted by the Final Rule, the Final Rule adds a restriction that only a limited subset of providers may provide it. The Final Rule provides that only physicians and other "advanced practice providers" may provide "nondirective pregnancy counseling." *Id.* at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)(i)). As a result, a sizeable portion of providers currently providing nondirective pregnancy counseling would not be permitted to continue to do so.[12] In Oregon, for example, about 33 percent of the nondirective pregnancy counseling is currently provided by registered nurses who are not APPs. Rimberg Decl. (OR) ¶ 30. Limiting the provision of nondirective pregnancy counseling to a subset of qualified providers, but allowing, without limitation, the provision of directive counseling in favor of pregnancy continuation, is contrary to the Nondirective Mandate.

Finally, the pregnancy counseling that HHS claims is "nondirective" and that *is* purportedly permitted is not consistent with the Nondirective Mandate. HHS directs that "abortion must not be the only option presented" and also that "[p]hysicians or APPs should

[12] HHS, Office of Population Affairs, *Title X Family Planning Annual Report: 2017 National Summary*, at 4 (Aug. 2018); *accord* Alifante Decl. (NJ) ¶ 28 ; Gillespie Decl. (WI) ¶ 28; David Decl. (NY) ¶¶ 42-44; Gallagher Decl. (VT) ¶ 6; Handler Decl. (NV) ¶ 11; Wilson Decl. (NC) ¶ 26; Anderson Decl. (HI) ¶ 12; Walker Harris Decl. (VA) ¶ 23.

discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented." 84 Fed. Reg. at 7747. The HHS redefinition of "nondirective" pregnancy counseling thus requires health care providers to disregard the requests of patients who only want counseling and information on abortion care in favor of governmentally mandated speech to the contrary.

The Final Rule violates the unambiguously expressed intent of Congress to require pregnancy counseling that is actually nondirective; indeed, the Rule expressly *prohibits* the nondirective counseling that the statute requires. For that reason, the States are likely to prevail on their claim that the Final Rule is contrary to law.

b. The gag and separation requirements contravene the Affordable Care Act.

The Final Rule is also directly contrary to key provisions of the ACA and in excess of HHS's statutory authority. 5 U.S.C. § 706(2)(A), (C). The ACA's plain text could not be clearer: It expressly prohibits HHS from issuing regulations that interfere with full and frank communications with medical providers and the provision of appropriate medical care. 42 U.S.C. § 18114(1)-(4). The ACA also prohibits regulations that violate principles of informed consent and the ethical standards of medical professionals. 42 U.S.C. § 18114(5). These provisions were designed to prevent exactly the type of agency rules at issue here: rules that annihilate long-standing protections for patients that entitle them to receive comprehensive medical advice. The gag requirement, the separation requirements, and the changes to the scope of the Title X program are all contrary to § 18114.

i. The gag requirement interferes with the provider-patient relationship and violates principles of informed consent.

First, the gag requirement contravenes at least five of the six subsections of 42 U.S.C. § 18114. By allowing health care providers to withhold requested medical information from

pregnant clients and prohibiting referrals for abortion care, the Final Rule has the effect of creating an unreasonable barrier to abortion care in violation of 42 U.S.C. § 18114(1). The Final Rule requires providers to answer a request for an abortion referral with a confusing and potentially misleading list, and the rule requires referrals of *all* pregnant women for prenatal and/or social services, regardless of whether they intend to continue their pregnancy. 84 Fed. Reg. at 7789 (to be codified at 52 C.F.R. § 59.14(b)).[13] These provisions will erect a barrier to accessing abortion care because providers will be unwilling to violate standards of professional ethics. For these same reasons, the Final Rule impedes timely access to services contrary to 42 U.S.C. § 18114(2)—indeed that appears to be the entire purpose of providing a list that conceals the identity of abortion care providers. The Final Rule's restrictions on counseling and referrals for abortion care would thus delay access to abortion care for those seeking that care.[14]

In addition, for all the reasons discussed, the gag requirement does—actually—gag providers. The Final Rule, therefore, "interferes with communications regarding a full range of treatment options between the patient and the provider," 42 U.S.C. § 18114(3), and "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," 42 U.S.C. § 18114(4).[15]

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[13] *Accord* PPFA Ltr. 14; Guttmacher Ltr. 7.

[14] ACOG Ltr. 5-6.

[15] In addition, the Final Rule requires providers to actively "encourage family participation" in the health services provided to minors, regardless of state laws that expand access to family planning services for minors. This requirement, which has only very narrow exceptions, is an unreasonable barrier to the ability of teenagers to obtain confidential medical care, interferes with the communication regarding treatment options between Title X providers and their patients, and will delay access to care. 84 Fed. Reg. 7717-18, 7787; *see* Byrd Decl. (DC) ¶ 8; Zoll Decl. (MA) ¶ 14.

For similar reasons, the gag requirement also violates 42 U.S.C. § 18114(5) by violating the principles of informed consent. Comments by the Guttmacher Institute explain that "Title X's long-standing counseling requirements . . . are essential to ensuring informed consent in reproductive health care—a bedrock principle of modern medical practice in the United States deeply rooted in legal, ethical, and medical standards developed over the course of decades." Guttmacher Ltr. 7.

The Final Rule similarly violates 42 U.S.C. § 18114(5) because it would require health care providers to violate their professions' ethical standards.[16] For example, the American College of Obstetricians and Gynecologists explains that physicians have an ethical obligation to "provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner, including raising the child herself, placing the child for adoption, and abortion." ACOG Ltr. 6. Similarly, the nurses' code of ethics indicates that "patients have the right 'to be given accurate, complete, and understandable information in a manner that facilitates an informed decision.'" AAN Ltr. 4. The American Academy of Nursing explains that this requires nurses to "share with the client all relevant information about health choices that are legal and to support that client regardless of the decision the client makes." *Id.* The biased and incomplete information required by the Final Rule would violate these standards.

For these reasons, the Final Rule's gag requirement is contrary to the ACA.

ii. The physical separation requirements create unreasonable barriers to medical care.

The Final Rule's separation requirements, 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15), also "create[] . . . unreasonable barriers to the ability of individuals to obtain

[16] *See* ACOG Ltr. 3-5; PPFA Ltr. 11 (citing standards of professional ethics).

appropriate medical care" and "impede[] timely access to health care services." 42 U.S.C. § 18114(1), (2). The separation requirements would create substantial impediments to accessing Title X services because they would require providers to implement onerous and extensive physical separation from all abortion-related activities. *See* 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.15). Providers would have to open a second clinic that does not share any of the same overhead services with their principal locations in order to continue Title X funding. Those who cannot afford the costs of doubling their expenditures may have no choice but to withdraw from the program.[17]

The separation requirements violate the ACA by depriving patients of access to providers. Effectively, the separation requirements target providers that have a demonstrated history of successfully delivering family planning services to their communities and jeopardize continuity of care for patients with existing relationships with Title X providers.[18] This is especially problematic because, "[f]or many clients, Title X providers are their only ongoing source of health care and health education."[19] Many clients also rely on Title X providers for testing and treatment related to sexually transmitted diseases as well as routine gynecological and breast cancer screenings.[20] The existing network of providers would be decimated by the separation requirements because "[o]ver forty percent of all services provided to Title X eligible

[17] Kost Decl. ¶¶ 102-104; Darney Decl. ¶ 18.

[18] *See* Tobias Decl. (NY) ¶¶ 44-45; David Decl. (NY) ¶ 41; Gillespie Decl. (WI) ¶ 25, 29; Handler Decl. (NV) ¶ 8; Holmes Decl. (VT) ¶ 18; Kunkel Decl. (NM) ¶¶ 22-25.

[19] HHS, Office of Population Affairs, Title X Family Planning Annual Report, 2016 National Summary, at ES-1 (Aug. 2017).

[20] AMA Ltr. 5.

recipients are provided by agencies that may also provide abortion . . . ."[21] Promulgating rules that deprive patients of medical care directly contravenes each provision of 42 U.S.C. § 18114.

