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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' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR FOR SUMMARY JUDGMENT AND CROSS-MOTION FOR SUMMARY JUDGMENT

February 13, 2020
With Oral Argument: 1:15 p.m.

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TABLE OF CITED COMMENTS
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Abbreviation	Organization Or Individual	Bates Range of Comment
AAMC	Association of American Medical Colleges	264535-264540
AAN	American Academy of Nursing	107970-107975
AAP	American Academy of Pediatrics and the Society for Adolescent Health and Medicine	277786-277796
AAPA	American Academy of Physician Assistants	106280-106281
AAUW	American Association of University Women	307782 -307786
ACLU	American Civil Liberties Union	305722-305736
ACNM	American College of Nurse-Midwives	315935-315938
ACOG	American College of Obstetricians and Gynecologists	268836-268853
ACP	American College of Physicians	281203-281211
AM	AccessMatters	256444-256455
AMA	American Medical Association	269330-269334
APHA	American Public Health Association	239893-239899
APIAHF	Asian & Pacific Islander American Health Forum	96230-96238
ASTHO	Association of State and Territorial Health Officials	199036-199044
AUCH	Association for Utah Community Health	84164-84167
BWW	Black Women for Wellness	248191-248200

Brindis	Claire Brindis, Dr.PH	388053-388066
Brown	Lori A. Brown, AIA	245854-245856
CAAG	Attorneys General of CA and Other States	245688-245712
CAP	Center for American Progress	309213-309222
CCHHS	Cook County Health and Hospitals System	305262-305263
CDIH	Chapa-De Indian Health	280721-280725
CHN	Community Healthcare Network	294153-294156
CPPP	Center for Public Policy Priorities	315477-315482
CRR	Center for Reproductive Rights	315959-316004
Drexel	Drexel College of Medicine Women's Care Center	293833-293841
Dehlendorf	Christine Dehlendorf, MD, MAS	251840-251843
EAH	Essential Access Health	245482-245496
EM	Empower Missouri	47946-47947
FAPP	Federal AIDS Policy Partnership	305095-305111
FPAM	Family Planning Association of Maine	239553-239564
FPCA	Family Planning Councils of America	385031-385035
FPCI	Family Planning Council of Iowa	279351-279363
Guttmacher	Guttmacher Institute	264415-264440
HIVMA	HIV Medicine Association	269713-269715
Human Coal.	Human Coalition and First Liberty	268383-268387
IPI	Institute for Policy Integrity	308568-308575

Imbody	Jonathan Imbody	69736-69743
JDP	Jane's Due Process	307165-307168
JIWH	Jacobs Institute of Women's Health	239147-239180
Johns Hopkins	Johns Hopkins Medicine Departments of Pediatrics and Gynecology and Obstetrics	285353-285354
LCCHR	Leadership Conference on Civil and Human Rights	306347-306349
LV	Legal Voice	310399-310411
MADPH	Massachusetts Department of Public Health	91190-91195
Minn Orgs	Minnesota Medical Association and other Minnesota organizations	243716-243718
MOFHC	Missouri Family Health Council	268685-268693
MSAHC	Mount Sinai Adolescent Health Center	106748-106755
NACCHO	National Association of County and City Health Officials	294042-294048
NACHC	National Association of Community Health Centers	263270-263273
NASW	National Association of Social Workers	107235-107241
NCSD	National Coalition of STD Directors	106826-106829
NFPRHA	National Family Planning & Reproductive Health Association	308011-308048
NHCHC	National Health Care for the Homeless Council	308419-308421
NIRH	National Institute for Reproductive Health	106456-106467
NLIRH	National Latina Institute for Reproductive	307451-307457

	Health	
NWLC	National Women's Law Center	280765-280775
NYAG	New York Attorney General	269292-269312
PPFA	Planned Parenthood Federation of America	316400-316495
PRI	Population Research Institute	243340-243359
Prine	Linda Prine, MD	5457
TNDOH	Tennessee Department of Health	102526-102529
TWHC	Texas Women's Healthcare Coalition	306444-306448
TxPEP	Texas Policy Evaluation Project	269930-269939
VTDOH	Vermont Department of Health	198204-198209
WAAG	Attorneys General of Washington and Other States	278551-278578
WVDH	West Virginia Department of Health and Human Resources	280808-280811

*Miscellaneous other sources from the Administrative Record are cited "AR" followed by the Bates number.

INTRODUCTION

The Defendants' March 4, 2019, overhaul of the Title X regulations, 84 FR 7714 *et seq*. (the Rule), should be set aside as arbitrary and capricious and contrary to law on myriad grounds. In adopting this Rule, Defendants (collectively, HHS) reversed course without the kind of cogent reasoning required to abandon HHS's own prior factual findings and upend the longstanding reliance of Title X health care providers and patients. HHS also repeatedly ignored the specific record evidence of the serious harms to the Title X program and exorbitant financial costs the Rule would impose, while asserting benefits that find no support in the record. In addition to being the product of arbitrary decision-making at every turn, the Rule contradicts the Title X statute, Congress's separate mandate that all Title X pregnancy counseling must be nondirective, and other statutory limits on HHS's rulemaking. The Rule greatly undermines, rather than rationally serves, the public health program HHS is charged with implementing. As explained below, HHS adopted a compliance "solution" in search of a problem and aimed to advance the interests of hypothetical, possible future providers who object to core Title X care.

