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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON,

Plaintiff,

v.

ALEX M. AZAR II, et al.,

Defendants.

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

Plaintiffs,

v.

ALEX M. AZAR II, et al.,

Defendants.

No. 1:19-cv-03040-SAB

THE NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

4/25/2019
With Oral Argument: 10:00 a.m.

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Plaintiffs move for a preliminary injunction to prevent a sweeping new rule, 84 Fed. Reg. 7714-91 (Mar. 4, 2019) (the "New Rule"), that would have a devastating impact on the Title X family planning program from taking effect on May 3, 2019. The New Rule violates multiple federal laws, lacks any sound justification, contravenes Congress's purpose in establishing the Title X program, and threatens irreparable harm to Plaintiffs and the millions of vulnerable patients that depend on this unique federal program for family planning health care.

For almost five decades, Title X has been a widely recognized public health success story. Title X grants fund a nationwide network of government and non-profit health care providers that make up-to-date, quality clinical care—including contraception, pregnancy testing and counseling, and other family planning services—available for free or at reduced cost to those who otherwise could not access it. The New Rule would reverse Title X's success and harm those Congress intended the program to serve by:

(1) forcing Title X clinicians to impose involuntary, directive counseling on pregnant patients that violates Congress's explicit statutory requirements and conflicts with the national clinical standards established by Defendant Department of Health and Human Services' ("HHS") for such counseling;

(2) establishing new "physical separation" and infrastructure spending rules that unnecessarily and untenably require participating health care providers to maintain duplicate facilities, staff, and records systems;

(3) pushing effective Title X providers across the country from the program, because they cannot comply with (1) and (2);

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and (4) encouraging hypothetical new Title X providers that have religious objections to core Title X services like biomedical contraception and referral for abortion within nondirective pregnancy counseling, as well as changing central features of the program to facilitate the objectors' participation, to the detriment of Title X patients.

All of these changes will leave Title X patients with substandard, misleading health care, and many fewer Title X points of access, putting them at risk for unintended pregnancies, undetected HIV and cervical cancer, and other serious repercussions.

The National Family Planning & Reproductive Health Association ("NFPRHA") is a non-profit membership organization suing on behalf of hundreds of Title X grantees or subrecipients of grants, spread across every state, that currently operate more than 3,500 Title X sites. NFPRHA and its co-plaintiffs show below that they have a strong likelihood of success on the merits of their Administrative Procedure Act ("APA") claims; that Plaintiffs throughout the country will suffer irreparable harms absent preliminary relief; and that an injunction against any enforcement of the New Rule is in the public interest.

I. BACKGROUND ON TITLE X AND THE CHALLENGED RULEMAKING

Title X, 42 U.S.C. § 300 *et. seq.*, is the only federal grant program dedicated to making "comprehensive voluntary family planning services readily available to all persons desiring such services." Pub. L. 91-572, 84 Stat. 1504 § 2(1). Congress created the program in 1970 to remedy low-income individuals' lack of access to modern, effective contraception and related medical care. Coleman Decl. ¶¶ 18-26

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(describing history). By law, Title X projects must prioritize providing care to low-income individuals, 42 U.S.C. § 300a-4(c), and patients' receipt of any information or services must be purely voluntary, *id.* § 300a-5. Plaintiffs set forth other terms of the Title X statute in their Complaint, at ¶¶ 57-60.

In addition, every year from 1996 to the present, Congress has enacted appropriations legislation that imposes further conditions on HHS's use of Title X funds. That legislation clearly states that—while funds provided to Title X projects "shall not be expended for abortions"—all pregnancy counseling in the program "shall be nondirective." *See* Pub. L. 115-245, 132 Stat. at 3070-71 ("Nondirective Mandate"). That means, as discussed further below, a Title X provider cannot direct patients toward a particular outcome for their pregnancy, and must instead offer patients neutral information about all options, including abortion or carrying the pregnancy to term. Nondirective pregnancy counseling allows patients rather than providers to determine the options discussed, with referral available to any option(s) at patient request.

Moreover, in 2010, Congress separately prohibited HHS from promulgating *any* regulations that contravene certain patient protection principles: HHS may not adopt rules that violate health care ethics or informed consent principles, restrict the ability of health care providers to communicate full information and all care options to their patients, or create unreasonable barriers to or delay timely access to appropriate medical care. 42 U.S.C. § 18114(1)-(5) ("Section 1554" of the Patient Protection and Affordable Care Act ("PPACA")).

Notably, these congressional enactments postdate the only other regulatory

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attempt in Title X's five-decade history to subvert the program's emphasis on offering voluntary, quality health care and to adopt, instead, directive counseling in which Title X providers would push all patients toward carrying a pregnancy to term. *See Rust v. Sullivan*, 500 U.S. 173 (1991). As HHS has acknowledged, its previous rulemaking attempt never took effect nationwide. 65 Fed. Reg. at 41,271. Responding to that aberrant effort, Congress has since made plain, through its Nondirective Mandate and specific limits on HHS's rulemaking authority, that it should not happen again. *See* Nondirective Mandate; Section 1554; Coleman Decl. ¶¶ 30-39 (describing congressional reactions to 1988 "gag rule" and *Rust*).

In fact, the Title X program has consistently offered information about and referral for abortion, upon patient request, as necessary aspects of nondirective pregnancy counseling, which treats all options—prenatal care, adoption, and abortion—equally. This method of counseling is consistent with longstanding HHS guidance and was enshrined in the agency's 2000 regulations. *See* 42 C.F.R. § 59.5(a)(5). Plaintiffs' Complaint describes in detail the current set of Title X regulations. *See* Complaint ¶¶ 61-74, 42 C.F.R. § 59.

Beyond these statutes and regulations, the current Title X program is also governed by HHS's Program Requirements and its national clinical standards for family planning care, "Providing Quality Family Planning Services" ("QFP"), which HHS's Centers for Disease Prevention and Control and Defendant Office of Population Affairs ("OPA") developed in conjunction with dozens of experts. *See* Coleman Decl. Exs. A, B. Again, these documents make clear that Title X family planning must offer low-income patients access to information about their

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options—whether for contraception or pregnancy—and provide the same type of health care that those with greater economic resources would receive.

Operating under the statutory and regulatory regime described above, the Title X program has flourished. *See* Coleman Decl. ¶¶ 54-109; Kost Decl. ¶¶ 18-72. In 2017, Title X funded approximately 90 "projects," which included more than 1,000 provider organizations and almost 4,000 sites. OPA, *Title X Family Planning Annual Report: 2017 National Summary*, at ES-1 (2018) ("FPAR"). Of the four million patients served, two-thirds had incomes below the federal poverty level ("FPL") and 90% had incomes at or below 250% of the FPL. *Id.* at 21. Title X patients are disproportionately people of color and ethnic minorities, with approximately one-third identifying as Hispanic or Latino/a. *Id.* at 12. Fourteen percent report limited English language proficiency. *Id.* at 22.

On June 1, 2018, HHS published a Notice of Proposed Rulemaking, 83 Fed. Reg. 25,502-33 ("NPRM"), proposing new regulations that are contrary to the governing statutes. HHS proposed to end the nondirective pregnancy counseling long provided within Title X, including by banning referrals to abortion and sending all Title X patients to prenatal care. In addition, the agency proposed drastic new "physical separation" requirements that would compel Title X sites to separate their facilities, staff, electronic systems, and patient access points from any non-Title X activities that might support the availability of abortion. This physical separation requirement —and consequent duplication of infrastructure—extends far beyond the financial separation that already governs Title X. Financial separation already ensures that Title X funds do not fund abortion care or anything

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other than permitted Title X program activities. *See* 42 U.S.C. § 300a-6; 42 C.F.R. § 59.9. HHS proposed numerous other new requirements to change who receives Title X funds. These changes would make it much more difficult for long-standing Title X providers to stay in the network and destabilize Title X's broad reach.

HHS sought these changes to open Title X to new providers with religious or moral objections to core aspects of Title X family planning services. *See, e.g.*, 83 Fed. Reg. at 25,516, 25,526. As part of this effort, HHS cited various "conscience protection" statutes that it maintained justified the New Rule. *Id.* (citing 42 U.S.C. § 300a-7 (Church Amendment); 42 U.S.C. § 238n(a) (Coats-Snowe Amendment); Pub. L. 115-141, 132 Stat. 348, 763 (Weldon Amendment)). None of these statutes, however, justify wholesale changes to Title X that would prohibit *all* Title X projects from referring for abortion or that allow objecting projects to withhold all information about abortion. Indeed, HHS concedes that "the Title X statute has coexisted with federal conscience laws for over 40 years." 84 Fed. Reg. at 7747.

