Emily Chiang, WSBA No. 50517
AMERICAN CIVIL LIBERTIES UNION
OF WASHINGTON FOUNDATION
901 Fifth Avenue, Suite 630
Seattle, WA 98164
Phone: 206-624-2184
Email: echiang@aclu-wa.org

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' REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

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

TABLE OF CONTENTS

AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
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Seattle, WA 98164
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TABLE OF AUTHORITIES

Cases

AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

Statutes

Other Authorities

Rules

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901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

Regulations

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Defendants devote the majority of their opposition brief, ECF No. 44 ("Opp."), to arguing against straw men—including dozens of pages on the theme that Plaintiffs seek to and must overturn *Rust v. Sullivan*, 500 U.S. 173 (1991), to succeed. That premise is wrong, as are Defendants' arguments that flow from it.

Defendants essentially ask the Court to ignore laws that Congress passed since *Rust* to limit HHS's Title X rulemaking. Defendants also would have the Court ignore the contents of the rulemaking record, including significant comments from leading medical authorities and currently-funded Title X entities—the record designed to inform HHS's actions and upon which its 2018 rulemaking must be judged. Under current law and on this record, HHS's rulemaking is contrary to multiple laws and an arbitrary, irrational step that will maim the Title X program.

Likewise, when it comes to the imminent irreparable harms that the New Rule will cause, Defendants skirt the issues and ignore the facts. Their brief never addresses Plaintiffs' eight declarations that detail how, when, and on whom—including Plaintiff Title X grantees, their clinicians, and especially their patients—the New Rule will impose an array of very real and serious injuries.

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A. Plaintiffs Do Not Seek to "Overrule" or "Supersede" *Rust*

Defendants repeatedly claim that this lawsuit "seeks to overrule" *Rust v. Sullivan*, 500 U.S. 173 (1991). *See, e.g.*, Opp. at 1, 18, 29-30, 34, 37. It does not. Nor does it need to do so for Plaintiffs to prevail on any of their claims.

The *Rust* Court determined that a particular agency interpretation of the Title X statute—and Section 1008 in particular—was one plausible construction of the

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901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

statute; that HHS's 1988 rulemaking was reasonably explained by the record before the agency then; and that it did not otherwise conflict with Congress's expressed intent as of that time. *Rust*, 500 U.S. at 183-90. In doing so, the Court held that Section 1008 was ambiguous and "does not speak directly to the issues of counseling, referral, advocacy, or program integrity." *Id.* at 184. The Court did not establish any binding reading of Section 1008. *Id.* at 184, 188.

Plaintiffs do not seek to overrule *Rust* or "implied[ly] repeal" Section 1008. Opp. at 2. Instead, while *Rust* held that the 1988 regulations were a permissible interpretation *at that time*, subsequent congressional enactments—the Nondirective Mandate and the PPACA's Section 1554—limit the agency's rulemaking authority in 2019 and render the New Rule unlawful. To state the obvious, *Rust* does not take those subsequent statutory enactments into account; nor does it bear on whether HHS engaged in reasoned decision-making on a 2018 rulemaking record.

Defendants' implied repeal arguments are irrelevant. Courts only consider implied repeal if "statutes are in 'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute.'" *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 663 (2007).

B. The Counseling Distortions Violate Current Law and Are Arbitrary Based on HHS's Current Rulemaking Record and Rationales

(1) The New Rule Is Contrary to the Nondirective Mandate

a. Pregnancy Counseling That Refuses to Address the Option of Abortion, Even When a Patient Asks, Cannot Be "Nondirective"

Defendants concede that "nondirective" pregnancy counseling "'is designed to assist the patient in making a free and informed decision,' presenting each

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Seattle, WA 98164
(206) 624-2184

option in a 'factual, objective and unbiased manner.'" Opp. at 27 (quoting 84 Fed. Reg. at 7747); *see id.* (nondirective counseling is "a neutral presentation"). But pregnant patients cannot make a "free and informed decision" based on "unbiased" factual information when their counseling excludes the option of abortion and diverts any questions about abortion toward information about keeping the pregnancy. The New Rule does just that. 84 Fed. Reg. at 7745 (what the New Rule calls "nondirective" counseling can completely exclude "information about abortion"). Indeed, each of subparts (i) through (iv) in Section 59.14(b) allows Title X providers to exclude abortion information and discuss only information about keeping the pregnancy. *Id.* ("Title X projects will not be required to offer … abortion information"). In this way—among many others—the New Rule violates Congress's mandate that "*all* pregnancy counseling [in the Title X program] shall be nondirective," Pub. L. 115-245, 132 Stat. at 3070-71 (2018) (emphasis added).

Defendants' arguments about how a Title X patient might address the "medical condition" of pregnancy, Opp. at 25, lose sight of the fact that there are just two choices for that medical condition: (1) maintaining or (2) terminating the pregnancy. Any further consideration of whether to pursue adoption is premised on the first path.[1] It is thus impossible for pregnancy counseling to be nondirective

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[1] This explains why, in a 2000 law involving counseling training for Title X and other providers, Congress emphasized that "adoption information and referrals to pregnant women" are to be included "on an equal basis with all other courses of action included in nondirective pregnancy counseling." 42 U.S.C. § 254c-6(a)(1).

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(206) 624-2184

if it refuses to address termination—one of two paths for pregnancy. ECF No. 34 at 12.

b. "Pregnancy Counseling" Includes Referrals

Contrary to Defendants' position here, Opp. at 23, the phrase "pregnancy counseling" includes referrals. *See* ECF No. 19-2 ("QFP") at 13-14 (discussing the importance of referrals in HHS's clinical guidelines on "Pregnancy Testing and Counseling"); 42 U.S.C. § 254c-6(a)(1) (Congress discussing providing "information and referrals" *within* "nondirective pregnancy counseling").