This Rule has already decimated the national Title X network and left whole states without any Title X services. The National Family Planning & Reproductive Health Association (NFPRHA), on behalf of its hundreds of affected members and with its named co-plaintiffs, now moves for summary judgment to prevent even more disruption as the physical separation deadline of March 4, 2020, approaches and as the Rule continues to enmesh providers and patients in family planning care that contradicts HHS's own clinical standards.

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IMPORTANT FACTUAL AND PROCEDURAL CONTEXT

1. Title X's Role and Operation. This Court is already familiar with the history of the Title X program, the statutes that govern its implementation—including those Congress has passed in recent years, and the important services Congress designed Title X to provide nationwide to patients that would otherwise not be able to afford high-quality family planning health care. *See* ECF No. 54 (Order Granting Preliminary Injunction) at 7-12 (describing history, nature of program, and governing statutes); *see also* ECF No. 18 at 1-7; ECF No. 51 at 1-16. Plaintiffs will not repeat their prior lengthy submissions on those topics here, but will instead highlight a few key points for the present dispositive cross-motions.

First, Congress created Title X because the "medically indigent" lacked up-to-date, clinical family planning options and were being short-changed by a limited patchwork of resources that did not extend throughout the country. S. Rep. No. 91-1004 at 9 (1970). Prior to Title X's enactment, low-income individuals were:

> forced to do without, or to rely heavily on the least effective nonmedical techniques for fertility control unless they happen to reside in an area where family planning services are made readily available by public health services or voluntary agencies.

Id. Congress established Title X to make "comprehensive voluntary family planning services readily available to all," to "enable public and nonprofit private entities to plan and develop comprehensive programs," and to fund related research, materials development, and training. Pub. L. 91-572, 84 Stat. 1504, § 2.

Second, as reflected repeatedly in this rulemaking's administrative record, Title X has over the last five decades set the "gold standard" for quality family

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planning care. AR406795 (Guttmacher Moving Forward report); *see also*, *e.g.*, ACOG Cmt 268837; Brindis Cmt 388054-388063. The network of Title X-funded providers built up over the program's history—approximately 90 grantees overseeing more than 1000 subrecipients at almost 4000 service sites when the Rule took effect—has historically ensured that its services are:

> voluntary, confidential, affordable and effective. Title X-supported health centers generally provide higher quality contraceptive care than other providers, including methods provided on site, protocols to help women avoid gaps in use and in-depth counseling tailored to clients' needs.

AR406787; *see also* AR406187 (2017 Family Planning Annual Rep.); *infra* at __.

Reproductive health-focused providers have predominated as the mainstays in Title X, and these specialized providers operate both within non-profit organizations and within public health departments or other public entities. *See* AR406795-99, 406815; NFPRHA Cmt 308040; AAUW Cmt 307784. The Office of Population Affairs' 2016 and 2017 Family Planning Annual Reports (FPARs), included in the rulemaking record, reflect that in those years, the program "demonstrate[d] [a] continued dedication to delivering services that meet the highest national standards. This dedication to service quality is matched by efforts to respond to health system changes and to increase the efficiency and financial sustainability of service operations through investments in health information technology and revenue diversification." AR407031-32; *see also* AR406189.

Third, for many years pre-dating the Rule, HHS has had in place stringent regulation and monitoring of the use of Title X funds. Sections 59.9 and 59.10 of the 2000 regulations, which the Rule leaves intact, make clear that any Title X

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funds "shall be expended *solely* for the purpose for which the funds were granted in accordance with the approved application and budget," the terms of the grant award, and the uniform HHS audit, cost, and other grants-management regulations. 42 C.F.R. §§ 59.9 (emphasis added), 59.10. Since inception, all Title X programs have been subject to Section 1008 of the statute, which forbids any appropriated funds from being "used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. The Office of Population Affairs (OPA) has long conducted financial and comprehensive reviews of Title X grantees, and grantees in turn oversee their subrecipients; these reviews employ a Program Review Tool that specifically examines policies, procedures, financial management systems, and financial records to ensure that Title X-funded providers are complying not only with Section 1008, but also with numerous other restrictions on the use of federal funds, *see* OPA Program Review Tool § 8.2, https://www.fpntc.org/resources/title-x-program-review-tool; NYAG Cmt 269295-97. *See* AR406965 (OPA summarized in 2017 that Title X projects were "closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion," and detailed the safeguards, including "periodic and comprehensive program reviews and site visits by OPA regional offices," that were already in place to ensure this compliance before the 2019 Rule).[1]

[1] For additional factual background on the Title X program and its past operation, Plaintiffs refer the Court to ECF No. 39, §§ 40-109; ECF No. 20, §§ 13-72; ECF No. 22, ¶¶ 3-26; and other previous declarants' factual descriptions of their Title X

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2. This Court's Preliminary Injunction Decision. On April 25, 2019, after a lengthy hearing, this Court preliminarily enjoined the Rule. ECF Nos. 56, 67. The Court found that each of the claims included in Plaintiffs' preliminary injunction motion "has merit and a likely chance of success." ECF No. 56 at 14-15.