Moreover, the separation requirements would effectively ensure that the majority of providers that do remain in the Title X program refrain from offering abortion counseling or referral services because to do so would trigger separation obligations that are simply too onerous for many providers to feasibly handle.[22] Thus, the separation requirements would deprive patients of both complete information and appropriate and available care–violating the ACA's requirement that HHS refrain from interfering with the communications between health care providers and their clients. 42 U.S.C. § 18114(1), (3), (4), (5).

iii. The Final Rule will decrease access to medically-approved family planning.

Additionally, the Final Rule would effectively deprive patients of evidence-based care, in violation of 42 U.S.C. § 18114(1) and (5). The Final Rule deemphasizes comprehensive contraceptive care that includes the full range of FDA-approved contraceptive methods. Under current rules, all Title X projects must "[p]rovide a broad range of acceptable and effective medically [i.e., FDA] approved family planning methods." 42 C.F.R. § 59.5(a)(1). The Final Rule removes "medically approved" from this provision. 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.5(a)(1)). This change would increase the participation of providers who provide less effective methods of contraception.[23] Indeed, the Final Rule adopts a definition of "family planning" that emphasizes fertility-based awareness methods (specifically, natural family planning) and permits Title X projects not to provide "every acceptable and effective family

[21] CBD Ltr. 2; *accord* ACOG Ltr. 11.

[22] *See* Alexander-Scott Decl. (RI) ¶ 19; Alifante Decl. (NJ) ¶ 30; Gillespie Decl. (WI) ¶ 29; Kunkel Decl. (NM) ¶ 23; Schaler-Haynes Decl. (NJ) ¶ 39; Wilson Decl. (NC) ¶¶ 37-38.

[23] Guttmacher Ltr. 15.

planning method or service." 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.2)). Numerous comments to the proposed rule explained that these changes would narrow the scope of methods and services available for patients under Title X by making it less likely that the full range of medically-approved contraceptives, including the most effective methods, remain available to those who need them.[24] By allowing funding for projects that have a limited non-evidence-based scope, while at the same time deemphasizing the need to offer a legitimately broad range of options, the Final Rule represents the kind of restriction and barrier that 42 U.S.C. § 18114 was designed to prevent. As HHS itself has recognized, "[c]ontraceptive services should include consideration of a full range of FDA-approved contraceptive methods."[25]

For all these reasons, Plaintiffs are likely to prevail on their claim that the Final Rule is contrary to the ACA and should be vacated on those grounds.

2. The Final Rule is arbitrary and capricious in violation of the APA.

Under the APA, the Court must "hold unlawful and set aside" agency action that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). Plaintiffs are likely to prevail on their claim that the Final Rule is arbitrary and capricious.

The APA requires an agency to engage in "reasoned decisionmaking" that rests on a "logical and rational" "consideration of the relevant factors." *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2706 (2015). Generally, to survive an arbitrary and capricious challenge, an agency must articulate a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43. Where an agency reverses a prior policy, however, it must provide "a more detailed justification than what would suffice for a new policy created on a blank slate." *FCC v. Fox*

[24] *See, e.g.*, AMA Ltr. 3-4; ACOG Ltr. 8-11; AAFP Ltr. 2; Guttmacher Ltr. 1-3.
[25] QFP at 7.

Television Stations, 556 U.S. 502, 515 (2009). In such circumstances, an agency acts arbitrarily and capriciously when it fails to offer a "reasoned explanation" for changing course, *State Farm*, 463 U.S. at 41-42, or refuses to consider "when its prior policy has engendered serious reliance interests," *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015).

In promulgating the gag requirement, the separation requirements, and the changes to the scope of the program, HHS disregards substantial evidence that the changes will diminish access to affordable and reliable reproductive-health-related services.

a. The Supreme Court's holding in *Rust v. Sullivan* does not give HHS license to revive outdated and irrelevant regulations.

First, HHS's revival of the gag and the separation requirements from the 1988 Regulations, without consideration of the experience and expertise over the last three decades from the Department itself, Title X grantees, or the leading organizations in the medical community, is arbitrary and capricious. HHS does not articulate new findings or information to support its promulgation of the gag and separation requirements. Instead, the Department relies heavily on the Supreme Court's decision in *Rust*, 500 U.S. at 189, which rejected the argument that the 1988 Regulations were arbitrary and capricious in violation of the APA. *See* 84 Fed. Reg. at 7766 ("Nothing in the [APA] precludes the Department from re-adopting regulatory provisions that it had previously adopted, successfully defended in court, and then rescinded."); *see generally id.* at 7714-86 (citing *Rust* 25 times). The holding in *Rust* on whether the 1988 Regulations were arbitrary and capricious, however, focuses on the process behind, not the substance of, the 1988 Regulations and (even setting aside the post-*Rust* enactment of the Nondirective Mandate and the ACA) does not insulate the gag or separation requirements in the Final Rule from challenge.

In 1988, HHS issued gag and separation provisions similar to those in the Final Rule primarily based on findings that the Government Accountability Office ("GAO") and the Office of the Inspector General ("OIG") published in 1982. *See* 53 Fed. Reg. 2922-24 (Feb. 2, 1988). The decision in *Rust* upheld HHS's reliance on the results from these "critical reports" for the 1988 Regulations. *See Rust*, 500 U.S. at 189. The *Rust* Court's holding has little bearing, however, on the question of whether HHS may rely, decades later, on that same information to reinstate the gag and separation requirements without regard to more recent developments. What served as a rational basis for the provisions in 1988 does not maintain that status indefinitely; survey results from a small set of Title X grantees in 1982 have limited applicability in 2019. *See Sierra Club v. E.P.A.*, 671 F.3d 955, 966 (9th Cir. 2012) (an agency stands on "shaky legal ground relying on significantly outdated data, given the amount of time that [new information] was available" before it acted). The decision in *Rust* does not give HHS license to blind itself to Title X's changing landscape.

In the 37 years since the GAO and OIG issued their reports, HHS has determined that the facts and assumptions supporting the 1988 gag and separation requirements were either incorrect or no longer relevant. As discussed *infra* III.A.2.b and III.A.2.c, recent evidence shows that the provisions are not only unnecessary to comply with Title X requirements, but also impose deleterious burdens on providers and beneficiaries. HHS's failure to take into account updated information about grantees' experience with Title X is arbitrary and capricious.

b. The gag requirement is arbitrary and capricious.

HHS's departure from its longstanding policy requiring healthcare professionals to provide nondirective pregnancy counseling is arbitrary and capricious. *See supra* III.A.1.a. HHS previously concluded that similar restrictions on counseling and referrals "endanger[ed] women's lives and health" and "interfere[d] with the doctor-patient relationship." 65 Fed. Reg. at

41271. HHS's abrupt reversal of course ignores its own experience in implementing Title X for decades, as well as the evidence commenters submitted, which demonstrate that the counseling and referrals for abortion do not encourage or promote abortion as a method of family planning. Furthermore, the Department disregards the consensus from leading medical organizations that the gag requirement contravenes the providers' ethical requirements and would force providers to either deliver substandard care or to withdraw from the program. There is no rational basis to support the gag rule.

(1) Mandatory referrals for prenatal care are coercive and not medically necessary. The Final Rule's directive mandating referral of all pregnant clients to prenatal care lacks sufficient justification. *See* 84 Fed. Reg. at 7789 (to be codified at 42 C.F.R. § 59.14(b)(1)). The Department has previously explained that if "projects were to counsel on an option even where a client indicated that she did not want to consider that option, there would be a real question as to whether the counseling was truly nondirective or whether the client was being steered to choose a particular option." 65 Fed. Reg. at 41273. In particular, HHS found that "requiring a referral for prenatal care" was "coercive" and "inconsistent" with the nondirective requirement. *Id.* at 41275.