Indeed, HHS itself describes nondirective pregnancy counseling as *including* referrals at various points in this challenged rulemaking. 84 Fed. Reg. at 7747 (discussing "nondirective pregnancy counseling, or *referrals made … during such counseling*") (emphasis added); *id*. at 7748 ("Referrals for … adoption are … permitted, as long as the counseling remains nondirective."); *id.* (arguing that the rule's "information and referrals do not necessarily render pregnancy counseling directive"). Defendants cannot avoid the ordinary meaning of pregnancy counseling, which includes information, discussion, and referrals, by citing generic Black's Law Dictionary definitions of "counseling" and "referrals." Opp. at 21-23.

c. The New Rule Fails To Make All Pregnancy Counseling Nondirective

Defendants' efforts to cast the New Rule as compliant with the Nondirective Mandate are counterfactual and each fail. Permitting Title X providers to refuse to discuss abortion and requiring them to deny abortion referrals are just two of the myriad forms of directive counseling introduced by the New Rule. NFPRHA Br. at 13-14. The New Rule also, without any medical support, falsely calls a prenatal

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901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

referral "medically necessary," requires that referral, and permits providers to tell patients of its "necessary." That is both directive and misleading. NFPRHA Br. at 13; ECF No. 34-1 at 13-15 ("Prenatal care is not medically indicated for patients who wish to terminate their pregnancies.") It becomes even more directive for patients that ask for abortion referral and are rebuffed, because that is forbidden.

Likewise, any list provided during pregnancy counseling (1) must include only "comprehensive primary health care providers (including providers of prenatal care)," a majority of which do not offer abortion, Section 59.14(2), and (2) cannot identify any abortion providers. That list is directive and biased toward prenatal care—particularly for patients who specifically seek abortion information and referral. Defendants downplay the directive nature of these provisions only by considering each in isolation, rather than in context: The parts work together to steer patients who seek information about termination toward prenatal care instead.

d. Defendants' Other Efforts to Negate the Plain Words and Binding Effect of the Nondirective Mandate Have No Merit

Contrary to Defendants' assertions, there is no "presumption against" appropriations requirements adding to or clarifying the requirements of underlying statutes. Opp. at 18, 21. This occurs all the time—appropriations bills are so long because they are full of enforceable provisos restricting the use of the allocated funds in various ways. *See, e.g.*, Pub. L. 115-245, 132 Stat. 2981; *see Dep't of Navy v. Fed. Labor Relations Auth.*, 665 F.3d 1339, 1349 (D.D.C. 2012) (enforcing substantive appropriations limits; Congress, not the Executive, controls the purse); *Cent. Montana Elec. Power Co-op, Inc. v. Admin. of Bonneville Power*, 840 F.2d

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Seattle, WA 98164
(206) 624-2184

1472, 1477 (9th Cir. 1988) (Congress "fully within its authority" to add "specific language to later appropriations bills" to fill in meaning of Flood Control Act). This is not a case like *Calloway v. Dist. of Columbia*, 216 F.3d 1 (D.C. Cir. 2000), Opp. at 2, 21, which involved *overturning* clear provisions of pre-existing statutes.

Rather, the Nondirective Mandate easily harmonizes with Section 1008 and Title X overall. This subsequent congressional requirement that "all pregnancy counseling" be nondirective is consistent with Section 1008's requirement that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning," 42 U.S.C. § 300a-6. As Defendants concede, any referral option for further medical care that is provided within Title X pregnancy counseling is for "medical care outside of the Title X program," *see* Opp. at 21 (abortion referral is to out-of-program care); *id.* at 25 (prenatal referral is to out-of-program care). Referring a pregnant patient *outside* a Title X project for abortion care does not include abortion *within* that Title X family planning program. The Supreme Court's holding in 1991 that Section 1008 was ambiguous, *Rust*, 500 U.S. at 184-87, plainly allows for this interpretation of 1008, and the Nondirective Mandate clarifies what is required in the Title X program.

Defendants also use an inapposite case and a mangled description of history to argue that a statute passed in 1992, but that was vetoed, somehow determines the meaning of the Nondirective Mandate as enacted each year from 1996 to the present. They rely on *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987), Opp. at 24, but that case dealt with sequential versions of bills in the *same* legislative session that culminated in the passage of a statute, not—as Defendants would use it

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Seattle, WA 98164
(206) 624-2184

here— with various proposals made years apart. Moreover, Defendants' history ignores that in 1993, HHS explicitly suspended any application of the 1988 "gag rule." In 1996, the agency was still in the process of finalizing an updated set of regulations. Thus, Congress in 1996 began including the Nondirective Mandate as an annual condition on Title X appropriations to ensure that the requirement of unbiased, neutral pregnancy counseling would continue in the program each year.

Finally, Defendants incorrectly argue—without any legal authority—that Plaintiffs lack standing to make some legal arguments, because other, non-plaintiff entities might try to comply with the new Counseling Distortions in different ways than Plaintiffs. Opp. at 27, 51. First, Plaintiffs plainly have standing to challenge the Counseling Distortions because the hundreds of NFPRHA members funded by Title X, *see* ECF No. 39 ("Coleman Decl.") ¶¶ 4-11 (facts showing associational standing) and all of the members' clinicians are bound by them; the New Rule requires all Plaintiff Title X-funded entities to change the information and referrals in their pregnancy counseling, or lose Title X funding. ECF No. 21-26, 39.

Second, in an APA challenge, "a single plaintiff, so long as he is injured by the rule, may obtain 'programmatic' relief that affects the rights of parties not before the court" in other ways. *Regents of the Univ. of Cal. v. DHS*, 908 F.3d 476, 511 (9th Cir. 2018). And, because Title X involves competitive funding, Plaintiffs are harmed by *others*' ability to secure funding and to operate on unlawful terms. *See City of L.A. v. Sessions*, 293 F. Supp. 3d 1087, 1100-01 (C.D. Cal. 2018). Defendants' unsupported effort to cabin Plaintiffs' challenge fails.

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(2) The New Rule Imposes Involuntary Counseling That Violates Title X

Contrary to Defendants' misstatements, *Rust* did not consider or rule on any claim that Title X's voluntariness protections had been violated. Opp. at 34. Defendants point to a lengthy quotation in the introductory paragraphs of the *Rust* opinion—which in passing describes the "voluntary" nature of Title X projects—but that occurs without any Supreme Court comment on the topic, and with no mention of Title X's separate, explicit voluntariness protections for patients in 42 U.S.C. § 300a-5 ("Section 1007"). That makes sense, because there was no claim under Section 1007 brought to the Court for it to consider in *Rust*.