Thus, for Plaintiffs' statutory violation and arbitrary rulemaking claims, the Court has already found Plaintiffs' proffered causes of action more than sufficient to at least state a claim. Defendants have no basis for their suggestion that the 229-paragraph Complaint, ECF No. 1 (Case No. 19-cv-03045), consists of mere '"[t]hreadbare recitals of the elements of a cause of action,'" ECF No. 112, Defendants' Motion to Dismiss or for Summary Judgment ("DOJ Br.") at 12.

3. The 2019 Rulemaking, Not One From Decades Earlier, Is At Issue. Likewise, in granting the preliminary injunction, this Court has already rejected HHS's repeated contention that *Rust v. Sullivan*, 500 U.S. 173 (1991), is a bar to Plaintiffs' 2019 claims. The 1988 rulemaking at issue in *Rust* involved different regulations, a different administrative record, and a different factual backdrop. As this Court emphasized at the April 25 hearing, the Government cannot "ignore[] some important action that's been taken in the last 30 years," ECF No. 67, Trans.

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programs. The Court may consider that background to fill in aspects of the complex workings of Title X and in assessing whether HHS has considered all relevant factors in the challenged rulemaking. *See, e.g.*, *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160-61 (9th Cir. 1980). But looking to those sources is not essential for Plaintiffs' success on this motion.

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53-54—whether with regard to intervening statutes, HHS's own 2000 factual findings, or the challenged 2019 rulemaking process, *see infra* at __.

Moreover, despite the extensive briefing and oral argument, both in this Court and in the Ninth Circuit, where Plaintiffs have highlighted the differences between HHS's actions in 1988 and those taken in 2019, the Government still persists in calling them "materially indistinguishable" and asserting that "[n]one of this is disputed." DOJ Br. at 17-19; *see also id*. at 1, 18 (falsely claiming HHS "readopted" 1988 regulations). On the contrary, as Plaintiffs have spelled out before, the material differences in these three-decades-apart actions include that:

- In 1988, HHS promulgated a wholesale ban on any counseling about abortion and (erroneously) argued to the Supreme Court that pregnancy counseling fell outside Title X's services, *see* Resp. Br. in *Rust*, 1990 WL 10012655 at *6; *Rust*, 500 U.S. at 200;
- Since 1996, Congress has made clear that pregnancy counseling is a Title X service and today, HHS has imposed a new, insidious counseling regime that allows individual providers to steer patients according to the providers' beliefs, contrary to patients' wishes, and without informing patients they are receiving substandard clinical care;
- Today, HHS has expanded the "physical separation" included in the 1988 regulations (but never implemented across the network) to add more onerous separation factors, including separate health records systems and separate entrances and exits, that had been explicitly rejected in the 1988 rulemaking;
- Today, HHS has added, without precedent, Section 59.18's infrastructure spending prohibition and other spending limits to further exacerbate the onerous "physical separation" requirement and constrain the effective operation of Title X projects;
- And today's rulemaking includes changes to the grant-making process and criteria, to program requirements, and to numerous record-keeping and compliance regulations, all in an attempt to favor "nontraditional" providers and add layers of new compliance steps never proposed in 1988.

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Compare 53 FR 2922 *et seq*. with 84 FR 7714 *et seq*.; *see* also, e.g., Ninth Circuit Case No. 19-35394, ECF No. 46, at 12-14 (collecting 1988 vs. 2019 differences).[2]

4. This Is The First Judicial Examination of the Ultimate Merits. Following considerable litigation about preliminary injunction and temporary stay issues, Plaintiffs now seek a final merits ruling from this Court. The Government, DOJ Br. at 2, errs (a) in referring to a "merits panel" of the Ninth Circuit, when no such panel decision has occurred, and (b) in directing the Court to treat as "persuasive" a motions panel's temporary stay-pending-appeal decision on which the Ninth Circuit has granted *reconsideration* through *en banc* review; that *en banc* panel is now considering the stay issue and the appeal of the preliminary injunction. All of these prior, preliminary stages of the litigation have proceeded on an expedited basis, have assessed likelihoods but not the ultimate merits of the claims, and were not briefed and argued on the full administrative record.

ARGUMENT

With the administrative record now available, it is clear that HHS's rulemaking was arbitrary throughout, oblivious to serious negative consequences, and unsupported by that record. The contrary-to-statute claims, with which this Court is already familiar, provide equally strong bases upon which to rule in Plaintiffs' favor. On multiple scores, Plaintiffs—not Defendants—are entitled to summary judgment, because HHS was not "permitted … to make the decision it

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[2] The NFPRHA Plaintiffs also incorporate by reference the Statement of Facts in Washington's Cross-Motion for Summary Judgment (WA SJ Br.) filed today.

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did" here. *Occidental Eng'g Co. v. Immigration & Naturalization Serv.*, 753 F.2d 766, 769 (9th Cir. 1985); 5 U.S.C. § 706(2)(A).