And in connection with the physical separation and other new "compliance" requirements, HHS invoked the putative aim of reducing the risk of "confusion" or "potential co-mingling" of Title X funds with funding recipients' non-program activities that might relate to abortion. 83 Fed. Reg. at 25,507-08. But the proposed rulemaking sets forth no evidence that might establish the need for any such requirements. Nor did HHS show there were new providers ready to fill the large gaps in the Title X network that both its proposed distortions of pregnancy counseling and its unworkable separation rules would create by making current organizations and clinicians unable to continue in the program.

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HHS's proposals to depart from its own clinical standards and to undo critical aspects of the Title X program triggered an outpouring of opposition, including by virtually every leading medical and public health organization in the country. Nonetheless, HHS proceeded to finalize the changes. In doing so, HHS failed to contend with the substance of opposing comments, the New Rule's conflicts with statutes, the lack of need for such upheaval, and the New Rule's serious harms to individual Title X patients and the public health overall.

II. STANDARD OF REVIEW

A. Preliminary Injunction Standard

"A party can obtain a preliminary injunction by showing that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in [its] favor, and (4) an injunction is in the public interest." *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (quotations and citations omitted). When the government is a party to the action, "the last two factors merge." *California v. Azar*, No. 18-15144, 2018 WL 6566752, at *9 (9th Cir. Dec. 13, 2018). Under the Ninth Circuit's "sliding scale" approach, these elements are "balanced, so that a stronger showing of one element may offset a weaker showing of another." *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017) (quotations and citations omitted).

B. Legal Standards for Applying the Administrative Procedure Act

Under the APA, a "reviewing court shall . . . hold unlawful and set aside agency action" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory . . . authority, or

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limitations." 5 U.S.C. § 706(2)(A), (C). To assess whether agency action is in "accordance with law" and statutory authority, courts use the traditional tools of statutory construction, including text, purpose, and history. *See Aragon-Salazar v. Holder*, 769 F.3d 699, 703-04, 706 (9th Cir. 2014) (citing *Chevron U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842-43 (1984)). If the "intent of Congress is clear," the reviewing court must enforce it. *Aragon-Salazar*, 769 F.3d at 703.

If the statute is "silent or ambiguous with respect to the specific issue," and the agency has used delegated authority to interpret it, courts review the agency's interpretation to determine whether it is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. Where the agency has not engaged in such interpretation, the court itself determines the meaning of the statute. *See Arrington v. Daniels*, 516 F.3d 1106, 1112-13 (9th Cir. 2008) (holding that courts may not rely on or defer to *post hoc* rationalizations for agency action).

Separate and distinct from the requirement that agencies act in accordance with law, the APA also requires agencies to "engage[] in 'reasoned decisionmaking.'" *Turlock Irrigation Dist. v. FERC*, 903 F.3d 862, 873 (9th Cir. 2018) (quoting *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998)). Agency decision-making "must be logical and rational," *Allentown Mack*, 522 U.S. at 374; it must be both "reasonable *and* reasonably explained." *Mfrs. Ry. Co. v. Surface Transp. Bd.*, 676 F.3d 1094, 1096 (D.C. Cir. 2012) (Kavanaugh, J.) (emphasis added). A rulemaking is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision

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that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Courts reject agency action where, for example, the agency has "failed to address significant objections and alternative proposals," *Beno v. Shalala*, 30 F.3d 1057, 1073 (9th Cir. 1994), failed to address the public health consequences, *Stewart v. Azar*, 313 F. Supp. 3d 237, 264 (D.D.C. 2018), issued "internally inconsistent" rules, *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1028 (D.C. Cir. 2018), or failed to justify departures from past practice, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016).

III. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

Plaintiffs are likely to prevail on their APA claims because the New Rule violates each of the governing statutes referenced above and is the product of arbitrary and capricious rulemaking. The New Rule violates Congress's Nondirective Mandate as well as Title X's voluntariness requirement and the PPACA's Section 1554, because it deprives pregnant patients of the full information they need, forces a prenatal referral on them, and unethically attempts to steer all of them toward carrying their pregnancy to term. *See* Part A(1)-(3). These counseling restrictions are also arbitrary, because HHS, *inter alia*, failed to respond rationally to comments cataloging their harms to the program, including the Title X provider departures they will trigger. *See* Part A(4).

The New Rule's physical separation and infrastructure provisions are also arbitrary and capricious for similar reasons. Without any reasoned justification,

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these provisions will upend grantees' reliance on decades of prior HHS regulations and guidance that has shaped their investments in long-term, sustainable family planning programs. *See* Part B(1)-(3). The new separation and infrastructure requirements also violate Section 1554 by creating barriers to timely patient care and interfering with access to information, among other harms. *See* Part B(4).

The rule's new grantee and provider selection provisions are also fatally flawed because they (1) promote new types of providers at the expense of patient access to Title X care; (2) attempt to usher in providers with religious objections to biomedical contraceptives, allowing them to severely constrict the contraceptive methods they might offer; and (3) impose new grant-making terms in violation of the Title X statute and in conflict with other HHS regulations. *See* Part C(1)-(3).

Finally, the entire New Rule is arbitrary, unreasoned, and beyond HHS's rulemaking authority because HHS failed to consider its impact on and harms to Title X *patients*. Moreover, HHS also shunted aside the consistent chorus of detailed objections and warnings from the leading medical, family planning, and public health organizations, without rational response, and adopted a scheme that will drive many providers from the program and restrict those that stay to providing substandard care. *See* Part D. The New Rule is irreconcilable with Congress's purpose in creating and funding Title X.

A. The New Rule's Pregnancy Counseling Distortions Violate Congress's Nondirective Mandate, Title X's Voluntariness Requirement, and the PPACA's Section 1554 and Are Arbitrary and Capricious

Pregnancy testing and counseling are "core family planning services." QFP at 13; Program Requirements at 5. Per the QFP, Title X providers offer pregnant

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patients medical information, all options, and space to discuss those options to help the patient decide what is right for her. QFP at 2, 13-14. Counseling also includes connecting the patient with referrals for whichever option(s) she is considering. *Id.* Above all, "client values guide all clinical decisions." *Id.* at 4. Thus, under the long-governing Title X regulations, providers must: (1) offer pregnant patients nondirective, factual counseling about each of their options (carrying the pregnancy to term and becoming a parent, adoption, and abortion); (2) provide, as part of that counseling, referrals to any of those options upon patient request; and (3) *refrain* from providing information or referral "with respect to any option(s)" that the patient "indicates she does not wish to receive." 42 C.F.R. § 59.5(a)(5).

The New Rule fundamentally remakes Title X's pregnancy counseling, rendering it directive, coercive, and misleading. It forces all pregnant patients to receive referrals for prenatal care, even if the patient wants an abortion, while simultaneously barring referrals for abortion care. It further slants the information patients receive by permitting providers, based on *providers*' preferences, to discuss only carrying the pregnancy to term and adoption (without mentioning abortion), and preventing all Title X providers from discussing only abortion—even if that is the only option of interest to the patient. *See* Sections 59.5(a)(5), (b)(1), (8), 59.14, 59.16. Other New Rule sections reinforce these counseling limitations, by, for example, excluding written materials that reference abortion from the premises of Title X projects. *See, e.g.*, Sections 59.2, 59.13, 59.15-59.18. The sections cited in this paragraph constitute the rule's "Counseling Distortions."

As shown below, the Counseling Distortions (i) violate Congress's

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Nondirective Mandate for pregnancy counseling; (ii) defy Title X's central tenet that all care within the program must be voluntary, and (iii) impede patient access to ethical and timely healthcare in contravention of Section 1554. The Counseling Distortions also reflect arbitrary and capricious decision-making on numerous grounds. For each of these four independent reasons, Plaintiffs are likely to prevail on their claims that the New Rule should be set aside under the APA.

(1) The Counseling Distortions Violate Congress's Nondirective Mandate

Since 1996, Congress has conditioned every annual Title X appropriation on the requirement that "all pregnancy counseling" provided within the program "shall be nondirective." Pub. L. 115-245, 132 Stat. at 3070-71; *see* Case No. 19-cv-3040, Dkt. 1, Complaint, n.15 (collecting historical citations). It is well established that Congress can legislate through appropriations acts. *See generally Robertson v. Seattle Audobon Soc'y*, 503 U.S. 429, 440 (1992). This includes, as here, adding conditions to congressional programs in subsequent appropriations riders that provide funds. *See Skoko v. Andrus*, 638 F.2d 1154 (9th Cir. 1979).