But this case *does* present that claim. The New Rule violates the explicit requirement in Section 1007 (a section of Title X called "Voluntary Participation") that "[t]he acceptance by *any* individual" of services or "information (including educational materials) provided through financial assistance under [Title X] … *shall be voluntary*." 42 U.S.C. § 300a-5 (emphasis added). Defendants misleadingly quote Section 1007 with the above language omitted, and argue as if only a separate, second requirement—that accepting Title X services not be a prerequisite for other programs—exists there. Opp. at 34. The New Rule imposes involuntary information on Title X patients and transfers decision-making about the information they will receive from the patient to the provider. Section 59.14(b); *see also* 84 Fed. Reg. at 7747 (if provider chooses to discuss abortion, they must also present "the possible risks and side effects to … the unborn child" of that procedure, even if the patient objects); NFPRHA Br. at 15-16. The Counseling Distortions violate 42 U.S.C. § 300a-5's voluntariness requirement.

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(3) The New Rule Violates Section 1554's Limits on Any HHS Rulemaking

In their response to Plaintiffs' claim under Section 1554 of the PPACA, Defendants do not dispute that the New Rule interferes with Title X patient-provider communications, creates unreasonable barriers and impedes timely access to medical care, and violates principles of informed consent—all but conceding the merits. *See* NFPRHA Br. at 16-18, 28. Because they cannot evade Section 1554's plain language, which prohibits HHS rulemakings like this one, Defendants instead ask the Court to ignore Section 1554 for a variety of reasons. Each of them fails.

First, the absence of specific references to Section 1554 in this rulemaking record does not excuse HHS from its "obligation to examine its own authority and not to promulgate implementing regulations in a way that exceeds its scope." *Sierra Club v. Pruitt*, 293 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018) (no waiver of APA claim where "the scope of the agency's power to act is concerned"). That is particularly true where, as here, the agency was apprised of the substance of the violation. *See Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010) ("Plaintiffs need not state their claims in precise legal terms, and need only raise an issue 'with sufficient clarity to allow the decision maker to understand and rule on the issue raised.'"). Commenters put HHS on notice that the New Rule would create unreasonable barriers to care, impede timely access to services, interfere with patient-provider communications, and violate ethical standards. *See* NFPRHA Comments at 6, 8-10; NFPRHA Br. at 15-20. Thus, the agency—whose analysis of Section 1554 in a contemporaneous rulemaking shows its awareness of the statute's requirements, *see* 83 Fed. Reg. 57,

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Seattle, WA 98164
(206) 624-2184

551-52 (Nov. 15, 2018)—cannot now claim waiver, as it had "sufficient notice … to afford it the opportunity to rectify the violations that the plaintiffs alleged." *Nat'l Parks*, 606 F.3d at 1065. This record more than satisfies the Ninth Circuit's "broad" interpretation of the administrative exhaustion needed to avoid waiving an APA claim, *see id.*; "plaintiffs need not cite the relevant statute or regulation to exhaust," and do not have to "invoke the exact legal terms of art drawn from … statutory authorities." *Ore. Nat. Desert Ass'n v. McDaniel*, 751 F. Supp. 2d 1151, 1161 (D. Ore. 2011) (cataloging features of Ninth Circuit exhaustion law).

Second, HHS's leading argument on the merits—that Section 1554 did not abrogate *Rust* or repeal Section 1008, Opp. at 29-30—mischaracterizes Plaintiffs' claim and *Rust* itself. *See supra* at 1-2. The presumption against implied repeals is irrelevant to this claim. Defendants' argument that the more "general" Section 1554 must yield to the more "specific" Section 1008, Opp. at 33, fails for the same reason: even if Section 1554 were more "general" than Section 1008 (it is not), the general/specific canon applies only when statutes irreconcilably conflict. *See In re Border Infrastructure Env. Litig.*, 915 F.3d 1213, 1225 (9th Cir. 2019).

Third, HHS is incorrect when it asserts that Section 1554 applies only to the PPACA itself and, even then, does not govern when a government grant program is at issue. *See* Opp. at 31-32. Section 1554 by its plain terms applies to "*any* regulation" promulgated by the Secretary of HHS. 42 U.S.C. § 18114 (emphasis added). That it applies "notwithstanding any other provision of this Act" does not limit Section 1554's scope to the PPACA; rather, the "notwithstanding" clause simply means that HHS still cannot promulgate "any regulation" that creates

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Seattle, WA 98164
(206) 624-2184

unreasonable barriers to health care, interferes with patient-provider communications, or violates ethical standards even if some other provision of the PPACA enacted simultaneously might seem to permit it.

Nor does the text of Section 1554 exclude federally funded programs like Title X from the statute's reach. HHS's argument hinges on the assertion that Section 1554's constraints on the agency's rulemaking authority "involve the denial of information or services to patients," whereas restrictions on activities conducted with government funding "den[y] nothing." Opp. at 31. But the word "denial" appears nowhere in Section 1554, which broadly applies to "any regulation" that HHS promulgates to "restrict" information, "interfere" with communication, or "impede" access, for example, 42 U.S.C. § 18114—not just to absolute denials. Where Congress has established and funded a health care program like Title X, the plain language of Section 1554 governs to ensure that HHS does not promulgate regulations violating its patient protections.

Finally, the Court should reject HHS's invitation to ignore Section 1554 altogether because the statute's language is "open-ended." Opp. at 32-33. Judicial review of agency action "is the rule, and non-reviewability an exception," *Ariz. Power Pooling Ass'n v. Morton*, 527 F.2d 721, 727 (9th Cir. 1975), and Section 1554's directives are sufficiently "clear and specific" to permit judicial review here, *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 411 (1971). As such, Section 1554 does not fall within the "very narrow exception" to the presumption of reviewability. 401 U.S. at 411 (declining to apply exception). That exception applies only in "those rare instances" where "there is no law to

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Seattle, WA 98164
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apply," such that a particular agency action is committed to agency discretion, *id.*; but Section 1554 is solely an explicit limit on agency rulemaking discretion. The narrow exception Defendants attempt to invoke does not permit courts to ignore clear statutory text, or abdicate their duty to "give effect, if possible, to every clause and word of a statute." *See Duncan v. Walker*, 533 U.S. 167, 174 (2001); *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("courts must presume that a legislature says …what it means and means in a statute what it says").