I. HHS ENGAGED IN ARBITRARY AND CAPRICIOUS RULEMAKING

A. Governing APA Standards and Overview of HHS's Failures

The courts have a narrow, but critical, role in scrutinizing administrative agency rulemaking to ensure that it is not arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983); *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1193-94 (9th Cir. 2008). To fulfill this role, judges undertake a "searching and careful inquiry" that applies the following standards. *Native Ecosystems Council v. Weldon*, 697 F.3d 1043, 1050 (9th Cir. 2012).

In all rulemaking, "the agency must examine the relevant data and articulate a satisfactory explanation for its action[,] including a 'rational connection between the facts found and the choice made.'" *State Farm*, 463 U.S. at 43 (citation omitted). An agency rule is arbitrary and capricious if, for example:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

463 U.S. at 43. An unexplained inconsistency between agency actions also shows arbitrariness. *Organized Vill. of Kake v. U.S. Dep't of Agriculture*, 795 F.3d 956, 966 (9th Cir. 2015) (en banc).

Both economic and non-economic costs (including to human health) are "centrally relevant" when agencies decide whether to regulate. *Michigan v. EPA*,

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135 S. Ct. 2699, 2707 (2015). Reasonable, non-arbitrary regulation "ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." 135 S. Ct. at 2707; *see also id*. ("No regulation is 'appropriate' if it does significantly more harm than good.").

When an agency changes its policy, it must, *inter alia*, display awareness that it is changing its position and provide "good reasons" for the change. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016); *see also Kake*, 795 F.3d at 966. If the changed position '"disregard[s] facts and circumstances that underlay or were engendered by the prior policy,'" a more detailed justification is required to explain and provide a reasoned basis for the new agency action. *Encino Motorcars*, 136 S. Ct. at 2125-27 (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)).

Merely reciting a justification or offering conclusory statements is never enough to establish reasoned decision-making. *Encino Motorcars*, 136 S. Ct. at 2127; *State Farm*, 463 U.S. at 52. And stating that a factor was considered is no substitute for considering it. *Beno v. Shalala*, 30 F.3d 1057, 1075 (9th Cir. 1994).

Here, HHS's 2019 promulgation of the Rule fell far short of these reasoned rulemaking standards. To highlight the main errors: First, HHS ignored the more exacting standard of *Encino Motorcars* and reversed course without the necessary well-reasoned basis. In particular, HHS's rulemaking failed to contend with and justify a departure from (a) the agency's own specific findings in 2000, (b) its own national clinical standards for family planning care, and (c) Title X providers' and patients' reliance for decades on HHS's previous, effective approach to creating

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and operating a national network of quality care. Second, HHS irrationally failed to consider the Rule's negative consequences for patients, even though the agency itself recognized the Rule would deprive patients of information they sought and mean that at least some longstanding Title X points of access would disappear. HHS attributed *zero cost* to the Rule's negative impacts on patients—whom Title X exists to serve—despite significant harms manifest from the record. This rulemaking evinced greater concern for potential conscience objections by hypothetical, possible future providers than for patients receiving Title X care.

Third, in another irrational approach to cost, HHS pulled out of thin air a far-too-low number for providers' attempted compliance with the Rule's new physical separation and infrastructure requirements. The agency's made-up number is nowhere explained or substantiated, and is contrary to specific record evidence. The record establishes much higher costs for the Rule's physical separation and infrastructure requirements and that those will seriously handicap future operation of the Title X program. Fourth, HHS drew a variety of other arbitrary lines in the specifics of the Rule, discussed below, that are not supported by the administrative record and that harm Title X's purpose. Fifth, HHS also made conclusory and illogical assertions that exaggerated any purported benefits from the Rule.

Finally, the rulemaking as a whole and in its specifics relied on irrational balancing, not rooted in the factual record before HHS, by (a) consistently putting "a thumb on the scale" to undervalue costs and overvalue purported benefits, *see Ctr. for Biological Diversity*, 538 F.3d at 1198; (b) asserting, *ipso facto*, that agency positions in 1988, three decades ago, can be resurrected today to support

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the Rule; and (c) sacrificing the overall functioning of the Title X program to much expanded, unnecessary "compliance" burdens and other tangential aims.

As the Ninth Circuit emphasized in *Center for Biological Diversity*, "[w]hat was a reasonable balancing of competing statutory priorities twenty years ago may not be a reasonable balancing of those priorities today." 538 F.3d at 1198. Moreover, an agency plainly does not act rationally by imposing requirements that undermine Congress's central purpose for the program the agency is trying to implement. 538 F.3d at 1195, 1197. In promulgating the Rule, HHS unlawfully lost its way by ignoring the record evidence before it in 2019, reflexively harking back to 1988, and irrationally moving ahead in the face of apparent, devastating costs to this unique national program and its vulnerable low-income patients.

B. HHS Arbitrarily Imposed the Pregnancy Counseling Distortions

In Sections 59.2, 59.5(a) & (b), 59.13-59.16, and 59.18 (the "Pregnancy Counseling Distortions"), HHS did an about-face after two decades under the 2000 regulations and newly decreed how Title X projects must control the information provided to pregnant women. But HHS lacked the detailed good reasons and rational connection to record evidence that might support such drastic changes.