Congress's Nondirective Mandate responded to the Supreme Court's view in *Rust* that the text of the Title X statute was ambiguous about '"whether clinics receiving Title X funds can engage in nondirective counseling including the abortion option and referrals.'" *Rust*, 500 U.S. at 185 (quoting Tenth Circuit and concurring in its finding of ambiguity); Coleman Decl. ¶¶ 30-39 (detailing history of responses to *Rust*). The Nondirective Mandate is a subsequent, unambiguous congressional command that Title X pregnancy counseling *must* be nondirective—neutrally offering information and referrals on all pregnancy options.

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"Nondirective" means what it says: Counseling must avoid bias and not steer patients toward or away from any particular path regarding their pregnancy. *See, e.g.*, 84 Fed. Reg. at 7744 n.72 (HHS quoting Congress's 2000 description of "nondirective counseling to pregnant women" as offering "adoption information and referrals to pregnant women on an equal basis with all other courses of action"); 141 Cong. Rec. H8250 (daily ed. Aug. 2, 1995) (statement of Rep. Greenwood) (upon introduction of 1996 rider, explaining that "it makes clear that all counseling must be nondirective"; "[c]ounselors in these programs . . . would simply lay out the legal options," not suggest patients choose a particular option); 83 Fed. Reg. at 25,512 n.41 (quoting earlier congressional statement that "nondirective counseling is the provision of information on all available options without promoting, advocating, or encouraging one option over another").

The New Rule's Counseling Distortions violate Congress's clear command and impose *directive* pregnancy counseling on Title X providers and patients through several provisions. First, the New Rule requires that when a Title X patient "is medically verified as pregnant, she shall be referred" for "prenatal health care," regardless of her needs or wishes. Section 59.14(b)(1). This new requirement falsely labels "prenatal health care" as "medically necessary" for all pregnant patients, even those who will terminate their pregnancy. *Id.* This is both directive and contrary to standards of care; if a patient chooses abortion, she should be referred and allowed to pursue that course without delay. QFP at 14.

Second, the New Rule couples this mandatory prenatal referral for all pregnant patients with an absolute bar on providing any direct or indirect referrals

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for abortion—or in any way assisting with such referrals—even if the Title X patient has already decided to terminate the pregnancy. Sections 59.5(a)(5), 59.14, 59.16. This aspect of the rule is clearly "directive" as it forbids for abortion what it mandates for prenatal care.

Third, the New Rule further distorts the information available to women who receive Title X counseling by requiring all providers who mention any information about abortion to also provide information about continuing the pregnancy—regardless of patient wishes. 84 Fed. Reg. at 7747-48. Indeed, a provider may refuse to discuss abortion at all and present patients only with information about continuing the pregnancy, maintaining the health of the "unborn child," and/or adoption. Section 59.14(b)(1)(i), (iii), (iv). What the New Rule calls "nondirective" counseling means providers must press prenatal care and can omit all abortion information, even if the patient objects. 84 Fed. Reg. at 7748.

Finally, the New Rule compounds its unbalanced counseling by permitting Title X projects to, at most, give pregnant patients a list of "comprehensive primary health care providers (including providers of prenatal care)"—even if the patient explicitly seeks only abortion information or abortion referral. Section 59.14(b)(1)(ii). Title X projects may include on the list primary care providers that also provide abortion care (if they know of any within this narrow subset of potential *primary care* abortion providers), but those must be a minority of the listed entities. Section 59.14(b)(2). What's more, the Title X provider may not indicate which entities on the list, if any, provide abortion. 84 Fed. Reg. at 7761.

In all these ways, the New Rule violates Congress's Nondirective Mandate.

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Accordingly, Plaintiffs are likely to prevail in showing the New Rule is contrary to law. *See* 5 U.S.C. § 706(2)(A).

(2) The Mandatory Prenatal Referral and Other Counseling That a Provider Can Impose on Patients Violates Title X's Voluntariness Requirement

The New Rule's Counseling Distortions are also contrary to law because they violate Title X's voluntariness requirement. Congress has directed that individuals' receipt of services or information funded by Title X "shall be voluntary," 42 U.S.C. § 300a-5, and that Title X grants support only "voluntary family planning projects," 42 U.S.C. § 300; *see also* Pub. L. 115-245, 132 Stat. at 3070-71 (in adopting the Nondirective Mandate, reiterating the "voluntary" nature of Title X services).

Patients must always retain their independence to decline information or services from a Title X provider. 42 U.S.C. § 300a-5. That is why the existing Title X regulations make explicit that a pregnant patient who does *not* wish to receive information, counseling, or referral about a particular option for her pregnancy can*not* be forced to do so. 42 C.F.R. § 59.5(a)(5)(ii).

Yet Section 59.14(b)(1) of the New Rule imposes a prenatal referral on all Title X patients, regardless of whether they consent or wish to receive one. Likewise, Section 59.14(b)(1) allows a Title X provider to give a patient information about maintaining the health of the "unborn child," regardless of whether she wishes to hear it—even over her objections. When a patient explicitly seeks to discuss only abortion, the Counseling Distortions nonetheless require providers to counsel her about carrying the pregnancy to term. 84 Fed. Reg. at

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7747. The New Rule, contrary to the Title X statute, involuntarily subjects patients to unwanted prenatal referrals and information. For this reason, too, Plaintiffs are likely to prevail under the APA in showing the New Rule is contrary to law.

(3) The New Rule's Counseling Distortions Violate Section 1554

The New Rule's Counseling Distortions also violate the explicit limits that Congress placed on HHS's rulemaking authority in Section 1554 of the PPACA. That statute requires that "the Secretary of [HHS] shall not promulgate any regulation that—"

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

42 U.S.C. § 18114(1)-(5).

HHS's Counseling Distortions contravene each of these prohibitions. As described above, the New Rule restricts Title X clinicians' ability to disclose "all relevant information to patients making health care decisions" and interferes with communication about the "full range of treatment options." It also creates "unreasonable barriers" and "impedes timely access" to abortion care by referring patients seeking an abortion referral to prenatal care instead, *see* Section 59.14(b)(1), and perhaps offering them an unlabeled, unexplained list of primary care/prenatal providers that may or may not include some who also provide abortion, Section 59.14(b)(1)-(2). Patients who seek abortion care are the only

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ones barred from accessing referrals that Title X patients otherwise freely receive for *out-of-program* care. *See* Section 59.5(b)(8).

Moreover, these Counseling Distortions violate medical "principles of informed consent" and "ethical standards." 42 U.S.C. § 18114(5). All of the leading medical associations explained to HHS that the Counseling Distortions would violate ethics and patients' rights to voluntary, informed decision-making. *See, e.g.*, Am. Acad. of Nursing Comments at 4 ("Code of Ethics for Nurses stipulates that patients have the right 'to be given accurate, complete, and understandable information in a manner that facilitates an informed decision'" and compliance with these ethical obligations depends "upon [patients'] both having all treatment options presented and referrals"); AMA Comments at 3 ("changes on counseling and referral . . . would not only undermine the patient-physician relationship, but also . . . force physicians to violate their ethical obligations"); ACOG Comments at 6 (referencing "the ethical obligations that physicians have to provide a pregnant woman who may be ambivalent about her pregnancy full information about all options in a balanced manner"); Am. Acad. of Physicians Assistants Comments at 2 (citing medical ethics); Ass'n of Am. Med. Colleges Comments at 2 (same). The ethical violations are compounded by the New Rule's involuntary "referral for [prenatal] services" when a patient does not wish to receive it. ACOG Comments at 3.

HHS acknowledged that some comments referenced ethical violations. 84 Fed. Reg. at 7745. But then it failed to contend with any of the cited ethical standards and obligations. HHS, with no support, simply stated: "HHS believes

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that medical ethics . . . are not inconsistent with this final rule." *Id.* at 7748. As the medical authorities, their codes of ethics, and their principles of informed consent establish, however, HHS has promulgated the New Rule in violation of Section 1554(5). *See also* Prager Decl. ¶¶ 17-36; Madden Decl. ¶¶ 19-35.

The New Rule is contrary to law because it conflicts with each of subsections (1)-(5) of Section 1554, as set forth above. Plaintiffs are therefore also likely to prevail because HHS acted contrary to law by violating the patient-protection rulemaking constraints of Section 1554.