(4) The Counseling Distortions Are Arbitrary and Capricious

As Plaintiffs have catalogued, HHS took impermissible shortcuts in promulgating the New Rule that render it arbitrary and capricious. NFPRHA Br. at 7-9, 18-20, 36-40. Defendants' response further exposes HHS's serious errors.

First, Defendants do not and cannot point to anything in HHS's rulemaking that even attempts to explain why the agency now abandons its own expert determination in the QFP of clinical standards for pregnancy counseling that should govern all Title X care, *see* NFPRHA Br. at 4-5, 19-20; ECF No. 19-2 (QFP, developed by the CDC and OPA within HHS) at 2, 13-14; ECF No. 19-1 at 5 (QFP incorporated into Title X's Program Requirements). Defendants acknowledge that a "more detailed justification" is required under *Encino Motor Cars* and *Fox Television* for changes in policy that contradict prior factual findings, Opp. at 43, but have no such justification for abandoning HHS's QFP standards.

Second, under any circumstances, conclusory or implausible assessments do not provide the required "reasoned justification" for agency decision-making. *See United Techs. Corp. v. Dep't of Defense*, 601 F.3d 557, 565 (D.C. Cir. 2010) (a

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"naked conclusion is not enough;" an "agency's conclusory or unsupported suppositions" get no deference); *Beno v. Shalala*, 30 F.3d 1057, 1075 (9th Cir. 1994). HHS has acted arbitrarily in failing to plausibly explain its bare assertions that it "does not agree" with the concerns of commenters that the New Rule will "negatively impact the quality" of services and that instead "improved client care" will somehow occur. 84 Fed. Reg. at 7723, 7780. But the failures here are not merely that HHS lacks evidence for its new position, *cf.* Opp. at 41; HHS also ignored its own earlier expert assessment in the QFP, *see* ECF No. 39 ¶¶ 14-15, 64-72, and much contrary evidence in the rulemaking record. *See Fred Mayer Stores, Inc. v. NLRB*, 865 F.3d 630, 638 (D.C. Cir. 2017) (rejecting as arbitrary agency's "failure to reasonably reflect upon the information contained in the record and grapple with contrary evidence"). Plaintiffs' arguments based on the QFP and on comments stressing the New Rule's conflict with clinical standards are not a "rehash;" they are bases for setting aside the rule for which Defendants have no response. *Compare* Opp. at 45-46 *with, e.g.*, Guttmacher Comments at 1-2, 7-8; PPFA Comments at 13-14; AAP Comments at 3-4; NFPRHA Comments at 4-6. An agency "cannot avoid its duty to confront inconsistencies" and to provide "a cogent explanation" for departing from its own prior findings by "blinding itself to them." *Humane Society of U.S. v. Locke*, 626 F.3d 1040, 1051 (9th Cir. 2010).

HHS's dismissal of objections to the New Rule based on medical ethics is no less faulty. Though HHS mentions certain ethical standards in its rulemaking, it then follows with *non sequiturs* that show departures from, not consistency with, ethical requirements. For example, as Defendants quote, the rulemaking mentions

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that ethics "require the medical profession to share full and accurate information with the patient, in response to her specific medical condition and circumstance." Opp. at 44. But the sentences that follow do *not* show the New Rule requires "full and accurate information" for patients; instead, they reveal it provides only for the optional provision of *some* information and unethically bars abortion referrals. *Compare* Opp. at 44 (quoting 84 Fed. Reg. at 7724) *with* NFPRHA Br. at 17. Such "sleight of hand" efforts are not reasoned and lawful agency decision-making. *Stewart v. Azar*, 313 F. Supp. 3d 237, 266 (D.D.C. 2018).

Instead of refuting the New Rule's clinical and ethical problems, Defendants retreat to citing *Rust* and referring to "conscience laws." But a legal opinion from 1991 does not explain why HHS has abandoned its own standards, developed by its experts just a few years ago. Likewise, no possible exemptions for certain religious objectors could rationally justify HHS's across-the-board abandonment of Title X's current pregnancy counseling requirements for the entire program.

In addition, HHS responded with only unsupported suppositions to the evidence before it that the New Rule will cause an exodus of Title X providers. Nowhere does the rulemaking acknowledge the data before HHS that providers serving over 40% of current Title X patients will leave the network if the referral ban takes effect. *See* NFPRHA Br. at 20. Defendants' litigation position calls this evidence mere "departure threats," Opp. at 47, but detailed comments from current providers and experts in the field explained to HHS precisely why these departures would necessarily occur. These are the very type of significant comments that an agency must substantively address for a rulemaking to pass muster.

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(206) 624-2184

HHS impermissibly refused to consider the magnitude and damage of those provider departures, while itself engaging in speculation that the new Counseling Distortions "*may* increase the number of providers in the program." 84 Fed. Reg. at 7782, 7780 (emphasis added). HHS's self-serving speculation does not find rational support in a description of general attitudes among Christian medical providers, 84 Fed. Reg. at 7780 n.138; there is no evidence such providers want to join Title X, much less in numbers that could offset all the experienced, departing providers. *See* PPFA Comments at 15-16; ECF No. 20 ("Kost. Decl.") ¶ 79. HHS acted arbitrarily in failing to assess the impact of provider departures and in using unfounded assumptions about theoretical new providers emerging. *See Stewart v. Azar*, 2019 WL 1375496, *9-10 (D.D.C. 2019) (agency cannot ignore commenters' detailed predictions of program losses, even if some uncertainty); ECF No. 38-1.

C. The Separation Requirements Also Are Contrary to Law and Arbitrary

Defendants assert, again, that *Rust* forecloses Plaintiffs' claims regarding the New Rule's separation requirements and infrastructure limits. They argue that *Rust* defeats these claims today because the Supreme Court "already upheld the separation requirements" under Section 1008 in 1991.[2] Opp. at 37. But *Rust*'s

[2] While Plaintiffs need not identify differences between the New Rule's requirements and those upheld in *Rust*, Defendants skip over, *inter alia*, that the new infrastructure rule, Section 59.18, has no 1988 analogue and that the 2019 separation factors are more onerous, *see* Section 59.15(a)-(d). Moreover, HHS published guidance on Title X funding separation in 2000, 65 Fed. Reg. 41,282,

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901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

rejection of arbitrary and capricious arguments in 1991 does not speak to whether HHS engaged in unreasoned decision-making and violated Section 1554 now.