HHS pays lip service to the importance of nondirective counseling under Title X, *see* 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.2) ("services are never to be coercive and must always be strictly voluntary"), yet mandates prenatal care referrals for all pregnant patients. *See* 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.14(b)(1)). HHS defines referrals for prenatal care, regardless of the views of the patient, as "nondirective" because they are "medically necessary." *Id.* at 7760. As an initial matter, HHS creates an untenable and internally inconsistent definition of referrals as simultaneously directive and nondirective: the

Final Rule characterizes unsolicited and mandatory referrals as nondirective in the prenatal care context, yet considers patient-requested referrals to be directive in the abortion context. *See* *Alliance for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1116-17 (9th Cir. 2018) (finding an agency's new definition of an existing term to be arbitrary and capricious where the new and existing definitions were internally inconsistent); *Arizona Cattle Growers' Ass'n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1242 (9th Cir. 2001) (an agency's position that is contrary to the "plain meaning of the statute" is arbitrary and capricious). Additionally, in support of its stated justification that prenatal care is "medically necessary" for all pregnant women even if they seek termination, HHS cites two sources that only explain the value of prenatal care to attaining positive birth outcomes among low-income women. *See* 84 Fed. Reg. at 7762 nn. 99, 100. These studies do not provide a rational basis for the conclusion that prenatal care is necessary or desirable for women seeking abortions. *See* *S. Yuba River Citizens League v. Nat'l Marine Fisheries Serv.*, 723 F. Supp. 2d 1247, 1256 (E.D. Cal. 2010) ("Even for scientific questions . . . a court must intervene when the agency's determination is counter to the evidence or otherwise unsupported.") (citing *Sierra Club v. E.P.A.*, 346 F.3d 955, 961 (9th Cir. 2003)).

(2) Referrals do not promote or encourage abortion. There is no rational basis for prohibiting providers from offering referrals upon the patient's request. HHS has specifically found, based on its experience and the expertise of providers, that referrals did "little, if anything, to encourage or promote the selection of abortion as a method of family planning." 65 Fed. Reg. at 4125. HHS provides no evidence to the contrary. *See supra* III.A.1.a (HHS itself and leading medical organizations consider referrals upon request to fall within the well-established definition of "nondirective counseling"). In the absence of reasoned analysis for revoking its prior rule, HHS's restrictions on referrals are arbitrary and capricious. *See* *Fox*

Television, 556 U.S. at 516 (noting that "a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy").

(3) Limiting who can provide pregnancy counseling is irrational. HHS is similarly unable to justify its requirement that medical professionals hold advanced degrees in order to provide pregnancy counseling. This change, which excludes a substantial proportion of provider personnel from giving counseling on all options for pregnant patients, lacks evidentiary support or even a purported rationale. HHS acknowledges that the "nondirective" counseling on abortion care the Rule authorizes complies with Title X's restriction on funding abortion for family planning purposes. *See* 84 Fed. Reg. at 7724, 7760. HHS is also aware that a large percentage of participants currently provide nondirective pregnancy counseling through nurses and medical assistants.[26] Yet, it nonetheless would prohibit a large section of the provider community from offering this crucial service.

HHS does not offer any reason for this limitation. HHS does not contend, nor is there any evidence to support the view, that pregnancy counseling requires specialized medical knowledge or that professionals without advanced degrees are unsuited to offer counseling in some other respect.[27] *See* *King Cty. v. Azar*, 320 F. Supp. 3d 1167, 1177 (W.D. Wash. 2018) ("HHS's failure to articulate *any* explanation for its action, much less a reasoned one based on relevant factors, exemplifies arbitrary and capricious agency action meriting reversal."). The gag requirement creates an irrational distinction between two categories of personnel, all of whom are qualified to give nondirective pregnancy counseling. *See* *Hicks v. Comm'r of Soc. Sec.*, 909

[26] AAN Ltr. 3 (nurse practitioners constitute 75 percent of clinicians at Planned Parenthood sites).

[27] *See* CA Ltr. 8; Alifante Decl. (NJ) ¶¶ 8, 28; Gallagher Decl. (VT) ¶ 6; Gillespie Decl. (WI) ¶ 28; Handler Decl. (NV) ¶ 11.

F.3d 786, 808 (6th Cir. 2018) (agency's distinctions between two classes of individuals must be based on sufficient justifications).

(4) Current regulations do not conflict with federal conscience statutes. As a rationale for the sweeping gag requirement, HHS offers speculative concerns about the current rule's consistence with federal conscience laws. Title X's facially neutral provisions do not conflict, however, with conscience statutes, which act as a shield against religious discrimination, not a sword to strike down neutral and generally applicable laws. *See generally* 83 Fed. Reg. at 3880 (addressing anti-discrimination provisions of conscience laws); *see also* 84 Fed. Reg. at 7747 (recognizing that Title X has coexisted with federal conscience laws for 40 years). Furthermore, OPA has confirmed that it "would not enforce [the] Title X regulatory requirement on objecting grantees or applicants," 83 Fed. Reg. at 25506 (quoting 73 Fed. Reg. at 78087), and that it is already responsible for ensuring that Title X grantees comply with federal conscience laws. 84 Fed. Reg. at 7747.

HHS offers no explanation or basis to conclude that these robust compliance mechanisms are insufficient. Indeed, HHS fails to provide a single example of a complaint about a Title X grantee's violation of conscience laws, and does not supply any other basis for concluding that the two sets of laws conflict. It is arbitrary and capricious for HHS to finalize significant changes to the rule to address a nonexistent problem. *See State Farm*, 463 U.S. at 43 (an agency may not "offe[r] an explanation for its decision that runs counter to the evidence before [it]"); *Nat'l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 841 (D.C. Cir. 2006) (agency rule was arbitrary and capricious where agency lacked any evidence to support key factual conclusion).

(5) The gag requirement undermines the provider-patient relationship. HHS failed to consider substantial evidence that the Final Rule would undermine the provider-patient

relationship by coercing medical professionals to violate their medical ethics standards and offer substandard care, in violation of OPA's own 2014 clinical guidelines. In order to avoid giving compromised care to patients, many grantees and subgrantees, including Planned Parenthood, have explained that they will no longer be able to participate in the program when the gag requirement becomes effective, which will unravel the current network of the Title X providers.[28] The resulting reduction of eligible providers would cause profound harm to the program's beneficiaries because, as explained above, *supra* III.A.1.b.iii, many clients rely on Title X providers as their only ongoing source of health care and education.[29] *See also infra* III.B.1.

Without explanation, HHS failed to consider the serious consequences that commenters have highlighted. *See State Farm*, 463 U.S. at 43 (an agency's failure to "consider an important aspect of the problem" renders a decision arbitrary and capricious); *see also Stewart v. Azar*, 313 F. Supp. 3d 237, 263 (D.D.C. 2018) (vacating HHS's regulations and explaining that "the Secretary never once *mentions* the estimated 95,000 people who would lose coverage, which gives the Court little reason to think that he seriously grappled with the bottom-line impact on healthcare") (emphasis in original). HHS summarily concludes that the rule does not "require health care professionals to violate medical ethics," 84 Fed. Reg. at 7748, and, in any case, that "information about abortion and abortion providers is widely available and easily accessible, including on the internet," *id.* at 7746. This is a stunning position: HHS is suggesting that,

[28] Commenters explained that providers would have to withdraw, and as a result, beneficiaries would have significantly reduced access to care. WA Ltr. 23-25; NY Ltr. 8-9; NY DOH Ltr. 1; CA Ltr. 10-11, 14; AMA Ltr. 4; ACOG Ltr. 10-13; AAN Ltr. 2-3; AAP Ltr. 1; PPFA Ltr. 13, 15-16; Guttmacher Ltr. 9-12.

[29] WA Ltr. 4, 6-9; NY Ltr. 2-4; NY DOH Ltr. 1; CA Ltr. 12, 15-16; AMA Ltr. 5; ACOG Ltr. 1-2; AAN Ltr. 3; PPFA Ltr. 1-2, 17-19; Guttmacher Ltr. 12-13.

rather than rely on trained health care professionals for counseling, patients seeking access to a legal medical procedure should instead surf the Internet for information.