(4) The New Rule's Counseling Distortions Are Arbitrary and Capricious

In addition to violating multiple statutes, the New Rule's Counseling Distortions are also arbitrary and capricious, because *inter alia* (i) HHS failed to consider the dignitary, medical, and collateral harms to the Title X patients involuntarily subjected to the Counseling Distortions; (ii) HHS jettisoned its own national standards of care adopted in the QFP for pregnancy counseling, without explanation; and (iii) HHS ignored comments that made clear that current providers serving more than 40% of Title X's patients would be forced from the program if the new bar on abortion referrals were imposed, leaving massive gaps.

Nowhere does HHS mention the discouragement, shame, and distrust that pregnant patients rebuffed by their health care providers in confidential pregnancy counseling will feel if the Counseling Distortions take effect. *See, e.g.*, Mt. Sinai Adolescent Health Ctr. Comments at 6 ("[T]his restriction on providing complete information will inevitably lead to frustration and perceived unresponsiveness on the part of our patients, making them less likely to return for future care . . . .").

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Title X serves patients with the least resources, limited English proficiency and education, and other vulnerabilities—these patients may not even know that abortion is legally available. Nevertheless, HHS implausibly suggests that there is no harm in depriving these patients of information about abortion, because it is "widely available . . . including on the internet." 84 Fed. Reg. at 7746; *cf.* Montana Primary Care Ass'n Comments at 3 (explaining Title X patients have low literacy, particularly "health literacy," and "lack regular access to communications tools (e.g., internet, phone)"). Many commenters called attention to the myriad ways patients would suffer from the Counseling Distortions, but HHS never looked at its proposed rules through the eyes of the patients Congress intended Title X to serve. That failure infects the entire New Rule, as addressed further below.

HHS also, without any discussion, rejected the expert conclusions and national standards of care that *HHS itself* spent years developing. The agency worked for four years to develop the QFP, using multiple panels of experts HHS chose. Coleman Decl. ¶¶ 14-15, 63-77. As discussed above, the QFP makes clear that proper pregnancy counseling offers both information and referral, QFP at 13-14, and is driven by the desires of the patient. *See supra* at 11. The QFP also emphasizes that pregnancy "counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG and AAP." QFP at 14. But HHS failed to consider or adequately respond to opposition to the new counseling rules by those very medical groups. *See* ACOG Comments at 8-9; AAP Comments at 3-4. The agency's failure to consider its own QFP standards and to respond to such comments is the definition of arbitrary and

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capricious action. *Humane Soc. of U.S. v. Locke*, 626 F.3d 1040, 1049 (9th Cir. 2010) (vacating agency decision made without "cogent explanation" for its conflict with agency's own previous scientific findings).

HHS also refused to confront—much less respond to—unequivocal statements from current providers that they would be forced to leave the Title X program immediately if "its proposed referral ban" and other Counseling Distortions were finalized, because those restrictions are at odds with their professional and ethical standards. PPFA Comments at 15. Planned Parenthood made clear that all of its providers—13% of all Title X sites that serve *more than 40% of all current Title X patients*—would immediately leave the Title X program if a ban on abortion referrals took effect. *Id*. at 16. Other commenters warned that other experienced, qualified clinicians would also leave. *See, e.g.*, Fam. Planning of S. Cent. N.Y. Comments at 1. But HHS simply ignored the impending exodus of sites and clinicians and the disruption to the Title X network that the Counseling Distortions would create. (Commenters also made clear that the separation requirements would trigger departures, too. *See infra* at 24-26.) An agency charged with funding health care for vulnerable patients is "entirely fail[ing] to consider an important aspect of the problem" when large numbers of existing, effective providers make clear they will immediately leave the program and cripple its operations if a proposed rule is adopted. *State Farm*, 463 U.S. at 43.

B. The New Rule's Destructive and Unjustified Separation Requirements and Infrastructure Limits Are Arbitrary and Contrary to Law

The New Rule further disrupts Title X care by imposing excessive "physical

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and financial separation" requirements between a funded entity's Title X activities and any abortion-related activities the entity undertakes outside the Title X project, without federal funds. 84 Fed. Reg. at 7764-67, 69. It empowers the Secretary of HHS to define the specific "integrity and independence" required for Title X sites on a case-by-case basis, but makes clear that exacting physical, staff, and systems separation—"bright line" separation—are required. *Id.* HHS emphasizes, for example, that employing one staff for Title X activities and a wholly separate one for any abortion-related activities is insufficient separation, that collocation of Title X activities and abortion-related activities within a single space is impermissible, and that separate electronic health record systems for Title X versus any abortion-related care are required. *Id.* Indeed, in connection with the new infrastructure spending limits, Section 59.18, HHS declares that "Title X projects would not share any infrastructure with abortion-related activities." 84 Fed. Reg.at 7774.

Sections 59.13, 59.15-16 and 59.18 (the "Separation Requirements") threaten to disrupt current Title X grantees, subrecipients, and service sites by requiring them to somehow separate and duplicate the physical, staff, and electronic components of their operations. If any of those resources are used for Title X purposes, HHS can require separate ones in order for the entity to engage in *any* non-Title X medical, education, or outreach activities that might even indirectly touch on abortion. These onerous and untenable new requirements are antithetical to Title X's ongoing service to patients, as explained below.

Plaintiffs are likely to prevail in their challenge to the Separation Requirements because they are arbitrary, not the product of reasoned decision-

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making, and erect unreasonable barriers in violation of Section 1554 and Title X. Among other failings, HHS did not justify its new departure from past agency practice, respond to significant objections, or adequately consider the Separation Requirement's costs, in either dollars or harm to the program.

(1) HHS Reversed Course and Adopted the Extreme Separation Rules and Infrastructure Limits Without Good Reason and Without Regard to Reliance

When changing longstanding policy, an agency must provide "good reasons for the new policy" and consider "serious reliance interests" engendered by the previous policy; otherwise, the regulation is unlawful. *Encino Motorcars*, 136 S.Ct. at 2126 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). HHS did neither.

The Separation Requirements abandon HHS's longstanding, explicit guidance that providers who offer both Title X and abortion care can utilize shared physical facilities (including, for example, shared examination and waiting rooms), shared staff, and shared records systems. 65 Fed. Reg. at 41,282. Strict financial separation, on the other hand, is already required. *Id.* Title X funds are already used solely for Title X purposes, kept separate from other funds, and spent and rigorously accounted for so that none are used for abortion care. *See* 42 C.F.R. §§ 59.5, 59.9. Providers also use "counseling and service protocols, intake and referral procedures, material review procedures" and other administrative means to keep the Title X program distinct from abortion care. 65 Fed. Reg. at 41,282. For decades, HHS has advised Title X recipients to rely on these means of organizing their health centers; they have arranged their facilities and operations to comply.

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The new Separation Requirements also apply to entities that do not provide abortion care, but engage in any abortion-related activity, including providing referrals for abortion, creating educational materials about it, or paying dues to membership organizations that protect access to it. 84 Fed. Reg. at 7769. These entities, too, have organized their Title X projects—including their locations, staffs, and systems—around the longstanding Title X rules that permit shared spaces, personnel, and other infrastructure (but strictly limit use of funds).

HHS claims it adopted the Separation Requirements to address "potential both for confusion and . . . co-mingling" or a "risk" of the "appearance and perception" of misuse of Title X funds. 84 Fed. Reg. at 7764-65. However, HHS offered *no* evidence of *any* misuse of Title X monies for abortion-related activities. *See, e.g.*, 84 Fed. Reg. at 7725 (conceding that the unrelated Medicaid billing issues HHS cited in the NPRM were not indicative of abuse of Title X funds); *see also Nat'l Fed'n of Indep. Bus. v. Perez*, 2016 WL 4766121, at *29 (N.D. Tex. June 27, 2016) (granting injunctive relief where agency had "not offered any evidence showing a new alleged need for its dramatically changed rule.").

In promulgating the New Rule, HHS failed to provide good reasons for the new policy, and "demonstrate[d] no true cognizance of the serious reliance interests at issue here—indeed, it does not even identify what those interests are." *N.A.A.C.P. v. Trump*, 315 F. Supp. 3d 457, 473 (D.D.C. 2018). HHS failed to acknowledge that Title X grantees and subrecipients have found accessible locations, purchased or leased land, built offices and clinics, hired and trained staff, established phone numbers, email addresses, and websites, and purchased records

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systems—relying on the agency's decades-long interpretation of Title X, expecting that shared facilities, personnel, and records systems would comply with regulations. *See, e.g.*, Maisen Decl. ¶¶ 23-37; Coleman Decl. ¶¶ 97, 122, 133-34.