1. *Failure to Rationally Explain Reversal of HHS's Prior Findings*

a. HHS's Factual Findings in 2000

i. In 2000, the Secretary of HHS specifically determined that the agency should reflect in the Title X regulations the "fundamental program policy" that pregnancy counseling is "a *necessary component* of quality" services. 65 FR at 41273 (emphasis added). HHS emphasized that "nondirective options counseling"

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is "a necessary and basic health service of Title X projects. Indeed pregnancy testing is a common and frequent reason for women coming to visit a Title X clinic[.]" 65 FR at 41273. HHS found pregnancy counseling as specified in its 2000 regulations consistent "with sound public health policy" and "with the prevailing medical standards recommended by national medical groups such as the American College of Obstetricians and Gynecologists [ACOG] and the American Medication Association [AMA]." *Id*.

ii. HHS also found in 2000 that *each client's particular requests must dictate the parameters* of their counseling. 65 FR at 41273. As the 2000 rulemaking explained, Title X providers should offer counseling on prenatal care, adoption, and pregnancy termination, and were "not restricted as to the completeness of the factual information they may provide relating to all options," but "if the client indicates she does not want information and counseling on any particular option, that decision must be respected." *Id*. HHS found that a counselor "removing an option from the client's consideration necessarily steers her toward the options presented" and is impermissible within Title X. *Id*.

iii. HHS specifically determined that "neutral, factual information" about abortion providers, like prenatal care or adoption providers, should be available upon patient request. 65 FR at 41274. The agency found, *inter alia*, that "it does not seem rational to restrict the provision of factual information" regarding referrals and that, "[s]ince the services about which pregnancy options counseling is provided are not ones which a Title X project typically provides, the provision of a referral is the logical and appropriate outcome of the counseling process." 65 FR

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at 41274. But HHS specifically found that requiring a referral for prenatal care, where the client rejected that option, should *not* occur, because of the coercive and directive nature of such an unwanted and unnecessary referral. 65 FR at 41274-75.

iv. Finally, HHS made detailed findings, including but not limited to the above, to reject suggestions that Title X's requirements for nondirective pregnancy counseling, including for abortion referral upon patient request, should be altered because of possible provider religious or moral objections. 65 FR at 41274-75.

The Government attempts to portray the 2000 rule as merely "a shift in approaches on the basis of 'experience.'" DOJ Br. at 6. But HHS made all of these findings and finalized the prior, 2000 regulations based on record evidence of "medical ethics," "good medical care," and the "prevailing medical standards" of leading medical organizations, as well as "longstanding [Title X] program practice." 65 FR at 41273-75 (citing not only comments from medical authorities but also the then-current ACOG policies and AMA Code of Medical Ethics).

b. HHS's Establishment of National Clinical Standards in 2014

In addition to these HHS factual findings that underlay the 2000 regulations, operation of the Title X program has engendered periodic HHS clinical updates to ensure that the program stays current with prevailing medical standards. Most recently, HHS's Centers for Disease Control (CDC) and Office of Population Affairs (OPA) collaborated on the 2014 publication known as the "QFP," which continues to govern national clinical practice today (and receives periodic updates and additions). *Providing Quality Family Planning Services*, ECF No. 19-2 (QFP).

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The CDC "has a long-standing history of developing evidence-based recommendations for clinical care" and the Title X program, implemented by OPA, "has served as the national leader in direct family planning service delivery" for decades. QFP at 2. HHS's two sub-agencies convened numerous panels of experts and engaged in rigorous review to develop the QFP. *See* QFP at 2. Its clinical "recommendations are intended for all current or potential providers of family planning services, including those funded by the Title X program." They are "used by medical directors to write clinical protocols that describe how care should be provided." QFP at 2, 3. HHS incorporates the QFP into its Title X requirements and its monitoring of grantees. *See* ECF No. 19-1 at 5-6.

i. The QFP classifies pregnancy testing and counseling as a core service that all family planning providers should offer. QFP at 2, 5, 13.

ii. HHS's QFP also repeatedly emphasizes that quality family planning care takes a "client-centered approach." The QFP uses the Institute of Medicine's definition to specify that "client-centered" care is "respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions." QFP at 4. The QFP highlights the need for family planning providers "to delivery high quality care to all clients" and to do so in a "culturally competent manner," which requires clinical professionals to "work effectively in cross-cultural situations." QFP at 2-3.

iii. The QFP further specifies that pregnancy test results "should be presented to the client, followed by a discussion of options and appropriate referrals." QFP at 14. That counseling should be "in accordance with

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recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP)." QFP at 13-14. The QFP itself emphasizes that "[r]eferral to appropriate providers of follow-up care should be made at the request of the client" and "[e]very effort should be made to expedite" referrals. QFP at 14.

iv. At the same time, HHS's QFP specifies that initial prenatal information is appropriate only "[f]or clients who are considering or choose to continue the pregnancy," again instructing providers to follow the recommendations of ACOG. QFP at 14; *see also id*. at 4 ("effective" and "client-centered" care does not include services that are not responsive to the specific patient's needs).

c. HHS Abandoned These 2000 and 2014 Findings on Proper Clinical Family Planning Practices Without Comment and Without Justification

In adopting the Rule, HHS failed to address its abandonment of these prior, repeated articulations of current clinical standards for family planning health care and instead simply turned them on their head without any rational justification. At the most basic level, HHS acted arbitrarily because it did not even acknowledge that it was contradicting its own carefully considered findings on the necessary components of family planning clinical practice. *See FCC v. Fox Television*, 556 U.S. at 515-516 (arbitrary for an agency to ignore that it is "disregarding facts and circumstances that underlay or were engendered by the prior policy"); *Nat'l Lifeline Assoc. v. FCC*, 921 F.3d 1102, 1111-12 (D.C. Cir. 2019) (agency acted arbitrarily in failing to acknowledge contradictions with previous findings as to the contours and effectiveness of a federal program for low-income consumers).