In any event, HHS does not provide citations to these allegedly available and accessible resources, let alone evidence-based, reliable resources. *See* Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2126 (2016) (a "summary discussion" offering "barely any explanation" does not suffice for APA purposes where an agency is overruling a long-held previous policy). HHS also arbitrarily failed to consider the costs associated with either delays in receiving abortion services, which will force more women to carry unwanted pregnancies to term or undergo riskier abortions, or the withdrawal of current providers from the program, which will destabilize the Title X network.[30] This refusal to quantify or fully explain the financial implications of the gag requirement is arbitrary and capricious. *See* *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agencies must "adequately analyze . . . the consequences" of their actions); *Nat'l Ass'n of Home Builders v. E.P.A.*, 682 F.3d 1032, 1039-40 (D.C. Cir. 2012) (an agency's reliance on a cost-benefit analysis that drastically underestimates the costs is arbitrary and capricious).

c. The physical separation requirements are arbitrary and capricious.

The Final Rule is arbitrary and capricious because it imposes onerous and irrational separation requirements on Title X providers that engage in abortion-related activities outside the Title X program. These separation requirements represent a radical departure from the Department's established policy of mandating financial, but not physical, segregation between a

[30] Commenters explained the social and financial consequences of reduced access to Title X providers. WA Ltr. 22-27; NY Ltr. 8-10; NY DOH Ltr. 1; CA Ltr. 10-16; AMA Ltr. 1-4; ACOG Ltr. 8-13; AAN Ltr. 2-3; AAP Ltr. 1; PPFA Ltr. 15-22; Guttmacher Ltr. 1-3. 7-18.

provider's abortion- and non-abortion-related facilities. *See* 65 Fed. Reg. 41276. HHS offers no reasoned analysis or substantiating evidence, but argues that these changes are necessary to ensure that grantees do not use, or appear to use, Title X funds for improper purposes. *See* 83 Fed. Reg. at 25507. In reaching this conclusion, however, HHS disregards findings from both its own auditors and state grantees that providers comply with Title X funding segregation requirements.

HHS does not identify any recent evidence or studies suggesting that grantees are improperly using Title X funds, are confused about proper segregation procedures, or otherwise need guidance on this issue. To the contrary, the record demonstrates that HHS and grantees have effectively established robust monitoring and auditing procedures that protect program integrity demands. OPA reported to the Congressional Research Service in 2017 and 2018 that Title X projects are "closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion."[31] Additionally, many state grantees have developed additional oversight mechanisms.[32] None of these numerous internal and external reviews revealed evidence of misuse or comingling of funds.[33] The Department's

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[31] Angela Napili, Cong. Research Serv., RL 33644, *Title X (Public Health Service Act) Family Planning Program* at 22 (Aug. 31, 2017); Angela Napili, Cong. Research Serv., R 45181, *Family Planning Program under Title X of the Public Health Service Act* at 14 (Apr. 27, 2018). Both reports explain that HHS's monitoring includes "(1) careful review of grant applications . . . (2) independent financial audits. . . (3) yearly comprehensive reviews of the grantees financial status and budget report; and (4) periodic and comprehensive program reviews and site visits by OPA regional offices." *Id.*

[32] WA Ltr. 17-19; NY Ltr. 4-6; CA Ltr. 19-20; Rimberg Decl. (OR) ¶¶ 31-26; Tobias Decl. (NY) ¶¶ 29-37; Alifante Decl. (NJ) ¶¶ 9-10; Walker Harris Decl. (VA) ¶ 20; Gillespie Decl. (WI) ¶ 8; Holmes Decl. (VT) ¶¶ 15-17; Kunkel Decl. (NM) ¶¶ 15-20; MacNaughton Decl. (MA) ¶ 7; Drew Decl. (MA) ¶ 8; Zoll Decl. (MA) ¶ 4; Preiss Decl. (MA) ¶ 7; Camp Decl. (CO) ¶ 21.

[33] Despite access to years of its own audit data, HHS identified only one example of Title X funding misuse two decades ago. 83 Fed. Reg. at 25509. Of the handful of examples that HHS offered of funding comingling, almost all involved irrelevant and outdated findings of allegedly

alleged concerns about Title X's program integrity requirements are not only speculative but also run contrary to the evidence before it. *See* *Planned Parenthood of Greater Washington & N. Idaho v. U.S. Dep't of Health & Human Servs.*, 328 F. Supp. 3d 1133, 1148-49 (E.D. Wash. 2018) (HHS's reversal of course on its project funding was arbitrary and capricious where "HHS's various stated rationales fail to take account of all the evidence before it and ignore the facts in favor of the Administration's political agenda," and "HHS's claim that the TPP Program as a whole was ineffective, is contradicted by the demonstrated evidence of the Program's success and HHS's own positive statements about the Program").

In addition to ignoring the evidence about use of Title X funds, HHS also failed to consider the reliance interests of both current providers and of patient beneficiaries.[34] The Final Rule will impose severe financial hardship on grantees and subgrantees that will drive providers out of the program.[35] As described *infra* III.B.1 and III.B.2, the reduction in service will have consequences on all aspects of reproductive health for low-income clients, from access to contraception and abortion to screening and treatment for sexually transmitted infections.[36]

HHS does not give serious consideration to the magnitude of these costs and summarily concludes that the changes to the rule will not "have a significant impact on access to services." 84 Fed. Reg. at 7782. Although HHS acknowledges that some providers may have to "relocate

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improper Medicaid billing practices. *Id.*; *accord* Rimberg Decl. (OR) ¶ 36.

[34] Commenters described the burden that the separation requirements would impose on current providers. WA Ltr. 23-27; NY DOH Ltr. 17-20; CA Ltr. 10-11; PPFA Ltr. 26-40; Guttmacher Ltr. 9-12.

[35] Several state grantees, in addition to Planned Parenthood sites, would have to withdraw from the program immediately due to both ethical concerns from the gag requirement and the burden of the separation requirements. WA Ltr. 23-25; NY Ltr. 8-9; CA Ltr. 10-12; AMA Ltr. 4; ACOG Ltr. 11-13; PPFA Ltr. 15; Guttmacher Ltr. 1-9, 19-20.

[36] WA Ltr. 23-26; NY Ltr. 8-9, 12-13; CA Ltr. 10-12; AMA Ltr. 4; ACOG Ltr. 11-13; AAN Ltr. 2-3; PPFA Ltr. 16-19; Guttmacher Ltr. 9-1, 19-20.

in response to the new [physical separation] requirement," it estimates that affected providers will only spend an average of between $20,000 and $40,000 to comply with the rule. *Id.* at 7781-82. The Department does not, however, offer any basis for its financial analysis, which differs drastically from estimates commenters have submitted.[37] Planned Parenthood, for example, estimates that the average expenditure would be $625,000 per provider.[38] HHS's disregard of reliance interests, in addition to its flawed financial analysis, is arbitrary and capricious. *See Fox Television Stations, Inc.*, 556 U.S. at 515 (an agency must provide a more detailed justification for a changed policy when prior policy "has engendered serious reliance interests"); *see also Regents of Univ. of California v. U.S. Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1045 (N.D. Cal. 2018) (agency action arbitrary and capricious where "[t]he administrative record includes no consideration to the disruption" it would cause).

d. Elimination of requirements to provide medically-approved contraceptive care is arbitrary and capricious.

HHS's abandonment of Title X's protection for medically-approved contraceptive care does not rest on a rational basis. The Final Rule makes two major changes to established Title X policies: (i) eliminating the requirement that family planning methods offered be "medically approved," and (ii) emphasizing "natural family planning" over contraceptive care. HHS does not provide adequate explanation for enacting changes that significantly dilute the quality and scope of Title X services.

[37] PPFA Ltr. 30-31; *see also* NY Ltr. 20-21; CA Ltr. 23; Letter from Clare Coleman, President & CEO, Nat'l Family Planning & Reprod. Health Ass'n, to Diane Foley, Deputy Assistant Sec'y for Population Affairs, U.S. Dep't of Health & Human Servs., at 37 (July 31, 2018), (estimating costs at $300,000 per site at the low end).

[38] PPFA Ltr. 32.