As Plaintiffs showed in their opening brief, HHS has not rationally explained why it is today abandoning longstanding policies (a) that providers who offer Title X and abortion care (or engage in any abortion-related activity) can utilize shared facilities, staff, and systems, so long as financial and programmatic separation is maintained and (b) that infrastructure spending is central to building and maintaining an effective Title X network. After decades of success with these, HHS offers no relevant data or plausible grounds for "prophylactic" rules based on risks that have *not* materialized. Opp. at 39. HHS has no "good reasons for the new policy" and failed even to consider serious reliance interests created by its previous ones. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

Defendants asserts that HHS adequately explained its policy reversals because: (1) Title X projects use flexible grants, which it claims "raise the specter of projects using Title X funds to build infrastructure" to support abortion, Opp. at 38; (2) from 2008 to 2014, an increased percentage of abortions were performed at "non-specialized sites," which "could be" Title X sites, 84 Fed. Reg. at 7765; and (3) overbilling in the Medicaid program "demonstrat[es] a need for clarity with respect to permissible activities" in Title X, Opp. at 39. None of these supplies a "good reason" for the onerous Separation Requirements, which will massively

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post-dating *Rust* and fully responding to any need for clearer operational guidance—HHS's primary justification in 1988, *Rust*, 500 U.S. at 187.

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disrupt Title X providers and needlessly impose high costs. Defendants claim that HHS's "concerns were more than theoretical," Opp. at 41, but they were not. HHS has identified *no* evidence of use of funds in violation of Section 1008 since adoption of the 2000 rules, *see supra* n.2. HHS admits that Medicaid overbilling does not establish that Title X grants are being misused. 84 Fed. Reg. at 7725. It has no showing of Section 1008 compliance issues despite decades of shared Title X physical facilities with abortion care or abortion-related activities.

Defendants' "public confusion" assertion fares no better. They offer the illusion of confusion by claiming some comments "assumed that abortion was a permissible method of family planning within the Title X program." Opp. at 39. This mischaracterizes the comments, which instead made a policy argument to "oppose defining 'family planning' to exclude abortion" and "urge the Department to define the term to include abortion." 84 Fed. Reg. at 7729. It does not follow that the public believes that Title X now covers abortion care or is confused.

Next, Defendants strangely claim that Plaintiffs' assertions that the Separation Requirements will force established providers to exit the Title X program "only justifies the Secretary's concerns." Opp. at 40. Current providers, however, will leave Title X care not because they have ever used Title X funds contrary to Section 1008, but because duplicating facilities, staff, and electronic health record systems, as the New Rule would require, is wasteful, untenable, and contrary to best medical practices. ECF No. 22 ¶¶ 43-48; *see also* ECF No. 21, 25, 26, 39. The greatly increased costs and harms are imposed by the New Rule itself.

Defendants essentially concede that HHS failed to consider reliance interests

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of Title X providers. On this basis alone, the Separation Requirements "cannot carry the force of law." *Encino Motorcars*, 136 S.Ct. at 2127. Defendants simply claim that Plaintiffs have no "legally cognizable reliance interests in the continued receipt of Title X grants" because Title X grants are provided in one-year increments over typically three-year project periods. Opp. at 42. But as Plaintiffs made clear in their opening brief, courts recognize reliance interests more broadly in assessing agency action under *Encino*. *See* NFPRHA Br. at 24; *Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 432 (E.D.N.Y. 2018) (even without protected "liberty or property interests …, it does not follow that [recipients] had no reliance interests …, such that" agency was free to act without considering reliance). Defendants ignore this on-point precedent and instead cite *Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31*, 138 S. Ct. 2448 (2018), an inapposite case that dealt with the Court's reasons for abandoning *stare decisis*, not agency action.

Finally, Defendants contend that "NFPRHA's flyspecking of HHS's [cost] analysis" goes "nowhere." Opp. at 49. But showing that HHS shirked its duty to assess the magnitude of the costs of the Separation Requirements is hardly "flyspecking." The agency downplayed the financial costs in the record by orders of magnitude and failed to contend at all with the costs to the Title X program and its patients from the inevitable departures of providers unable to comply with the New Rule. To wit, HHS merely increased its "central estimate" of the cost to come into compliance from $20,000 (in the NPRM) to $30,000 (in the final rule) for each of only 20% of sites, 84 Fed. Reg. at 7781-82—despite comments noting that it would cost $300,000-600,000 per site. *See* PPFA Comments at 32;

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NFPHRA Comments at 37; ECF No. 38-1 at 16-19. HHS also failed to include any costs for an even larger number of affected sites—those that do not offer abortions but engage in any of the "abortion-related activity" that also triggers the separation requirements under the New Rule. Because HHS did not rationally consider costs to providers and to the program's functioning, it acted arbitrarily.

In addition, as Plaintiffs established in the opening brief, the Separation Requirements are contrary to Section 1554. NFRPHA Br. at 28-29. Defendants do not even try to refute the facts that the new separation and infrastructure rules will create unreasonable barriers to obtaining medical care, impede timely access to care, and restrict the full disclosure of all relevant information to patients.

D. The New Rule's Provisions that Aim to Change the Provider Network Also Contradict Title X, Violate Section 1554, and Are Arbitrary

In cursory attempts at countering Parts III(C)(1)-(3) of Plaintiffs' opening brief, Defendants ignore some arguments and mischaracterize others. Defendants' deflection notwithstanding, Plaintiffs' arguments there show additional arbitrary and unreasoned elements that further expand the harms of the New Rule.

First, the confusion created by Section 59.5(a)(12) of the New Rule cannot be remedied by *post hoc* discussions with HHS, as Defendants suggest. That subsection, one of the Title X program "requirements," describes what each Title X project "must" include (and, confusingly, reads they "must: [s]hould"). NFPRHA Br. at 30. None of those terms provides mere "encouragement" of primary health care access, contrary to Defendants' claim. *See* Opp. at 49. Instead, Section 59.5(a)(12) imposes an altogether new *requirement* that blocks

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rural Title X sites where no primary health care is available. It also enshrines contradictory terms and standard-less phrases into a regulation that is not now alterable by informal "interaction" with HHS. *Cf.* Opp. at 49-50. HHS finalized those terms without reasoned justification, consideration of proposed alternatives, or effort to avoid their disruption of rural Title X care. *See* NFPRHA Br. at 29-31.