HHS is not "free to disregard reliance interests engendered by the longstanding interpretation of [Title X] when it alters its regulations." *Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 431 (E.D.N.Y. 2018). Courts have held, for example, that beneficiaries of the Deferred Action for Childhood Arrivals (DACA) program have reliance interests despite the contingent, discretionary nature of DACA benefits. *See id.*; *see also Regents of Univ. of Cal. v DHS*, 279 F. Supp. 3d 1011, 1045 (N.D. Cal. 2018), *aff'd* 908 F.3d 476 (9th Cir. 2018); *see also N.A.A.C.P.*, 315 F. Supp. 3d at 473. HHS has acted arbitrarily and impermissibly in its reversal of course and its new requirement of separation.

(2) HHS Also Acted Arbitrarily By Failing to Respond to Significant Comments on the Infeasibility of Compliance and Network Disruption

The New Rule is arbitrary and capricious on those grounds alone, but HHS also ignored objections that the Separation Requirements will make it effectively impossible for many quality family planning care providers to stay in the Title X program. For example, grantees like the Family Planning Council of Iowa, which has operated a Title X project for decades, explained that it and organizations like it "will find it extremely difficult and burdensome to comply with the new requirements if they are adopted, and many organizations will determine that they cannot do so." FPCI Comments at 6-7. And subrecipients like Drexel College of Medicine Women's Health Center, a Title X provider in Philadelphia, commented

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that it "would have a difficult, if not impossible task" in "trying to accomplish sufficient physical separation." Drexel Comments at 5.

HHS states that it "disagrees" with the contention that the Separation Requirements "will destabilize the network of Title X providers" because the Rule "continues to allow organizations to receive Title X funds . . . as long as they comply with the physical and financial separation requirements." 84 Fed. Reg. at 7766. Merely acknowledging such objections—or stating the tautology that if organizations somehow comply, then there will be no disruption—is no substitute for actually weighing the evidence. *See Am. Coll. of Emergency Physicians v. Price*, 264 F. Supp. 3d 89 (D.D.C. 2017) (agency must respond in a reasoned manner to comments that raise significant problems). Myriad comments show that current providers, in fact, will struggle to comply, would have to drastically change their operations to do so, and may be forced to leave Title X. *See, e.g.*, Federal AIDS Partnership Comments at 7-8. HHS provided no reasoned response.

(3) HHS Vastly Underestimated Cost and Failed to Weigh the Significant Program Harms Against the Absence of Program Need or Benefit

In further violation of the APA, HHS failed to consider the extreme financial costs caused by the Separation Requirements—both the costs needed to separate initially and ongoing costs to maintain separate facilities with separate staff and systems. Furthermore, HHS considered only Title X providers that also offer abortions for its estimates of cost impact. But that approach does not account for all the entities that may not provide abortions, but nevertheless engage in the other abortion-related activity that HHS now targets for separation. HHS then estimated,

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without any support, that only 15% of Title X sites are not in compliance with the Separation Requirements, and each would incur $30,000 to come into compliance.

As the Missouri Family Health Council (Missouri's sole Title X grantee) stated, this "estimate is completely unrealistic—it typically costs hundreds of thousands, or even millions, of dollars to locate and open any health care facility (and would also cost much more than $10-30,000 to establish even an extremely simple and limited office), staff it, purchase separate workstations, set up record-keeping systems, etc." Missouri FHC Comments at 8; *see also* NFPRHA Comments at 37 ("hundreds of thousands of dollars or more" per health center to pay for all the components of separation); PPFA Comments at 32 (average estimated compliance cost per site nearly $625,000, based on construction and build-out costs). HHS does not acknowledge these estimates—let alone respond to them or substantiate its contention that costs would be minimal. *See, e.g., Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 2019 WL 1082162, at *18 (D.D.C. Mar. 7, 2019) (holding agency's failure to consider cost of implementing the regulation was arbitrary and capricious and vacating regulation).

Moreover, the costs of separation are grossly disproportionate to the level of funding that most Title X health centers receive. In many projects, there are numerous organizations and dozens of health center sites receiving funding. *See* Coleman Decl. ¶¶ 7, 127. Even a multi-million dollar annual grant, used to fund those dozens of sites, is not commensurate with spending hundreds of thousands per site to undertake separation and then bearing the ongoing costs to staff and operate it. Moreover, these duplicative facilities and costs are not rational for

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public agencies or non-profit organizations to attempt to undertake—when the entities' purpose is aiding the public health, not construction or multiplication of facilities and systems. *See Faith Int'l Adoptions v. Pompeo*, 345 F. Supp. 3d 1314, 1333 (W.D. Wash. 2018) (rejecting agency position as "simply illogical" and finding no intent by lawmakers for "such an unnecessary waste of resources").

The new limits on infrastructure spending also impose unnecessary costs and are irrational for operating Title X projects. According to HHS's interpretation of Section 59.18, as soon as that provision takes effect, it will be impermissible for Title X funds to pay the Title X project's pro-rata share of utility bills, EHR monthly fees, staff training programs, etc., if an entity's other, non-Title X programs include any abortion-related activities or expression. 84 Fed. Reg. at 7773-74. In limiting infrastructure spending, HHS even challenges using Title X funds for outreach workers to distribute condoms and encourage patients to visit Title X facilities—though Title X regulations undisturbed by the New Rule specifically *require* such activity. *Id.*; *cf.* 42 C.F.R. § 59.5(b)(3).

HHS's new limits on using Title X funds for infrastructure expenses are contrary to Title X's explicit statutory intent to fund both the "establishment and operation" of projects. 42 U.S.C. § 300. Title X grants have long funded, with HHS encouragement and pre-approval in grant budgets, critical infrastructure to keep the lights on, the staff trained, and the doors open at Title X sites. *See* 84 Fed. Reg. at 7773-74. However, without justification, HHS now imposes new infrastructure limits and other unclear spending constraints (such as allowing only "direct implementation" costs) to unduly limit the use of Title X funds and impair

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projects' functioning. *See also ANR Storage Co.*, 904 F.3d at 1026-28 (agency cannot "turn[] on a dime" in its reasoning).

(4) The Separation Requirements Also Violate Section 1554

Finally, Plaintiffs are also likely to succeed on the merits because the Separation Requirements conflict with the PPACA and thus are contrary to law.

First, the New Rule requires, *inter alia*, separate facilities, separate personnel, and separate health care records from any activities that "refer for," "support[,]" "encourage, promote, or advocate for abortion." Sections 59.14-59.16. It therefore "creates . . . unreasonable barriers . . . to obtain[ing]" abortion care and "impedes timely access" to abortion "health care services," contrary to the express prohibition in 42 U.S.C. § 18114(1)-(2). Indeed, the New Rule is designed to have that unlawful effect: it prohibits any "assist[ance]" for women seeking abortions or actions to make abortion accessible. Section 59.16. Entities can provide a referral for abortion, if at all, only in a separate facility through a different staff member than they use for any Title X activities. But Title X patients will not know where to find such a separate facility, because Title X providers cannot inform them of it. *See* Section 59.14(c)(1) (ban on indirect referral).

Second, the Separation Requirements also bar the provision of Title X family planning care immediately following an abortion. For example, insertion of an IUD (paid for with Title X funds) post-procedure for these patients who wish to avoid pregnancy—at a particularly safe time to do an insertion—would be prohibited because the two types of medical care can no longer be collocated. *See* Dr. Prine Comments at 1. Therefore, the New Rule also "creates unreasonable

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barriers" and "impedes timely access" to Title X contraceptive care.

Third, the New Rule mandates that Title X health centers have separate office entrances, phone numbers, email addresses, and websites from now-prohibited activities. When Title X providers change their addresses, numbers, and websites to comply, patients will have difficulty finding sites they previously visited. *See* Institute for Policy Integrity Comments at 5. This, too, is an unreasonable, unnecessary barrier to medical care in violation of Section 1554.

Fourth, the Separation Requirements prevent the availability "in any fashion" of written materials regarding abortion. 84 Fed. Reg. at 7790. They thereby restrict, hand in hand with the Counseling Distortions, "full disclosure of all relevant information to patients making health care decisions" about whether to continue or terminate their pregnancy. 42 U.S.C. § 18114(4).

For all these reasons, Plaintiffs are likely to succeed on the merits of their APA claims with respect to Sections 59.13, 59.15-16, and 59.18 of the New Rule.

C. The New Rule Exceeds Title X's Limits and Is Arbitrary In Its Moves to Change the Composition of the Title X Provider Network

Plaintiffs are also likely to prevail in showing that the New Rule departs from Title X and adopts several arbitrary changes to alter the type of providers in the Title X program—each to the detriment of Title X patients, based on irrational purported reasoning, and without responding to significant comments, including those that raised less harmful alternatives. Sections 59.5 and 59.7 impose these changes, in conjunction with other, intertwined parts of the New Rule.