As described *supra* III.A.1.b.iii, the current rules protect the patients' ability to learn about and obtain a range of medically-approved contraceptive methods. The Final Rule alters this policy by promoting natural family planning options, regardless of their acceptance in the medical community, and weakening the focus on FDA-approved contraceptive care. 84 Fed. Reg. at 7787 (to be codified at 42 C.F.R. § 59.2). HHS provides a definition of family planning that disproportionately highlights non-contraceptive methods. Of the five family planning methods that the Final Rule describes, four are abstinence, natural family planning, other fertility-awareness-based methods, and referral for or information about adoption;[39] the fifth is contraception. *Id.*

Despite these changes to the scope of Title X services, HHS barely acknowledges that any of these revisions depart from existing policies. Rather, HHS contends that the Final Rule simply clarifies or corrects prior definitions that had the potential to cause confusion. *See id.* at 7729-31, 7733, 7741, 7743. There is no evidence, however, that the definitions of "medically approved" or "family planning" caused any grantees or prospective grantees confusion.[40] In the absence of any rational explanation, the Department's erosion of long-standing policies that ensure access to a broad range of medically-approved contraceptive care is arbitrary and capricious. *Wild Rockies*, 907 F.3d at 1116-17 (rejecting an agency's explanation that "newly-added" "criteria" merely "flesh[ed] out" the "existing definition" where the new definition conflicted with established agency policy).

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[39] *See* Guttmacher Ltr. 4 (less than 0.5% of Title X clients use natural family planning as their primary method of contraception).

[40] HHS's own clinical guidelines, in addition to grantees and providers, have construed "medically approved family planning" to mean FDA-approved methods. QFP at 7; WA Ltr. 14; NY Ltr. 9; NY DOH Ltr. 6; CA Ltr. 17-18; ACOG Ltr. 10-11; AAN Ltr. 5; PPFA Ltr. 65-66; Guttmacher Ltr. 1-2.

HHS also failed to adequately consider the objections that these changes invite antiabortion counseling organizations (often referred to as "crisis pregnancy centers"), which often do not employ any medical staff or provide the most common forms of FDA-approved contraceptives, to be eligible for Title X funding.[41] As many commenters observed, allowing entities that refuse to offer information or services relating to medically-approved contraception to participate will degrade the quality of care patients receive and strain the resources of the program.[42]

3. The Final Rule was promulgated without observance of procedure required by law.

In addition, the Final Rule should be preliminarily enjoined because Plaintiffs are likely to succeed on their claim that Defendants have failed to comply with the APA's procedural requirements. Under the APA, the Court must "hold unlawful and set aside" agency action that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Among other procedural requirements, the APA generally requires agencies to publish a notice of proposed rulemaking and solicit public comment on all rulemakings. *Id.* § 553. The required notice must describe "either the terms or substance of the proposed rule or a description of the subjects and issues involved," *id.* § 553(b)(3), and must be sufficient to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c). "Review of an agency's procedural compliance with statutory norms is an exacting one." *NRDC v. EPA*, 683 F.2d 752, 760 (3d Cir. 1982) (citation omitted).

Here, the Final Rule falls short of the APA's procedural requirements both because HHS's restrictions on who may provide nondirective pregnancy counseling was not a logical

[41] Guttmacher Ltr. 15.

[42] WA Ltr. 13-15; NY Ltr. 9; CA Ltr. 17-18; AMA Ltr. 3; ACOG Ltr. 10; PPFA Ltr. 64-67.

outgrowth of the Proposed Rule, and because HHS failed to disclose sufficient information about its cost-benefit assumptions to allow informed comment by affected parties.

First, the Final Rule is procedurally invalid under the APA because the Final Rule's limit on pregnancy counseling to physicians or APPs only, 84 Fed. Reg. at 7789, was nowhere described in – and was not reasonably foreseeable from – the Proposed Rule. The Proposed Rule's discussion of nondirective counseling was limited expressly to abortion. *See* 83 Fed. Reg. at 25506-07 n.11, 25518 n.55. Yet the Final Rule includes a new and unprecedented requirement that medical professionals hold advanced degrees in order to provide nondirective pregnancy counseling. 84 Fed. Reg. at 7761, 7789. This new restriction would prohibit, for example, registered nurses and medical assistants from providing the allegedly "nondirective" pregnancy counseling the Final Rule allows (including allowable counseling on abortion), causing dramatic disruption to the Title X program given the large share of family planning services that medical professionals who do not hold advanced degrees currently provide. *See supra* III.A.1.a and III.A.2.a.

The Supreme Court has explained that the APA's notice requirement "mean[s] that the final rule the agency adopts must be a logical outgrowth of the rule proposed." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (citation omitted). In determining whether a final regulation fails the logical outgrowth test, the Ninth Circuit "consider[s] whether the complaining party should have anticipated that a particular requirement might be imposed." *Envtl. Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 851 (9th Cir. 2003).

Here, there was no way for interested parties to have anticipated that the Department intended to impose speaker-based restrictions, tied to educational attainment levels, on all nondirective pregnancy counseling – there simply was no notice of this limitation anywhere in

the Proposed Rule. Because the notice of proposed rulemaking "did not afford interested parties the opportunity to comment" on this significant substantive change, Plaintiffs are likely to succeed on the merits of their claim that the Final Rule violated the APA. *Nat. Res. Def. Council v. EPA*, 279 F.3d 1180, 1186-89 (9th Cir. 2002) (concluding that the agency's notice and comment procedure was inadequate where a final permit redefined the area within which water quality standards could be violated, with no notice or opportunity to comment on whether the new definition complied with state environmental requirements); *see also Alameda Health Sys. v. Ctrs. for Medicare & Medicaid Servs.*, 287 F. Supp. 3d 896, 918-19 (N.D. Cal. 2017).

Second, HHS failed to disclose sufficient information in its regulatory impact analysis to satisfy the APA's notice requirement, because it did not sufficiently identify and quantify the costs and benefits of the intended rulemaking. *See* 83 Fed. Reg. at 25521. This analysis included no estimate for the costs of the proposal for patients, including the health-related costs of any increase in unintended pregnancies and sexually transmitted infections. *Id.* at 25524-25. And the analysis included an estimate of the costs of complying with the physical separation requirement that projected – with no support or quantitative basis – a "central estimate of $20,000" for each affected service site to "come into compliance with the physical separation requirement in the first year."[43] *Id.* at 25525.

These omissions evade the APA's procedural protections that ensure agency regulations are tested through exposure to public comment. "'[T]he Administrative Procedure Act requires

[43] The regulatory impact analysis in the Final Rule similarly includes no quantification of the costs this regulation will impose on patients, and fails to include any economic analysis of the Final Rule's revised definition of "low income family." 84 Fed. Reg. at 7779-82. The Final Rule revised its estimated costs for the physical separation requirement to a "central estimate of $30,000" per affected service site, again without providing any support or quantitative basis for that "central estimate." *Id.* at 7781-82.

the agency to make available to the public, in a form that allows for meaningful comment, the data the agency used to develop the proposed rule.'" *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1132-33 (D.C. Cir. 1995) (quoting *Engine Mfrs. Ass'n v. EPA*, 20 F.3d 1177, 1181 (D.C. Cir. 1994)).

B. The States will suffer irreparable harm absent preliminary injunctive relief.

To be entitled to preliminary relief, the States must "demonstrate that irreparable injury is likely in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis omitted). The focus is "on irreparability, 'irrespective of the magnitude of the injury.'" *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (quoting *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir. 1999)). The States are highly likely to be irreparably injured immediately upon the Final Rule's implementation if the Court does not grant preliminary relief.

1. Irreparable harm to Plaintiffs' sovereign and quasi-sovereign interests

The implementation of the Final Rule on May 3 would immediately injure the States' interests in protecting the health of their residents, and public health more broadly, by destroying the established network of Title X providers and compromising the quality of care beneficiaries receive. It would also immediately injure the States' sovereign interests in regulating the practice of the medical professions. *See* *Watson v. State of Maryland*, 218 U.S. 173, 176 (1910) ("It is too well settled to require discussion at this day that the police power of the states extends to regulation of certain trades and callings, particularly those which closely concern the public health."); *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 792 (1975) (states have "broad power to establish standards for licensing practitioners and regulating the practice of professions").