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Instead, both in the rulemaking and in this litigation, HHS has not addressed its factual foundations for the 2000 pregnancy counseling requirements, ignoring its findings then of "prevailing medical standards" and the necessary respect for patient's own articulated needs. DOJ Br. at 6, 23 (incompletely referencing only "experience" as the foundation for the 2000 regulations). Likewise, HHS has not acknowledged its own expert findings in the QFP (now contradicted by the Rule) or the QFP's central role—by HHS's own design, as stated there—in defining for clinicians nationwide "how to provide family planning services." QFP at 1-2. The rulemaking never even mentions the QFP, nor is it included in the administrative record (though numerous commenters referenced and relied upon the QFP in identifying serious problems with the Rule, *see*, *e.g.*, ACOG Cmt 268843-44; Guttmacher Cmt 264415-16, 264422; NFPRHA Cmt 308016; PPFA Cmt 316412; JIWH Cmt 239147-49; ACNM Cmt 315936).[3]

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[3] HHS makes no sense in arguing that it need not have considered the QFP because it could not "substantively go beyond the 2000 regulations." DOJ Br. at 32 n.4. The QFP contains official HHS findings that supported and implemented the 2000 regulations—not that "go beyond" them, and it reflects exactly the type of previous findings an agency must address to rationally reverse course. "An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past," but must instead provide a "reasoned explanation" for abandoning them. *Kake*, 795 F.3d 968-69 (citations omitted).

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HHS never attempted to explain, for example, why pregnancy counseling is no longer a necessary, core family planning service that should be offered by all Title X projects. Nor did HHS provide any rational explanation for reversing clinical principles to let individual Title X *providers* make their own personal choices about the pregnancy information a patient might receive, *see* Section 59.14(b)(1)(i)-(iv), instead of insisting upon client-centered care. Client-centered care retains for *patients* their voluntary, independent control based on their needs and values—including when it requires cross-cultural care by providers. Similarly, HHS offered no cogent explanation for the Rule's unprecedented interpretation of "nondirective" pregnancy counseling—contrary to HHS's own previous findings and instructions—that (a) allows a provider to omit any information about abortion, even in response to patient questions, and (b) insists on a provider discussing prenatal care even when the patient says no to such a discussion. 84 FR at 7747-78. Though HHS itself rejected universal, mandatory prenatal referrals as unnecessary in its previous findings, this rulemaking claims they are "medically necessary" for all, without providing explanation or substantiation for that contention. Section 59.14(b). "The absence of a reasoned explanation for disregarding previous factual findings violates the APA." *Kake*, 795 F.3d at 969.

In addition, HHS not only left unaddressed these contradictions with the agency's own prior factual determinations about professional family planning standards, but also compounded that error many times over: HHS ignored the patient harms imposed by the new Pregnancy Counseling Distortions; irrationally dismissed the distortions' negative impact on Title X providers; failed to consider

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harms to the overall Title X program; exaggerated asserted benefits; and adopted the new pregnancy counseling scheme and numerous arbitrary distinctions within it in the absence of a reasoned basis. The same leading medical authorities that HHS had previously relied upon, as well as public health experts, government agencies, Title X providers, and others, warned HHS of the harmful health care impacts and these irrational missteps. But, as elaborated below, HHS went ahead, acting contrary to the record and without reasoned justification in all these ways.

2. *Failure to Rationally Consider Patient, Provider, and Program Costs*

In stark conflict with the record evidence, and blind to even its own descriptions of harm, HHS irrationally attributed "no costs" of any kind to its pregnancy counseling changes. That alone renders HHS's rulemaking arbitrary.

a. The Rule Imposes Unresponsive, Substandard Health Care on Patients

Instead of guaranteeing Title X patients access to the core family planning service of pregnancy counseling, responding to each patient's individual needs and questions during that counseling, and prohibiting the provider from pushing information on the patient that is not welcome—all as required by HHS's own current clinical standards in the QFP—the Rule newly allows providers to skip nondirective counseling, discuss only continuing a pregnancy and protecting the "unborn child," regardless of the patient's wishes, and rebuff patient questions about abortion. Section 59.14(b). It also permits giving patients that seek abortion referrals a confusing list of comprehensive primary care providers that might, but need not, include a source for abortion care, and forbids labelling any such source.