(1) <u>The New Rule Blocks Title X Providers Without Primary Care On Site or Nearby, Hampering Title X to Purportedly Expand Care Outside It</u>

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Section 59.5 defines the programmatic "requirements" for Title X family planning projects. The New Rule creates a new subpart in 59.5(a), such that "[e]ach project supported under this part must:"

> (12) Should [sic] offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

See 42 C.F.R. § 59.5(a); 84 Fed. Reg. at 7787-88 (Section 59.5(a)(12)).

Numerous commenters alerted HHS that the geographic proximity requirement would block existing or future Title X sites in areas where low-income patients lack access to primary care and Title X sites offer the *only* health care. HHS had no answer. Moreover, HHS failed to address the many comments that emphasized this change is exceedingly unclear in mixing "requirements," "must," and "should;" and in not defining what HHS deems a "robust referral linkage" or "in close proximity." Title X providers *already* establish referral relationships with primary care providers for their patients. *See* 42 C.F.R. § 59.5(b)(1), (8). Thus, this new subsection merely confuses and creates an obstacle to Title X family planning clinics where access to any health care is needed most.

For instance, the Association of State and Territorial Health Officials ("ASTHO") specifically warned HHS that, in "primary care health professional shortage areas," this part of the New Rule may prevent state and local health agencies from maintaining or opening Title X sites. ASTHO Comments at 2. ASTHO emphasized that "most state and local health agencies do not provide direct primary care," and that HHS provided no definition of "close physical

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proximity" or of what "robust referral linkages" would entail. *Id.*

The West Virginia Department of Health, that state's Title X grantee, made clear that West Virginia residents would be left with "no access to any services if some providers are barred from becoming a Title X clinic, due to the lack of close proximity to more comprehensive services." WVDH Comments at 1; *see also* PPFA Comments at 16 ("Fifty-six percent of Planned Parenthood health centers are in health provider deserts."). West Virginia specifically proposed that "rural areas with already limited access to healthcare" be an exception "to allow for rural clients to receive key family planning services" through Title X, even if no primary care is available nearby. WVDH Comments at 1; *see also* ACOG Comments at 13. HHS failed to acknowledge these concerns, to create an exception, or even to clarify "close physical proximity" and "robust referral linkages."

Instead, HHS simply asserted that onsite or close linkages to primary care should take precedence, 84 Fed. Reg. at 7749-50, regardless of the negative impact on the reach of Title X care into underserved communities. But that reasoning impermissibly prioritizes expanding comprehensive primary care—which is not Title X care—over access to quality family planning services, Title X's purpose. *See Beno*, 30 F.3d at 1073-75 (agency violates APA by ignoring "significant objections and alternative proposals" and failing to consider its decision's danger to the benefit program's recipients); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008) (agency must consider "responsible alternatives" and give "reasoned explanation" for rejection).

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(2) The New Rule Encourages Title X Sites Offering Single or Limited Methods of Contraception and Methods Not Medically Approved, While Opening Title X to Providers With Religious Objections to Core Care

Congress's motivating purpose for the Title X program sought to open access to "a broad range" of family planning methods for low-income patients, so that they could afford modern medical advances and have truly free choice in making contraceptive decisions. 42 U.S.C. § 300; Coleman Decl. ¶¶ 18-24. Per HHS's own QFP, providers should employ the "full range of FDA-approved contraceptive methods" in treating their patients, while letting "client values guide all clinical decisions." QFP 4-5; 8 (after taking a medical history, providers should describe "all contraceptive methods that can be used safely" by that patient).

Despite strong objections from leading medical and public health experts, HHS now (i) seeks providers with "conscience concerns" that would limit the range of family planning methods they are willing to offer, *see* 83 Fed. Reg. at 25,526; 84 Fed. Reg. at 7743; (ii) removes the phrase "medically approved" from 42 C.F.R. § 59.5(a)(1), after enforcing "medically approved" as a key component of that regulation for almost 20 years; and (iii) emphasizes that Title X-funded "entit[ies] may offer only a single method or a limited number of methods" of family planning, "as long as the entire project offers a broad range of methods and services." Section 59.5(a)(1). *Cf.* ACOG Comments at 8-10 (opposing these changes, stressing lack of safeguards for all patients' access to the contraceptive choice that will work best for them); AMA Comments at 3-4 (changes will "undermine the quality and standard of care upon which millions of women depend"); APHA Comments at 5; Guttmacher Comments at 15; Dr. Dehlendorf

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Comments at 2 (changes harmfully "lower[] the bar" by prioritizing faith-based provider concerns over patient preferences and needs).

As commenters explained, the combination of these changes exacerbates their harmful impact—HHS is inviting in religious objectors at the same time as it is emphasizing it will allow sites that provide only a single or limited contraceptive method(s). Religious objectors could refuse to counsel about IUDs or other methods to which they object, while offering only natural family planning, the least effective barrier methods, or non-medically approved approaches. Moreover, such sites will not have to notify patients that they are receiving artificially limited choices, and Title X projects—which commonly span an entire state or other large area—will not have to ensure that patients have ready access to full-service Title X sources of care. *See* ACLU Comments at 14; 84 Fed. Reg. at 7741 ("patients [will] struggle to find providers that offer desired services"); *cf.* Pub. L. 91-572 § 2(1), 84 Stat. 1504 (stating first purpose of Title X to make "comprehensive voluntary family planning services readily available to all").

In response, HHS saw "no cause for concern" and did not take into account the combined effect of (a) new religious-objector providers that oppose many contraceptive methods, (b) the option of single- or limited-service sites, and (c) the removal of "medically approved." 84 Fed. Reg. at 7742 (failing to consider that the New Rule's accompanying changes would render single- or limited-method sites more harmful); *see Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1072-73, 1075 (9th Cir. 2018) (agency acted arbitrarily by failing to consider "additive" and "synergistic" effects). HHS also asserted interests in allowing

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"entities to provide services for which they have particular expertise" and "clients [being] more likely to visit clinics that respect their views and beliefs," but both those interests are already served by the status quo and the QFP standard of care.

The record establishes that the new providers HHS seeks and the changes to Section 59.5(a)(1) will combine to limit, rather than expand, choice for Title X patients, contrary to HHS's bare assertions. These changes merely "protect the ability of health care providers . . . with conscientious objections" to severely limit the range of contraceptive care they offer with Title X funds, 84 Fed Reg. at 7743, at the expense of patients, without patient knowledge, and contrary to the bedrock purpose of Title X. *Cf.* Pub. L. 91-572 § 2(1), 84 Stat. 1504; Coleman Decl. ¶¶ 18-24, 116. They conflict with Title X, violate Section 1554(1)-(3), and constitute arbitrary, unfounded rulemaking.

(3) The New Rule Imposes a Vague, All-Encompassing Eligibility Hurdle for Applications and New Application Review Criteria That Depart from Title X and HHS's General Grant-Making Rules and Are Arbitrary

HHS administers numerous competitive grant programs like Title X and has adopted general rules for all such grants that establish a fair and merit-based system for considering competing applications, including by using knowledgeable outside reviewers. *See* 45 C.F.R. § 75.200-18, App. I; HHS, *Grants Policy Statement* (Jan. 1, 2007). Under these rules, HHS requires any eligibility requirements to be "clearly stated." 45 C.F.R. § 75, App. I(C)(3). Eligibility typically turns on the type of entity—as it does in the Title X statute. *See* 42 U.S.C. § 300(a); 42 C.F.R. § 59.3 (a) ("[a]ny public or nonprofit entity . . . may apply for a [Title X] grant"). If a grant program uses other eligibility (or "go-no-

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go") criteria to determine whether an application will be considered, those must be "objective criteria." *Grants Policy Statement* at I-11. HHS states, as to eligibility requirements and the separate criteria used by merits review panels, *see* 45 C.F.R. § 75.204; 84 Fed. Reg. at 7755: "The intent is to make the application process transparent so applicants can make informed decisions when preparing their applications to maximize fairness of the process." 45 C.F.R. § 75, App. I(E)(1).