Harm to the health and public health of all the residents in the States is likely for at least two reasons. First, when the Final Rule becomes effective, Title X grantees and providers would

be required to immediately comply with most of the Rule's requirements. However, many Title X grantees and subgrantees (participating clinics) would be unable to comply and would, therefore, suddenly become ineligible, mid-grant, for Title X funds on May 3, 2019. For example, Planned Parenthood affiliates, which now provide contraceptive services for 40 percent of all Title X beneficiaries,[44] would discontinue their participation in Title X if the Final Rule goes into effect.[45] Indeed, in Vermont, Planned Parenthood is the only provider of Title X services.[46] States expect other current Title X providers to similarly become ineligible for Title X funds because, among other reasons, they will refuse to compromise their professional ethics.[47] Some grantees themselves, including New York, Oregon and Hawai'i, would be at risk of losing all Title X funding, and every Title X clinic in their current networks would withdraw from the program.[48] This sudden exodus would cause an immediate and dramatic reduction (if not elimination) of the Title X provider networks in each State, causing residents of those States to lose access to the Title X provider they count on for care.[49] This would have a significant public

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[44] *See* Kost Decl. ¶ 69.

[45] Kost Decl. ¶ 109; Guttmacher Ltr. Table 1 (of all contraceptive care for Title X beneficiaries, Planned Parenthood services account for 88% in Connecticut, 42% in Illinois; 60% in Michigan; 71% in Minnesota; 72% in New Jersey; 52% in New York; 100% in Vermont; and 79% in Wisconsin); PPFA Ltr. 15; CA Ltr. 10-11; WA Ltr. 23-24; NY Ltr. 8; Keenan Decl. (CT) ¶ 5; Lytle-Barnaby Decl. (DE) ¶¶ 27-29; Brandt Decl. (MN) ¶ 9; Charest Decl. (MI) ¶ 8; Walker Harris Decl. (VA) ¶ 25; Lightner Decl. (IL) ¶ 33; Skinner Decl. (CT) ¶ 24.

[46] Holmes Decl. (VT) ¶¶ 6, 19.

[47] Rimberg Decl. (OR) ¶ 44; Kost Decl. ¶ 108; Alexander-Scott Decl. (RI) ¶ 12; Alifante Decl. (NJ) ¶¶ 17, 27, 30; Gallagher Decl. (VT) ¶ 23; Gillespie Decl. (WI) ¶ 27; Holmes Decl. (VT) ¶¶ 18-19; Schaler-Haynes Decl. (NJ) ¶ 40; Rattay Decl. (DE) ¶ 19; Childs-Roshak Decl. (MA) ¶ 16; Reece Decl. (CO) ¶¶ 11, 15; Camp Decl. (CO) ¶ 26.

[48] Tobias Decl. (NY) ¶ 43; Rimberg Decl. (OR) ¶¶ 38, 44; Anderson Decl. (HI) ¶ 6.

[49] Rimberg Decl. ¶ 45; Darney Decl.18; Kost Decl. ¶ 109-118; David Decl. (NYPHS) ¶ 41; Gallagher Decl. (VT) ¶ 25; Gillespie Decl. (WI) ¶ 27; Holmes Decl. (VT) ¶¶ 18-19; Schaler-Haynes Decl. (NJ) ¶ 27; Tobias Decl. (NY) ¶¶ 44-45; Brandt Decl. (MN) ¶ 10; Charest Decl. (MI) ¶¶ 8-9; Cooke Decl. (MA) ¶ 10; Childs-Roshak Decl. (MA) ¶ 17; Drew Decl. (MA) ¶ 15;

health impact. For example, unintended pregnancies would increase, sexually transmitted infections would go undetected and untreated, and cancers would not be diagnosed in early, more easily-treatable, stages.[50]

States that are eventually able to replace their subgrantees would only be able to start repairing their Title X networks after delay and disruption.[51] Finding new clinics and attracting health care professionals that are willing to comply with the Final Rule, able to absorb the need for care, and located in the places where care is needed, would take time, if it is possible at all.[52] It would also take time to complete the administrative work required to make sure those new clinics meet the necessary standards to be a part of the Title X network.[53] Meanwhile, Title X patients—and the public health in the States—would suffer. *See* *Planned Parenthood of Greater Washington*, 328 F. Supp. 3d at 1150 (reduction in services and funding to state's pregnancy prevention program is irreparable injury); *accord* *Doe v. Trump*, 288 F. Supp. 3d 1045, 1082 (W.D. Wash. 2017).

Second, for those grantees and providers that continue to accept Title X funds and could comply with the Final Rule should it be implemented, the quality of care provided would be

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Ross Decl. (MA) ¶ 16); Preiss Decl. (MA) ¶ 10; Reece Decl. (CO) ¶¶ 4, 15-16; Skinner Decl. (CT) ¶ 25.

[50] Kost Decl. ¶ 82; Darney Decl. ¶¶14, 17-23; *see also* Alexander-Scott Decl. (RI) ¶¶ 11, 13; Walker Harris Decl. (VA) ¶ 16; Gallagher Decl. (VT) ¶ 26; Gillespie Decl. (WI) ¶ 30; Holmes Decl. (VT) ¶ 18; Schaler-Haynes Decl. (NJ) ¶¶ 31-32; Camp Decl. (CO) ¶ 26; Wilson Decl. (NC) ¶ 19; Keenan Decl. (CT) ¶¶ 6-7, 11; Stephens Decl. (DE) ¶ 19; Rattay Decl. (DE) ¶¶ 20-21, 23-27; Anderson Decl. (HI) ¶¶ 18-19; Skinner Decl. (CT) ¶ 27.

[51] *See* Guttmacher Ltr. 9-10 ("Guttmacher analyses estimate that other Title X sites would have to increase their client caseloads by 70%, on average" to absorb demand of former providers); *see also* Gallagher Decl. (VT) ¶¶ 24-25; Gillespie Decl. (WI) ¶¶ 25, 29; Holmes Decl. (VT) ¶ 18; Kunkel Decl. (NM) ¶ 23; Rattay Decl. (DE) ¶ 20; Kost Decl. ¶ 112.

[52] *See* Stephens Decl. (DE) ¶22; Charest Decl. (MI) ¶ 10.

[53] *See* NY DOH Ltr. 22; Alexander-Scott Decl. (RI) ¶ 19; Gillespie Decl. (WI) ¶ 29; Kunkel Decl. (NM) ¶¶ 23-24; Cooke Decl. (MA) ¶ 13.

greatly diminished, which would negatively impact patient and public health. Title X providers would be required to provide care that contravenes national professional standards and ethical guidelines.[54] The result would be that patients no longer receive complete information and unbiased care, which will lead to less informed decision-making about both abortion and contraception, in addition to corrosion of trust between the patient and the provider.[55] Recipients of substandard care would be at risk of undergoing later, and less safe, abortions or carrying an unwanted pregnancy to term. Because abortion is a time-sensitive procedure and risks increase as weeks pass, compelling women who have chosen to have an abortion to delay their care needlessly increases their health risks.[56] If a woman is unable to obtain a timely abortion, both she and the future child are more likely to suffer both emotional and financial hardship.[57]

The harmful consequences to the public health of implementing the flawed and unlawful regulations are irreparable. HHS's interference with the States' sovereign interests in regulating the practice of professions—including the counseling and referrals that medical professionals are qualified by their licenses to provide—is also irreparable. The Plaintiff States are entitled to injunctive relief.

2. Irreparable harm to the States' proprietary interests

Implementation of the Final Rule would also inflict irreparable economic injury on the

[54] Kunkel Decl. (NM) ¶ 22; Childs-Roshak Decl. (MA) ¶ 14; Preiss Decl. (MA) ¶ 14; MacNaughton Decl. (MA) ¶ 14; Ross Decl. (MA) ¶ 14; Zoll Decl. (MA) ¶ 12; Kost Decl. ¶¶ 91-95; Camp Decl. (CO) ¶ 26; David Decl. (NY) ¶ 39; Tobias Decl. (NY) ¶ 43; Skinner Decl. (CT) ¶ 24.