Similarly, Defendants ignore a central component of Plaintiffs' argument in Part III(C)(2) of their opening brief: the New Rule's admitted *effort to bring providers with conscience objections to biomedical contraceptives into Title X care*, despite the facts that (a) Title X was created for the purpose of expanding access to such contraceptives and (b) making a full range of FDA-approved contraceptives available to patients is the current clinical standard for family planning care. NFPRHA Br. at 32. Defendants here have not offered any explanation for how bringing in *objecting* providers—coupled with the New Rule's removal of any "medically approved" requirement and encouragement of limited-method sites—possibly furthers Title X's statutory purpose of providing quality, comprehensive family planning care. Likewise, during the rulemaking, HHS did not plausibly respond to the many comments showing how these components of the New Rule combine to harm the program and patients. NFPRHA Br. at 32-34.

In addition, Defendants ignore that the New Rule's all-encompassing, subjective eligibility requirement is not authorized by Title X and is inconsistent with HHS's specification in general regulations of how grant-making should occur. NFPRHA Br. at 34-36. This eligibility hurdle of "clearly" and "affirmatively" describing future planned compliance with every single subpart of the Title X

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regulations, Section 59.7(b), does not "prevent the misuse of funds" after grants are made—when those Title X regulations themselves regulate all grantees' activity. Nor does this threshold that all must cross enable decisions about where "better" to direct funds, contrary to HHS's bare assertion. Opp. at 52. Likewise, HHS offers no support for its assertion that this *added* step would "save" money instead of increasing cost, over and above the cost of the HHS competitive review panels that would still need to be convened. *Id.* There is no reasoned basis for this expansive and unchallengeable Title X eligibility test contrary to HHS's own general rules.

Finally, Defendants have no answer for the inconsistency within Section 59.7(c)(2). They have no coherent explanation of how some competing Title X applicants can be assessed on their ability to procure "diverse" provider entities but others will not be—all under a single criterion for scoring them against one other. NFPRHA Br. at 36. Defendants also fail to justify HHS's quest for diverse subrecipients as an end in itself. Opp. at 53. This Section 59.7(c)(2) priority is just another means by which HHS seeks to introduce "nontraditional" providers into Title X, 84 Fed. Reg. at 7754, in lieu of and to upend the existing providers that now effectively deliver care according to QFP standards. HHS does not show how this could possibly help, not hurt, the Title X program. NFPRHA Br. at 36, 38-40.

E. HHS's Rulemaking Frustrates the Congressional Purpose of Title X and Harms the Patients It Was Created to Serve, Dooming the New Rule

Courts must be vigilant against "the unauthorized assumption by an agency of major policy decisions properly made by Congress," *Am. Ship Building Co. v. NLRB*, 380 U.S. 300, 318 (1965), and cannot "rubber-stamp … administrative

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decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Bureau of Alcohol, Tobacco & Firearms v. Fed. Labor Relations Auth.*, 464 U.S. 89, 97–98 (1983); *Bresgal v. Brock*, 843 F.2d 1163, 1168 (9th Cir. 1987). As Plaintiffs have shown, *see* NFPRHA Br. at 36-40, and Defendants do not attempt to counter, the New Rule will so rip apart the Title X program, drive away its providers, and reduce low-income patients' access to quality family planning care that it cannot be squared with congressional purpose and fails for that reason alone.

As the motion sets forth, Title X's purpose is to provide "comprehensive voluntary family planning services … to all persons desiring such services" and "to remedy low-income individuals' lack of access to modern, effective contraception and related medical care." NFRPHA Br. at 14; ECF No. 39 at 18-29. Plaintiffs have detailed here, as the comments did earlier, the many means by which the New Rule will disrupt the national Title X network and prevent the program from serving many of the vulnerable, "medically indigent" patients it was intended to serve. NFPRHA Br. at 36-45; ECF No. 39 ¶ 21. And for those patients that are able to participate in Title X, they will no longer have access to the uniform, quality care that HHS's own national standards require. NFPRHA Br. at 36-45.

Where, as here, the agency's "interpretation is plainly at odds with the statutory scheme" and where Defendants primary response is to implore the court to blindly "defer[]to the Secretary's interpretation," the rule cannot stand. *Sunshine Health Sys., Inc. v. Bowen*, 809 F.2d 1390, 1398-99 (9th Cir. 1987). In this case, HHS single-mindedly seeks shelter in Section 1008 and a decades-old

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interpretation of it in *Rust*, without regard to all the statutory provisions that now govern and the rulemaking record's big picture: widespread harm to the scope and functioning of the Title X program, leaving its patients deprived of care. *Cf. Vance v. Hegstrom*, 793 F.2d 1018, 1022 (9th Cir.1986) ("In prescribing standards … the Secretary may not read [one] subsection … independently of" others.).

Moreover, the New Rule's explicit goal of recruiting more providers that refuse to offer biomedical contraceptives and other core aspects of standard family planning care, while pushing out reproductive health-focused providers, further sacrifices Title X's purpose. NFPRHA Br. at 2-6, 32-45. An "administrative construction[] of a statute that [is] inconsistent with the statutory mandate or that frustrate[s] the policy that Congress sought to implement" should be rejected. *S. Cal. Edison Co. v. FERC*, 770 F.2d 779, 782 (9th Cir. 1985).

II. PLAINTIFFS FACE WIDESPREAD AND IRREPARABLE HARM

Defendants mischaracterize Plaintiffs' demonstrated harms as limited to three types: impact on services, harm to the provider-patient relationship, and harm to "third party" patients and the public health. In fact, Plaintiffs have established a much broader set of imminent and irreparable harms they will suffer if the New Rule takes effect. Those include harm to Plaintiffs' clinical staff from providing substandard and unethical care; harm not only to health care services but also to the public-service missions and reputations of Plaintiff grantees, subrecipients, and individual providers; harm of unnecessary compliance costs to attempt to implement this unlawful rule; and, most egregious, harms to Plaintiffs' patients that are properly part of Plaintiffs' asserted injuries. NFPRHA Br. at 40-44.