Yet the New Rule does not treat as controlling the "any public or non-profit entity" eligibility standard in the Title X statute, 42 U.S.C. § 300(a), and 42 C.F.R. § 59.3(a), a regulation that HHS is not amending. The New Rule instead imposes another sweeping and subjective eligibility determination to be made by the HHS Secretary before an application's merits will even be considered; this added scrutiny is inconsistent with "any public or non-profit entity" being eligible. Moreover, this new Section 59.7(b) piles vagueness upon vagueness by asking applicants to "clearly describe" their "plans for affirmative compliance" with every single one of the dozens of subparts in the 19 Title X regulations; that includes, for example, Sections 59.5(a)(12) ("robust referral linkage … in close proximity"), (a)(13) ("adequate oversight and accountability for quality and effectiveness"), 59.15 ("integrity and independence"), and 59.18 (unclear infrastructure and "direct implementation" restrictions). And then the New Rule empowers HHS to subjectively decide if an application is not "clear" or "affirmative" enough on any one part and reject it out of hand. That occurs without regard to the application's programmatic merits, the proposed project area's needs, or whether there is any competing application to serve that area. The record is devoid of support for

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HHS's contentions that such a burdensome and unpredictable new eligibility threshold is necessary to "avoid misuse of funds" by grantees or to limit the workload of merits review panels, 84 Fed. Reg. at 7754. It conflicts with Title X by altering its specific eligibility terms, and uniquely subjects Title X applicants to an arbitrary, subjective, and unfair process, inconsistent with HHS's general rules.

The New Rule's merits review criteria also include unsupported and arbitrary new provisions that depart from the Title X statute and will undermine Title X's success. For example, Section 59.7(c)(2) describes a single criterion with multiple aspects, one of which will only be applied to *some* applicants—without explaining how competing applicants under this variable criterion can fairly be scored against each other. That part of Section 59.7(c)(2) would rank some applicants on their "ability to procure a broad range of diverse" subrecipients, "including those who are nontraditional," 84 Fed. Reg. at 7754—despite HHS's lack of any evidence that prioritizing new and different subrecipients would help, rather than harm, the effectiveness of Title X. HHS has not shown or even rationally explained how changing the Title X network for the sake of provider diversity would "improve or expand the quality" of services for patients, 84 Fed. Reg. at 7755, especially where the record confirms that patients prefer and get the best care from the types of providers already prevalent in Title X. *See, e.g.*, Guttmacher Comments at 3, 10, 13-14. The new, convoluted criteria in Section 59.7(c) are contrary to Title X, arbitrary, and internally inconsistent.

D. HHS Ignored Central Issues for the Title X Program—Negative Impact on Patient Care, Departure of Providers, and Public Health Harms—and Rejected Health Experts' Consensus Opposition to the New Rule

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Apart from its numerous specific legal flaws, the entirety of the New Rule is impermissible because it is fundamentally at odds with Congress's purpose in establishing and funding the Title X program: providing access to comprehensive, quality family planning care to aid the reproductive autonomy of those with few economic resources. *See* Coleman Decl. ¶¶ 18-24. This rulemaking is arbitrary, unreasoned, and contrary to law because it fails throughout to consider how it injures Title X patients and ruptures the Title X provider network.

Remarkably, HHS's rulemaking never considered or weighed the harmful impact on Title X patients of depriving them of voluntary, informed decision-making and quality care, consistent with HHS's own national standards. HHS ignored not just the harms to individual patients but to the public health overall, from the provider departures and large service gaps in the national network that the New Rule will cause. Similarly, HHS ignored the outsized, unnecessary financial costs that the New Rule will impose. And HHS proceeded in the face of uniform opposition from the country's leading medical and public health authorities.

An agency may not "[i]gnore [e]vidence," including regarding public harm, that is inconvenient or at odds with its conclusion. *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018). Federal courts have rejected other actions by HHS that jeopardize the public health aims of a federal program without adequate consideration of the actions' consequences. *See Stewart*, 313 F. Supp. 3d at 264 (faulting the Secretary for granting waivers "with no idea of how many people might lose Medicaid coverage and thus 'fail[ing] to consider an important aspect of the problem'"). HHS's failure to address comments raising "problems with the . . .

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regulation that, if legitimate, could prevent the regulation from accomplishing the Departments' stated goal," renders the rule arbitrary. *Am. Coll. of Emergency Physicians*, 264 F. Supp. 3d at 96. If such problems threaten to "*defeat the purpose of the protections in the statute*," the agency must rationally and coherently respond. *Id.* (emphasis in original). Here, it did not do so.

Under the New Rule, patients will receive inadequate care and unduly limited options not only in Title X pregnancy counseling, but also if they visit a one-method or limited-method Title X provider that fails to offer a broad range of contraceptive options and objects to discussing any others. Patients will also be confused and deprived of ongoing access to care if their long-standing source of free care—the local Title X provider—is pushed from the program and disappears. Yet HHS never considered the experience of and injuries to current and future Title X patients as information, options, and sites are taken away.

As the comments to HHS exhaustively showed, provider departures will occur at the grantee, subrecipient, and individual clinician level. These will result from not only the Counseling Distortions, but also from (i) the new infrastructure and separation requirements, (ii) the need to collocate Title X sites with or near primary care, (iii) the demand to add "diversity," regardless of how the care at new sites compares with that of current providers, and (iv) through HHS's use of the new, subjective eligibility hurdle for ongoing grant funding. But HHS does not respond to the weighty evidence in the record that significant provider departures will indeed occur as a result of these multiple new requirements, and merely suggests that there are new providers waiting to apply, without substantiating that

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contention. *Nat. Res. Def. Council, Inc. v. EPA*, 859 F.2d 156, 210 (D.C. Cir. 1988) (agency actions based on mere speculation are arbitrary and capricious). HHS finalized the New Rule in the face of overwhelming opposition from medical authorities and experts in providing family planning care. *See, e.g., supra* at 17-20, 25-30. The agency obscured this uniform medical opposition by generally referring to "commenters" and failing to credit commenters' expertise. But when an agency charged with protecting the public health treats reputable scientific thought dismissively and offers no comparable analysis of its own, its rulemaking is arbitrary. *See Nat'l Mining Ass'n v. Zinke*, 877 F.3d 845, 868 (9th Cir. 2017) (agency must "consider[] the available scientific data" in its analysis).

Indeed, HHS was dismissive even of the numerous expert comments that explained that disruption of the Title X network would reverse the past success of the Title X program. These experts showed that diminished access to Title X sites and a reduced range of contraceptive options at some sites that remain, particularly those of religious objectors, would impede the program's ability to assist patients in the prevention of unintended pregnancies, and thus increase abortions as well as expenses paid by publicly-funded health care for additional births. Likewise, fewer STIs, including HIV, and cervical cancers would be detected and treated. The agency ignored or paid mere lip service to the many comments sounding these evidence-based public health alarms. *See, e.g.*, Guttmacher Comments at 19; Baltimore City Health Dep't Comments at 1-4. The New Rule is arbitrary and capricious because its effect—decimating the provider network and causing public health harms to low-income patients—directly undermines the very purpose of

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Title X. *See Ctr. for Biological Diversity v. EPA*, 722 F.3d 401, 411 (D.C. Cir. 2013); *Shays v. FEC*, 528 F.3d 914, 932 (D.C. Cir. 2008).

IV. PLAINTIFFS AND THEIR PATIENTS WILL SUFFER IRREPARABLE HARM IF THE NEW RULE TAKES EFFECT

Irreparable harm is injury "for which there is no adequate legal remedy." *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014). The New Rule will irreparably harm Plaintiffs, including their members, clinicians, and patients on whose behalf they sue, *see* Complaint ¶¶ 21-30; Coleman Decl. ¶¶ 4-11. *See generally* Kost Decl. ¶¶ 35-124; Harris Decl. ¶¶ 60-72, 87-97.

If the New Rule is allowed to take effect, it will immediately put all Title X grantees, subrecipients, and individual clinicians to a "Hobson's Choice" between two untenable options, both of which will cause irreparable harm. *See Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1057 (9th Cir. 2009). If the Plaintiff organizations and their clinicians stay in the program, the rule will force each of them to provide substandard pregnancy counseling in violation of medical ethics—harming both providers and patients and eroding the trust at the heart of the patient-clinician relationship. Prager Decl. ¶¶ 17-18, 22-23, 32 (quoting ACOG and AMA ethics and guidelines); Madden Decl. ¶¶ 20, 25, 28 (same); *see* Kruse Decl. ¶¶ 12-13, 38 (the new requirements "would force me to disrespect, contradict, and patronize my patient, compounding her feelings of isolation and vulnerability" (citing ANA ethics)); Maisen Decl. ¶ 41; *see Stuart v. Camnitz*, 774 F.3d 238, 255 (4th Cir. 2014) (describing injury to physicians and patients flowing from the "contravention of medical ethics"). If, on the other hand, current provider

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organizations and clinicians cannot bear to provide such substandard care or cannot afford to separate, they must leave the Title X program—and cease providing care for the high-need, low-income patients who depend on them. *See* Cantrell Decl. ¶¶ 36-49; Kruse Decl. ¶¶ 29-40; Prager Decl. ¶ 48; Madden Decl. ¶ 35. The Ninth Circuit has held that such a forced choice between two harmful paths warrants preliminary injunctive relief. *See Am. Trucking Ass'ns, Inc.*, 559 F.3d at 1057.