[55] Byrd Decl. (DC) ¶¶ 4, 7; Handler Decl. (NV) ¶ 9; Gillespie Decl. (WI) ¶ 28; Kunkel Decl. (NM) ¶ 22; Kost Decl. ¶ 95.

[56] Darney Decl. ¶ 13; Kost Decl. ¶ 93; *see also* *Doe v. Bolton*, 410 U.S. 179, 198 (1973) ("Time, of course, is critical in abortion," because "[r]isks during the first trimester of pregnancy are admittedly lower than during later months.").

[57] Darney Decl. ¶ 14; Schaler-Haynes Decl. (NJ) ¶¶ 35-37; Childs-Roshak Decl. (MA) ¶ 19.

States. Economic harm is not ordinarily considered irreparable. *L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1202 (9th Cir. 1980). It is irreparable, however, where, as here, the party seeking relief will not be able to recover monetary damages to compensate for the impacts caused by an illegal rule. *See* 5 U.S.C. § 702 (permitting relief "other than money damages"); *see also California*, 911 F.3d at 582-84 (finding that states would suffer irreparable economic harm if HHS rules limiting insurance coverage of contraceptives were not enjoined). This is the case here for multiple reasons.

The loss of Title X providers who are unable to comply with the Final Rule on May 3, 2019, and/or the physical separation requirement on March 4, 2020, would cause economic harm to the States. As noted, many Title X providers would become ineligible and State residents will lose access to care. As a result, State residents will develop health care needs that would have previously been prevented or treated at early stages at Title X clinics. States would incur treatment costs in their state Medicaid and other programs that they would not otherwise have incurred.[58] For example, lack of access to the most effective contraceptives will result in unplanned pregnancies and State costs for delivery and infant care.[59] Lack of access to preventive cancer screenings is likely to result in later-discovered cancers that require more

[58] Byrd Decl. (DC) ¶¶ 6-9; Walker Harris Decl. (VA) ¶ 25; Rimberg Decl. (OR) ¶ 47; Darney Decl.¶¶ 16, 19; Kost Decl. ¶¶ 52-61, 82, 123; Alexander-Scott Decl. (RI) ¶ 11; Gillespie Decl. (WI) ¶ 30; Handler Decl. (NV) ¶ 9; Holmes Decl. (VT) ¶ 18; Kunkel Decl. (NM) ¶ 25; Schaler-Haynes Decl. (NJ) ¶¶ 33-34; Tobias Decl. (NY) ¶¶ 48-49; Keenan Decl. (CT) ¶ 11; Brandt Decl. (MN) ¶¶ 11-12; Charest Decl. (MI) ¶ 7; Childs-Roshak Decl. (MA) ¶ 18; Skinner Decl. (CT) ¶ 30.

[59] Darney Decl. ¶ 14, 16; Kost Decl. ¶ 66; Rimberg Decl. (OR) ¶ 47; Alexander-Scott Decl. (RI) ¶ 11; Alifante Decl. (NJ) ¶ 24; Gillespie Decl. (WI) ¶ 30; Handler Decl. (NV) ¶ 9; Holmes Decl. (VT) ¶ 18; Schaler-Haynes Decl. (NJ) ¶ 32; Keenan Decl. (CT) ¶ 11; Drew Decl. (MA) ¶¶ 19-20; Zoll Decl. (MA) ¶¶ 11, 13.

significant treatment regimens at advanced stages.[60] States will incur costs to treat those conditions as well through their Medicaid programs.[61]

Some States may ultimately consider trying to plug the gap left by the loss of Title X providers with state funds. In that case, those States' taxpayers will bear the cost. Those taxpayer funds would not be recoverable in the event the Final Rule is vacated and its implementation is ultimately enjoined in a final judgment. *See* 5 U.S.C. § 702 (permitting relief "other than money damages"). Other States may be unable to cover the loss of funds and must face the significant public health and economic consequences. Irreparable economic harm will result in either case.

Some grantee States face an additional type of proprietary harm because they face a "Hobson's choice." Their options are (1) implement costly changes to their policies and administrative structure for utilizing Title X funds in order to accept Title X funding under conditions they believe are unlawful; or (2) forfeit Title X funding and suffer the economic and public health consequences.[62] A Hobson's choice can establish irreparable harm. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (holding that a forced choice between acquiescing to a law that the plaintiff believed to be unconstitutional and violating the law under pain of liability was sufficient to establish irreparable injury). Courts have applied the same irreparable injury analysis when the alleged harm was a denial of statutory, rather than constitutional rights. *See O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 342 F.3d 1170, 1187 (10th Cir. 2003); *Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996).

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[60] Darney Decl. ¶ 22. Gillespie Decl. (WI) ¶ 30; Handler Decl. (NV) ¶¶ 8-9; Holmes Decl. (VT) ¶ 18; Nelson Decl. (MD) ¶ 17.

[61] Handler Decl. (NV) ¶ 9.

[62] *See, e.g.,* Anderson Decl. (HI) ¶¶ 2, 6; Schaler-Haynes Decl. (NJ) ¶ 40.

Because the States are likely to suffer irreparable harm to their sovereign and quasi-sovereign interests as well as their proprietary interests from the implementation of the Final Rule, the Final Rule should be preliminarily enjoined.

C. The balance of equities and public interest sharply favor preliminary relief.

The balance of the equities and public interest tip sharply in the States' favor. When the government is a party, courts consider the balance of equities and the public interest together. *Jewell*, 747 F.3d at 1092. The Title X program has successfully provided high-quality reproductive health care to low-income people across the country for decades. Protecting access to family planning services regardless of income is clearly in the public interest. It is also evident that "[t]here is generally no public interest in the perpetuation of an unlawful agency action." *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). On the other hand, "there is a substantial public interest in 'having government agencies abide by the federal laws that govern their existence and operations.'" *Id.* at 12 (citation and internal quotations omitted).

If implemented, the Final Rule will cause irreparable and grave harm to the Plaintiff States and the health of their residents. The financial costs to the States will ultimately be borne by the taxpayers, which is also adverse to the public interest. By contrast, defendants will not be harmed by a preliminary injunction. Indeed, because the federal government would share increased Medicaid costs with the States, provisional relief will also protect the federal fisc. Provisional relief will preserve the status quo pending resolution of the merits of the Plaintiff States' challenges. The only cost to the agency of a preliminary injunction is the continuation of a regulatory regime that has been in place and working effectively for millions of Americans for decades. The balance of the equities and the public interest therefore support the entry of preliminary relief.

D. Scope of provisional relief

The Court should enjoin Defendants from implementing the Final Rule without geographic restriction or, in the alternative, postpone the effective date of the Final Rule pursuant to 5 U.S.C. § 705 to preserve the status quo pending judicial review.

The purpose of interim equitable relief "is not to conclusively determine the rights of the parties. . . but to balance the equities as the litigation moves forward," bearing in mind "'the overall public interest.'" *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (quoting *Winter*, 555 U.S. at 26). Because the Final Rule violates federal law and is arbitrary and capricious, and because "[f]orcing federal agencies to comply with the law is undoubtedly in the public interest," *Cent. United Life, Inc. v. Burwell*, 128 F. Supp. 3d 321, 330 (D.D.C. 2015), *aff'd*, 827 F.3d 70 (D.C. Cir. 2016), enjoining Defendants from implementing the Final Rule without geographic limitation is the appropriate balance of the equities as this litigation moves forward.

To be sure, the Ninth Circuit has recently cautioned district courts to be mindful that preliminary injunctive relief not be overbroad. *See, e.g.*, *California*, 911 F.3d at 582-84. But as the Supreme Court has held, the "scope of injunctive relief is dictated by the extent of the violation established, not by the geographical extent of the plaintiff class." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Here, Plaintiffs have demonstrated a likelihood of success on the merits of their claims that Defendants violated the APA, and nationwide relief is the usual course in an APA action because "when a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated – not that their application to the individual petitioners is proscribed." *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *see also NAACP v. Trump*, 315 F. Supp. 3d 457, 474 n.3 (D.D.C. 2018) (order setting aside agency decision under APA did not implicate any concerns about nationwide injunctions).