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Defendants try to exclude from the Court's consideration the immediate and unavoidable harms to Plaintiffs' patients by suggesting that Plaintiffs are legally forbidden from asserting their interests. Opp. at 57. But it is well-established that reproductive health care providers can proceed on behalf of themselves and their patients, including in seeking preliminary relief. *Singleton v. Wulff*, 428 U.S. 106, 111, 118 (1976) (health care providers' interest in providing care is "inextricably bound up" with patients' rights to access care); *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004); *see also Pa. Psychiatric Soc. v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 291 (3d Cir. 2002) (same applies to asserting patient interests in non-constitutional claims).

Defendants fail to address any of Plaintiffs' own declarations, ECF 21-26, 39, and erroneously argue there is no "imminence" here. Opp. at 57. But it is clear that the ban on abortion referrals and thus pregnancy counseling contrary to HHS's own standards commences on day one. Section 59.5(a)(5). The New Rule's coercive counseling will mislead patients and forestall or foreclose their access to care, as well as undermine Plaintiff providers. Plaintiffs have established—though Defendants try to overlook, Opp. at 57—that *every* Title X patient who receives a positive pregnancy test at a Title X facility is subject to these harms. So, too, the New Rule will force health care providers to choose between providing that substandard care or ceasing to provide care to Title X patients—breaking the trust at the heart of the patient-provider relationship and losing a role in Title X and its funding. ECF 20-26, 39. That Defendants contest that their rule violates clinical or ethical standards or is unlawful does not diminish Plaintiffs' showing of harm.

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Defendants further contend that, because referrals purportedly remain available *outside* of Title X, no harm will befall Title X patients or providers, Opp. at 56; but that argument ignores the sweep of the New Rule's limits. As Plaintiffs' provider-declarants have explained, though, for patients counseled within Title X, there will be *no* opportunity to direct the patient to abortion care. *See* ECF 23-25. That is because referring patients to any type of care or resource outside the Title X project so that they can obtain an abortion referral would contravene the New Rule as an indirect means of referral. *See* Section 59.14(c). The New Rule thus traps providers and their patients into coercive counseling, with no means of transferring Title X patients to nondirective care outside Title X.

Defendants cannot refute that each Plaintiff individual health care provider, subrecipient, and grantee will have to make the same "Hobson's choice" to provide substandard care and attempt to comply with the unworkable separation and infrastructure rules, *or* leave the program and lose their Title X role, along with its funding. *See Am. Trucking Ass'ns, Inc. v. City of L.A.*, 559 F.3d 1046, 1057 (9th Cir. 2009); ECF No. 39 ¶¶ 117-152. Either way will harm each Plaintiff entity's health care mission. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016). Network provider losses, added strain on remaining providers, and curtailed health care services are inevitable, not speculative; and they will leave the Title X program in disarray, causing extensive public health harms. Kost Decl. ¶¶ 73-124. Defendants' conclusory assertion that the New Rule says this is not so does not change the irreparable harm facts in the record before this court. Where patient access to health services will be interrupted or compromised, a

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"preliminary injunction to preserve the status quo properly avoids the risk that [patients] will needlessly suffer that irreparable injury while this case is pending." *Planned Parenthood Ariz. v. Betlach*, 899 F. Supp. 2d 868, 886 (D. Ariz. 2012).

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST WEIGH IN FAVOR OF A PRELIMINARY INJUNCTION

As this court has explained in analogous litigation, the balance of the equities and the public interest, including public health, weigh substantially in favor of a preliminary injunction. *Planned Parenthood of Greater Wash. & N. Idaho v. HHS*, 328 F. Supp. 3d 1133, 1152-53 (E.D. Wash. 2018). Defendants' attempt to rely on *Maryland v. King*, 567 U.S. 1301 (2012), is misplaced—an injunction here would not thwart "statutes enacted" by the people's representatives or interfere with a state's criminal law enforcement. Opp. at 58. Instead, it would continue "the status quo (which has been in existence for . . . decades)," in administering a complex federal program, during the pendency of this litigation" that challenges the legality of substantially disruptive regulatory changes. *Ramos v. Nielsen*, 336 F. Supp. 3d 1075, 1080 (N.D. Cal. 2018).[3]

Moreover, Defendants' effort to foreshadow a remand without vacatur turns the law upside-down. "[V]acatur is the normal remedy" in an APA case like this one. *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014). And there is no reason to contemplate departing from that norm; HHS could not cure

[3] Defendants' false assertion that an injunction would force it to disburse funds contrary to Title X, Opp. Br. 58, is one more attempt to mischaracterize *Rust* and Section 1008 as requiring the 1988 regulatory scheme, which they do not.

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the many substantive infirmities with the New Rule via remand. *Id*.

IV. THE NEW RULE SHOULD BE ENJOINED COMPLETELY

A. A Nationwide Injunction Is Necessary to Protect Plaintiffs

Plaintiff NFPRHA sues in a representational capacity on behalf of its members, including hundreds of grantees and subrecipients across the country. Coleman Decl. ¶¶ 6-7. As a result, nationwide relief is not only appropriate, but also necessary to provide Plaintiffs complete relief. *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). Where, as here, nationwide relief is *required* to provide plaintiffs the relief they seek, such relief does not pose the risk of the kind of overreach that the Defendants posit. *Id.* Defendants' reliance on *California v. Azar*, 911 F.3d 558 (9th Cir. 2018), is therefore misguided. There, the Ninth Circuit reaffirmed that "'there is no bar against nationwide relief in federal district court or circuit court,'" and simply reiterated that "such broad relief must be '*necessary* to give prevailing parties the relief to which they are entitled.'" *Id.* at 582 (quoting *Bresgal*, 843 F.2d at 1170–71). That court explained that on a record that established effects primarily in California and to some extent in a limited number of plaintiff-states, such relief was not required. *Id.* at 584. The record here, by contrast, establishes Plaintiffs' harms nationwide.