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These Pregnancy Counseling Distortions impose serious costs on patients by depriving them of standard medical care; withholding relevant information and delaying their access to complete counseling and further care; undermining the patient-provider trust that is essential for patients' effective care and for their willingness to seek future help from medical providers; and frustrating, shaming, and confusing patients, rather than serving their needs through patient-centered interactions. *See*, *e.g.*, ACOG Cmt 268838-41; AMA Cmt 269330-32; AAP Cmt 277788-89; AAMC Cmt 264536; NLIRH Cmt 307455-56; FAPP Cmt 305098-100 EM Cmt 47947; NFPRHA Cmt 308018-20 (explaining that among its harms, the incomplete and misleading counseling under the Rule will injure "dignity[] and self-determination," be compounded by "confusion and delay," and "destroy trust in the provider"); MSAHC Cmt 106753 (the Rule's "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."). Indeed, HHS admitted that "the quality of communication" between clinicians and patients affects health care outcomes, 84 FR at 7783, and included a study on that topic in the record, *see* AR406971 *et seq*. ("Impact of the Doctor-Patient Relationship"), but then *failed* to account for any costs to patients from the Rule's inadequate, unresponsive, and confusing pregnancy counseling.[4]

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[4] In the Rule, HHS flouts the essential teachings of this source it selected: That source emphasizes that over the last several decades, the doctor-patient relationship has shifted to a model where, whenever medically feasible, the "physician's role is

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b. The Rule Forces Title X Providers to Violate Professional Standards

Likewise, the administrative record is replete with evidence from the country's highest medical authorities that the Rule imposes serious costs on medical providers: To comply with the Rule's Pregnancy Counseling Distortions means providing care below current professional standards and means violating the ethical principles that govern the practice of medicine. The Rule's limited pregnancy counseling is contrary to HHS's own QFP, and also fails to satisfy the clinical practice recommendations of ACOG and AAP, which HHS incorporated into the QFP. *See* ACOG Cmt 268838-41 (referencing ACOG policies and opinions); AAP Cmt 277788-89 (counseling changes "conflict [] with medical practice guidelines, including those of the American Academy of Pediatrics"); *see also* FPCA Cmt 385053 (the Rule, including in changes to pregnancy counseling, "undermine[s] the evidence-based standard of care" in the QFP, set after extensive review by HHS of "best practices and current research").

In addition, the very institutions that establish the governing ethical principles for the types of clinicians who participate in Title X care made clear to HHS that the Rule's Pregnancy Counseling Distortions were contrary to medical ethics. The AMA, which wrote and interprets the Code of Medical Ethics,

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to elicit a patient's goals and to help achieve these goals." AR406973. The doctor-patient relationship is "a fiduciary relationship in which … the physician agrees to respect the patient's autonomy … explain treatment options [and] provide the highest standard of care," among other obligations. AR406972.

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emphasized that the Rule "would force physicians to violate their ethical obligations," including because of the inability to provide abortion referrals upon patient request. AMA Cmt 269332; *see also* AAPA Cmt 106281 (to comply with its ethical principles, physician assistants "must … be able to provide referrals" for the care that is desired by their patients and "have an ethical obligation to provide … unbiased clinical information"); NASW Cmt 107236-37 (NASW Code of Ethics, like other codes in the medical profession, emphasizes that clinicians must respect patient self-determination and "have an ethical obligation to put the needs of patients first;" "withholding information without the patient's knowledge or consent" and "the prohibition on abortion referrals contravenes medical ethics"). Similarly, the American Academy of Nursing, which represents *inter alia* nurse practitioners, nurse midwives, and registered nurses, cited the Code of Ethics for Nurses to alert HHS to the fact that the Rule would require them "to violate their professional ethics in order to participate in Title X." AAN Cmt 107973.[5]

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[5] Medical professionals also have ethical obligations to help ensure that low-income persons and historically disadvantaged communities have access to health care. *See, e.g.,* ACNM Cmt 315937; NASW Cmt 107237; AAN Cmt 107971; AMA Code of Medical Ethics Opinion 11.1.4, ANA Code of Ethics for Nurses Provision 8. The ethical quandary between (a) acceding to the Rule's unethical counseling provisions or (b) leaving Title X and its provision of free care for vulnerable patients reveals the Hobson's choice the Rule creates—it leaves no path for avoiding ethical and other harms.

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Thus, the Rule requires Title X clinicians to provide health care that falls below current clinical standards, including the QFP, harming clinician-patient relationships and causing ethical and reputational injuries for Title X medical professionals. The record thoroughly catalogued and substantiated these negative impacts, yet HHS failed to acknowledge *any* costs to Title X providers from the Rule's new, changed counseling scheme. *See* 84 FR at 7719 ("no costs"); *see also id*. at 7777 (claiming no "non-quantified costs" of any kind from the Rule).