In addition, the States' challenge is to a federal health care regulation that Defendants themselves described as necessary to provide national uniformity in the administration of the Title X program. *See, e.g.*, Final Rule, 84 Fed. Reg. at 7782-83; Proposed Rule, 83 Fed. Reg. at 25525-26. Where the challenged agency action has nationwide impact, a nationwide injunction is appropriate and advances the public interest by promoting efficiency and certainty. *Cf. Texas v. United States*, 809 F.3d 134, 187-88 (5th Cir. 2015) (affirming nationwide injunction for uniform immigration rules).

Plaintiffs' expansive geographic presence also minimizes any concerns about this Court's power to award relief without geographic limitation. Plaintiffs in this action are 21 States located in nine of the twelve federal judicial circuits. The plaintiffs in the related challenge before this Court include the American Medical Association, the largest professional association of physicians, residents, and medical students in the country, with members who practice and reside in all States. *See* Complaint ¶ 25, *Am. Med. Ass'n v. Azar*, No. 6:19-cv-00318-MC (filed Mar. 5, 2019). This is not a case where a single plaintiff seeks to leverage a localized dispute into national relief; it is instead a challenge by plaintiffs with national scope to an unlawful regulation with significant national impact.

In the alternative, the Court should stay the effective date of the Final Rule pending adjudication of this case on the merits, as permitted by the APA. Section 705 permits this Court to "postpone the effective date of an agency action" where "necessary to prevent irreparable injury . . . pending conclusion of the review proceedings." 5 U.S.C. § 705. Courts assessing requests for a Section 705 stay apply the same four-factor test used to evaluate requests for preliminary injunctive relief. *Bauer*, 325 F. Supp. 3d at 104-05. Here, for the reasons discussed in Parts III.A to III.C above, Plaintiffs have satisfied the typical four-factor showing required of a

request for preliminary injunctive relief. The Court should therefore stay all implementation deadlines in the Final Rule pending resolution of this case on the merits, to avoid irreparable harm to Plaintiffs.[63] *See, e.g.*, *Texas v. U.S. Envtl. Prot. Agency*, 829 F.3d 405, 435 (5th Cir. 2016); *B & D Land and Livestock Co. v. Conner*, 534 F. Supp. 2d 891, 905 (N.D. Iowa 2008); *Salt Pond Assocs. v. U.S. Army Corps of Eng'rs*, 815 F. Supp. 766, 774-75 (D. Del. 1993).

[63] The Final Rule contains an "effective date" of May 3, 2019, and a series of "compliance dates" that follow (including a May 3, 2019 deadline to comply with the gag requirement; a July 2, 2019 deadline to comply with the financial separation requirement; and a March 4, 2020 deadline to comply with the physical separation requirement). 84 Fed. Reg. at 7714, 7791. Because the Department described all of the Rule's compliance dates by reference to the Rule's effective date, however, a Section 705 stay of the effective date would appropriately stay all compliance dates as well. *Id.* at 7774 (describing the Rule's "compliance dates" as the date "by which covered entities must comply with [certain] sections after their effective date"); *id.* at 7775 (unless specified, the compliance date for all requirements of the Rule is "the effective date").

IV. Conclusion

Plaintiffs respectfully request that the Court enjoin implementation of the Final Rule.

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Respectfully submitted,

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Appendix 1 – Index of Submitted Declarations

	Short Title	State	Full Title
1	Alexander-Scott Decl. (RI)	Rhode Island	Declaration of Dr. Nicole Alexander-Scott, Director of Rhode Island Department of Health, in Support of States' Motion for Preliminary Injunction
2	Alifante Decl. (NJ)	New Jersey	Declaration of Joseph L. Alifante in Support of States' Motion for Preliminary Injunction
3	Anderson Decl. (HI)	Hawaii	Declaration of Bruce S. Anderson, PH.D. in Support of States' Motion for Preliminary Injunction
4	Brandt Decl. (MN)	Minnesota	Declaration of Joan Brandt in Support of States' Motion for Preliminary Injunction
5	Byrd Decl. (DC)	District of Columbia	Declaration of Melisa Byrd
6	Camp Decl. (CO)	Colorado	Declaration of Jody Camp in Support of States' Motion for Preliminary Injunction
7	Charest Decl. (MI)	Michigan	Declaration of Deanna Charest
8	Childs-Roshak Decl. (MA)	Massachusetts	Declaration of Dr. Jennifer Childs-Roshak, MD, MBA
9	Cooke Decl. (MA)	Massachusetts	Declaration of Margret R. Cooke, Esquire
10	Darney Decl.		Declaration of Dr. Blair Darney in Support of States' Motion for Preliminary Injunction
11	David Decl. (NY)	New York	Declaration of Lisa M. David in Support of States' Motion for Preliminary Injunction
12	Drew Decl. (MA)	Massachusetts	Declaration of John J. Drew, MBA
13	Gallagher Decl. (VT)	Vermont	Declaration of Meagan Gallagher in Support of States' Motion for Preliminary Injunction
14	Gillespie Decl. (WI)	Wisconsin	Declaration of Katie Gillespie in Support of States' Motion for Preliminary Injunction
15	Handler Decl. (NV)	Nevada	Declaration of Beth Handler in Support of

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	Short Title	State	Full Title
			States' Motion for Preliminary Injunction
16	Holmes Decl. (VT)	Vermont	Declaration of Breena Holmes in Support of States' Motion for Preliminary Injunction
17	Keenan Decl. (CT)	Connecticut	Declaration of Mark Keenan in Support of States' Motion for Preliminary Injunction
18	Kost Decl.		Declaration of Kathryn Kost in Support of Plaintiffs' Motion for Preliminary Injunction *AMA v Azar*, Case No. 6:19 cv 00318-MC
19	Kunkel Decl. (NM)	New Mexico	Declaration of Kathyleen Kunkel in Support of States' Motion for Preliminary Injunction
20	Lightner Decl. (IL)	Illinois	Declaration of Shannon Lightner in Support of States' Motion for Preliminary Injunction
21	Lytle-Barnaby Decl. (DE)	Delaware	Declaration of Ruth Lytle-Barnaby, MSW
22	MacNaughton Decl. (MA)	Massachusetts	Declaration of Honor MacNaughton, MD
23	Nelson Decl. (MD)	Maryland	Declaration of Karen Nelson in Support of States' Motion for Preliminary Injunction
24	Preiss Decl. (MA)	Massachusetts	Declaration of Rachel Preiss, NP
25	Rattay Decl. (DE)	Delaware	Declaration of Karyl T. Rattay, M.D., M.S.
26	Reece Decl. (CO)	Colorado	Declaration of Melanie S. Reece, PH.D. in Support of States' Motion for Preliminary Injunction
27	Rimberg Decl. (OR)	Oregon	Declaration of Helene Rimberg in Support of States' Motion for Preliminary Injunction
28	Ross Decl. (MA)	Massachusetts	Declaration of Dr. Gabrielle Ross, PhD, MPH, MIA
29	Schaler-Haynes Decl. (NJ)	New Jersey	Declaration of Magda Schaler-Haynes in Support of States' Motion for Preliminary Injunction
30	Skinner Decl. (CT)	Connecticut	Declaration of Amanda Skinner in Support of

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	Short Title	State	Full Title
			States' Motion for Preliminary Injunction
31	Stephens Decl. (DE)	Delaware	Declaration of Thomas E. Stephens, MD
32	Tobias Decl. (NY)	New York	Declaration of Lauren Tobias in Support of States' Motion for Preliminary Injunction
33	Walker-Harris Decl. (VA)	Virginia	Declaration of Vanessa Walker Harris, MD in Support of States' Motion for Preliminary Injunction
34	Wilson Decl. (NC)	North Carolina	Declaration of Walker Wilson in Support of States' Motion for Preliminary Injunction
35	Zoll Decl. (MA)	Massachusetts	Declaration of Dr. Cheryl Zoll, PhD