It is infeasible, furthermore, to preliminarily block the New Rule only as to NFPRHA members (as Defendants suggest), because that would result in patchwork application to some grantees with non-member subrecipients, or non-

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member grantees with member-subrecipients. Such application would be impossible under the New Rule because grantees are affirmatively charged with policing subrecipients' compliance. Section 59.1(a). Defendants do not and cannot explain how Plaintiffs' members could possibly comply with such a ruling.

What is more, preliminary relief as to NFPRHA members does nothing to protect those members from being forced to compete for a finite pool of federal funds on unfair terms. *Washington v. Reno*, 35 F.3d 1093, 1104 (6th Cir. 1994) (explaining that an injunction as to plaintiffs alone would not prevent the disputed pool of federal funds from being dispersed to third-parties on legal terms that plaintiffs contest); *City of L.A.*, 293 F. Supp. 3d at 1100-01 (same). Grant competitions are typically run by HHS regionally and HHS adjusts funding as it see fits from place to place – indeed, it need not fund projects in every state. Similarly, grantees' geographical reaches may overlap; many states have multiple grantees. Nationwide relief is necessary to give Plaintiffs complete relief from enforcement of the New Rule's terms and from their negative competitive effects.

B. The Entire Rule Should Be Enjoined Pending a Merits Determination

Enjoining the New Rule in its entirety serves the purpose of a preliminary injunction: "to preserve the status quo ante litem pending a determination of the action on the merits." *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1024 (9th Cir. 2016). Ignoring this basic principle of injunctive relief, Defendants insist that the New Rule is severable at this early stage and ask the Court to limit the scope of any preliminary relief to specific provisions. Their argument fails for two reasons.

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First, as Plaintiffs show above and in their initial motion papers, this rulemaking process and its outcome in the New Rule were infected with serious flaws that will require it to be vacated as a whole. Indeed, an agency action based on a flawed legal premise—for example, that *Rust* controls to permit the New Rule—is arbitrary and must be set aside. *See Regents of Univ. of Cal. v. DHS*, 279 F. Supp. 3d 1011, 1037, 1042-43 (N.D. Cal. 2018), *aff'd* 908 F.3d 476 (9th Cir. 2018). In addition, Plaintiffs have shown that the New Rule will fundamentally undermine Congress's purpose for the Title X program, and is unlawful as a whole for that reason too. *See supra* at 21-23. This Court's equitable powers appropriately preserve the status quo now, rather than attempt to carve up the rule.

Second, the sections of the New Rule reference and depend upon each other, and are so intertwined that they do not "function sensibly" alone, Opp. at 66. The mere existence of a sentence in the Supplementary Information expressing HHS's preference that any provisions not enjoined "should remain in effect" does not answer the severance question. *See MD/DC/DE Broadcasters Ass'n v. F.C.C.*, 236 F.3d 13, 22 (D.C. Cir. 2001). In this case, severance is not workable or appropriate because HHS has written interlocking provisions for a common purpose that will be impaired on their own. *See id.* The New Rule's Executive Summary makes clear that HHS intended it to be an integrated, sweeping regulation to "ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning, as well as related statutory requirements." 84 Fed. Reg. 7715. The challenged enforcement and grant-making provisions, *see* Section

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(206) 624-2184

59.7, 59.17(d), and 59.18, for example, each explicitly incorporate "any other section of this rule" (or similar words to that same effect); *see also* Section 59.13.

All of the challenged sections making up the Counseling Distortions and the Separation Requirements, as defined in Plaintiffs' initial brief, pull in definitions from Section 59.2, including the too-limited definition of "Advanced Practice Provider" for pregnancy counseling. And the Counseling Distortions and Separation Requirements function together, not sensibly apart: Sections 59.5 and 59.14, two of the important, interlocking restrictions on counseling, explicitly help define the universe of abortion-related activities for which separation is required under Sections 59.13, 59.15, and 59.18. Conversely, the separation factors of Section 59.15 and the "infrastructure" spending limits are tied to and help implement the Counseling Restrictions—any materials referencing abortion, including for pregnancy counseling, must be separated from Title X projects, Section 59.15(d), and appropriate Title X funding uses are newly limited to "direct implementation" of activities "expressly permitted by this regulation," Section 59.18. The Court should not attempt to surgically sever or re-write any of these provisions for purposes of the preliminary injunction. Doing so would "impair the function" of the remainder of the rule. *See Davis Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1460 (D.C. Cir. 1997).

V. CONCLUSION

For all the reasons in this reply brief and in Plaintiffs' opening brief, the New Rule should be preliminarily enjoined in its entirety to prevent irreparable harms to Plaintiffs during the pendency of this action.

AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184

DATED: April 19, 2019 By: */s/ Emily Chiang*

Joe Shaeffer, WSBA No. 33273
MACDONALD HOAGUE & BAYLESS
705 Second Ave, Suite 1500
Seattle, WA 98104
joe@mhb.com

Emily Chiang, WSBA No. 50517
AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
901 Fifth Avenue, Suite 630
Seattle, WA 98164
echiang@aclu-wa.org

Nicole M. Argentieri*
Jennifer B. Sokoler*
Brandon D. Harper*
O'MELVENY & MYERS LLP
Times Square Tower
7 Times Square
New York, NY 10036
212-326-2000
nargentieri@omm.com
jsokoler@omm.com
bharper@omm.com

Sara Zdeb*
O'MELVENY & MYERS LLP
1625 Eye Street NW
Washington, DC 20006
202-383-5300
szdeb@omm.com

Ruth E. Harlow*
Fiona Kaye*
Anjali Dalal*
Elizabeth Deutsch*
Brigitte Amiri*
AMERICAN CIVIL LIBERTIES UNION FOUNDATION
125 Broad Street, 18th Floor
New York, New York 10004
212-549-2633
rharlow@aclu.org
fkaye@aclu.org
adalal@aclu.org
edeutsch@aclu.org
bamiri@aclu.org

*Admitted *pro hac vice*

Attorneys for Plaintiffs

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 19th of April, 2019, at Seattle, Washington.

/s/ Emily Chiang

Emily Chiang, WSBA No. 50517

AMERICAN CIVIL LIBERTIES UNION OF WASHINGTON FOUNDATION
901 Fifth Ave, Suite 630
Seattle, WA 98164
(206) 624-2184