Multiple layers of the New Rule's harms to Plaintiff organizations and clinicians warrant injunctive relief. The Counseling Distortions, the Separation Requirements, and the other disruptive and compromising features of the New Rule will harm Plaintiffs' missions, reputations, and goodwill in their communities, whether they remain in the Title X network or leave it. *See* Adams Decl. ¶¶ 27-68; Cantrell Decl. ¶¶ 37-49; Maisen Decl. ¶¶ 9, 34, 48; Coleman Decl. ¶¶ 3, 122, 150-51. These threatened harms to organizational purpose are further grounds for relief. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016) (recognizing harm to organizational mission as meriting a preliminary injunction); *Rent-A-Ctr., Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991) (recognizing "intangible injuries" to organizational "goodwill" as grounds for a preliminary injunction).

Some Plaintiff grantees and subrecipients will be forced to eliminate sites or participation in Title X altogether due to loss of their clinical staff or an inability to comply with the New Rule's terms. *See* Adams Decl. ¶¶ 33-40, 48-51 (discussing loss of subrecipients); Cantrell Decl. ¶¶ 43-47, 51; Maisen Decl. ¶¶ 34, 42. When that occurs, the affected grantees and subrecipients will lose all or a significant

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portion of their Title X funding mid-grant, *see* Adams Decl. ¶¶ 52-59; Cantrell Decl. ¶ 48; Coleman Decl. ¶¶ 147-51, causing irreparable harm through "reduce[d] services." *Planned Parenthood of Greater Wash. & N. Idaho v. HHS*, 328 F. Supp. 3d 1133, 1150-51 (E.D. Wash. 2018) (enjoining disruption of federally-funded services mid-grant); *see Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 242-44 (D.D.C. 2014) (funding loss for non-profit health care providers constitutes irreparable injury because it would "reduc[e] . . . services" for patients, including low-income patients, or require re-allocation of funding that would collaterally reduce services). The Ninth Circuit has held it is an abuse of discretion to fail to credit harms like the "threaten[ed] . . . future availability of services for the service recipients." *Arc of Cal. v. Douglas*, 757 F.3d 975, 991 (9th Cir. 2014).

For Plaintiff grantees and subrecipients that try to remain in the program, they will immediately have to expend scarce resources to address the New Rule's vague separation, infrastructure, and other requirements. *See* Adams Decl. ¶¶ 53-70; Coleman Decl. ¶¶ 124-36, 148-50; Eastlund Decl. ¶¶ 13-20. Such compliance costs to conform to a challenged rule have, alone, been recognized as grounds for preliminary injunctive relief. *See Texas v. EPA*, 829 F.3d 405, 433-34 (5th Cir. 2016) ("[C]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220-21 (1994) (Scalia, J., concurring))).

The New Rule also will subject grantees to the opaque and unfair new eligibility requirement and challenged grant-making criteria. Because HHS will be empowered to summarily deem applicants ineligible under Section 59.7(b) to even

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compete for Title X funds, grantees will have no choice but to expend tremendous resources to attempt to explain and affirmatively plan the *strictest* possible compliance necessary for each of the New Rule's elements. *See* Adams Decl. ¶¶ 64-70; Coleman Decl. ¶¶ 140-41. Being forced to compete for a federal grant on unfair terms, too, constitutes irreparable injury warranting relief. *City of L.A. v. Sessions*, 293 F. Supp. 3d 1087, 1100-01 (C.D. Cal. 2018) (enjoining challenged grant terms wholesale, not only as to plaintiffs, to "ensure an even playing field").

Finally, as soon as the New Rule's changes are imposed on the program they will harm—irreparably—Title X patients across the country, including Plaintiffs' patients. Kost Decl. ¶¶ 73-124. Pregnant Title X patients at all Title X sites will face coercive, misleading pregnancy counseling, contrary to clinical and ethical standards. *See* Maisen ¶¶ 40-42; Coleman ¶¶ 117-23. Mandatory prenatal referrals and information, together with a ban on abortion referrals and misleading information about the availability of abortion care will cause dignitary injury and "forestall or foreclose" patients' access to care. Kruse Decl. ¶ 37. After all, Title X is often "a patient's only viable way to access additional health care because of language, literacy . . . , or economic barriers," and without referrals and information through the program, many patients will have no practical means of accessing care. Kruse Decl. ¶¶ 36-37; *see* Prager Decl. ¶¶ 31, 40, 44-45; Madden Decl. ¶¶ 44-53. Patients seeking contraceptive care, too, stand to be injured: The New Rule permits religious objectors, for example, to offer limited contraceptive options, non-medically approved approaches, and no information for patients informing them that other options are available. Kost Decl. ¶¶ 96-101. The New

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Rule will cause Plaintiffs' patients irreparable injury through delay or obstruction of patients' access to health care. *See Rodde v. Bonta*, 357 F.3d 988, 999 (9th Cir. 2004) (recognizing delay in access to health care as irreparable injury for preliminary injunction); *see also Planned Parenthood of Kan. v. Andersen*, 882 F.3d 1205 (10th Cir. 2018) (same, with reproductive care).

The New Rule's disruption to the Title X network will further injure patients. Title X patients across the country will suffer a loss of reproductive and sexual health services, including loss of access to effective (but expensive) contraceptives, to HIV and STI testing, and to cancer screening, as providers are forced to reduce services or even shutter. The diminished Title X care will cause unintended pregnancy rates to rise and other public health consequences to be felt broadly. Kost Decl. ¶¶ 73-83, 123-24. These individual and public health harms cry out for relief. *See Planned Parenthood Ariz., Inc. v. Betlach*, 899 F. Supp. 2d 868, 886 (D. Ariz. 2012) (discussing public health harms from reduction in reproductive care to low-income patients).

The threatened irreparable harm for Plaintiffs, their members, and their patients is nationwide: NFPRHA represents Title X funding recipients in all states and two territories. Coleman Decl. ¶¶ 6-7; *Richmond Tenants Org. v. Kemp*, 956 F.2d 1300, 1302, 1308-09 (4th Cir. 1992) (nationwide injunctive relief is appropriate where plaintiff's members reside nationwide). NFPRHA's grantee-members compete for Title X funds in all 10 HHS regions. Coleman Decl. ¶¶ 6-7; *see Washington v. Reno*, 35 F.3d 1093, 1104 (6th Cir. 1994) (explaining that nationwide injunctive relief is appropriate where plaintiffs challenge unlawful

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distribution of finite federal funds); *City of L.A.*, 293 F. Supp. 3d at 1100-01 ("ensur[ing] an even playing field" in grant administration required). A preliminary injunction preventing any enforcement of the New Rule in any jurisdiction is required to provide Plaintiffs with complete relief. *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (citing *Califano v. Yamasaki*, 442 U.S. 682 (1979)); *Bresgal v. Brock*, 843 F.2d 1163, 1171-72 (9th Cir. 1987).

V. THE BALANCE OF THE EQUITIES AND THE PUBLIC INTEREST SUPPORT A PRELIMINARY INJUNCTION

The balance of the equities—which merges with the public interest, *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014)—tips sharply in favor of preserving Plaintiffs' ability to provide patients with family planning services under the terms, regulations, and standards of care that have governed Title X for many years. As this court explained when enjoining the government's cancelation of a federal pregnancy prevention grant, the public interest supports relief because it "prevent[s] harm to the community," where the government's action would block "potential beneficiaries from benefiting from valuable programs" mid-grant. *Planned Parenthood of Greater Wash.*, 328 F. Supp. 3d at 1152-53. In contrast, the government suffers no harm by continuing "the status quo (which has been in existence for . . . decades) . . . during the pendency of this litigation." *Ramos v. Nielsen*, 336 F. Supp. 3d 1075, 1080 (N.D. Cal. 2018).

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Each factor of the governing standard favors a preliminary injunction. Thus, this Court should completely enjoin any use of the New Rule to protect Plaintiffs.

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DATED: March 22, 2019 By: *s/ Emily Chiang*

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DECLARATION OF SERVICE

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

DATED, this 22nd of March, 2019, at Seattle, Washington.

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