Instead, HHS offered only conclusory assertions that it "disagrees with commenters who contend" that the Rule infringes on "ethical[] or professional obligations of medical professionals," or cited a few inapposite sources, such as *Rust* and *Roe v. Wade*, 410 U.S. 113 (1973). *See*, *e.g.*, 84 FR at 7724, 7745, 7748. HHS never discussed actual ethical principles or professional standards, and proceeded in the face of the authoritative, overwhelming chorus of comments in this record from the country's leading medical authorities that establish the 2019 Rule's professional harms.[6] HHS's "conclusory statements do not suffice to

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[6] HHS errs in asserting that the existence of separate ethical or legal protections for providers' "conscience objections" means that the Rule does not itself impose ethical violations by (i) forbidding Title X pregnancy counseling to include abortion referrals upon patient request and (ii) requiring it to press prenatal information on all pregnant women, even those seeking an abortion. *See, e.g.*, 84 FR at 7748; DOJ Br. at 34-35. No medical provider must participate in Title X health care or undertake to counsel pregnant women. If clinicians do undertake to

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explain" HHS's decision-making, *Encino Motorcars*, 136 S. Ct. at 2127, and "offer[ing] an explanation for its decision that runs counter to the evidence before the agency" is arbitrary and capricious, *State Farm*, 463 U.S. at 43.

Moreover, even if HHS had a separate potential justification for imposing substandard clinical care and ethical violations on Title X providers (which it does not), the agency would still have to rationally weigh these costs the Rule imposes against that justification. The arbiters of medical ethics like the AMA, HHS's own principles in the QFP, and the thousands of clinicians who individually or through their professional associations submitted comments detailing the Rule's conflicts with professional care establish objective, real world provider injuries that HHS cannot simply sweep away. *See Ctr. for Biological Diversity*, 538 F.3d at 1200 (agency acted arbitrarily by assigning zero value to a relevant factor reflected in the record); *Make the Road New York v. McAleenan*, No. 19-cv-2369, 2019 WL 4738070 at *35 (D.D.C. Sept. 27, 2019) ("an agency cannot possibly conduct reasoned, non-arbitrary decision making concerning policies that might impact *real* people and not take such *real life circumstances* into account").

HHS's extraordinary arbitrariness here is underscored by the fact that it failed to consider *any* cost from all these professional, dignitary, and reputational harms (and the accompanying costs to patients) made clear by current Title X

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provide that counseling, however, they cannot ethically deny patients abortion information or referral, or force prenatal information or referral upon them. *See, e.g.*, ACP Cmt 281207 (citing its ethics manual); *supra* at 20-21.

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providers and the leading medical associations, but did credit the asserted "benefit" of "reliev[ing] burdens on conscience that some entities and individuals [may have] experienced from complying with the previous requirement" and a similar "conscience" benefit for hypothetical future Title X applicants. 84 FR at 7719. It did so despite failing to document the existence or reach of any such entities or individuals and while contending that, even before the Rule, OPA "would not enforce" the 2000 regulations' requirements for pregnancy counseling if any such conscience objection were raised, 84 FR at 7746. *See also infra* at 30. An agency cannot rationally "put a thumb on the scale" by considering asserted effects it prefers but refusing to credit evidenced, countervailing harms. 538 F.3d at 1198.

c. The Rule Shrinks the Provider Network and Disrupts the Title X Program

The costliest harms from the Rule's pregnancy counseling scheme are all the provider departures from the Title X network that the record established would rapidly unfold. The Rule causes provider departures through its distortion of the provider-patient relationship and conflicts with professional norms, discussed above; it thereby also ushers in an ongoing obstacle to quality provider organizations and clinicians joining Title X in the future. These snowballing harms have now taken away many patients' access to *any* Title X services—and what is supposed to be a nationwide safety net of free, federally-funded, quality care—thus spreading injury far beyond Title X's substandard pregnancy counseling. Yet, again, HHS in its rulemaking irrationally attributed "no costs" to this disruption of the Title X provider network from the Rule. 84 FR at 7719.

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In so doing, HHS arbitrarily acted contrary to the record. *State Farm*, 463 U.S. at 43. Knowledgeable commenters provided specific, unequivocal evidence of the large network gaps that would follow if HHS proceeded to ban abortion referrals. Planned Parenthood Federation of America (PPFA), for example, repeatedly alerted HHS that if "the proposed ban on abortion referrals" were finalized, all Planned Parenthood providers "would be forced to decline Title X funds" because such a ban is "fundamentally at odds" with medical professionals' obligations. PPFA Cmt 316476; *see also id*. 316401, 316414. PPFA also made explicit what HHS already knew: that Planned Parenthood sites treated a high percentage of all Title X patients, including in areas not served by other resources. PPFA highlighted that, while its health centers "represent only 13 percent of Title X service sites, they serve over 40 percent of the program's patients." PPFA Cmt 316477. "Fifty-six percent of Planned Parenthood health centers are in health provider deserts, where residents live in areas that are medically underserved and they may have nowhere else to go to access essential health services without Planned Parenthood." *Id*. Despite this detailed evidence and further explanation in PPFA's 96 pages of comments, HHS erroneously declared that "commenters did not provide evidence that the rule will negatively impact the quality or accessibility of Title X services" by virtue of provider departures (and the Rule's ongoing disincentives against quality providers participating in Title X). 84 FR at 7780.

Similarly, the Family Planning Councils of America, a coalition of longstanding, large Title X-funded grantees, explained to HHS how the Rule, including the counseling distortions "would greatly reduce the number of high

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quality providers willing and able to deliver" Title X services. FPCA Cmt 385034; *see also* NFPRHA Cmt 308014-21 (explaining in detail why the counseling changes, "if adopted, will drive a number of Title X providers from the program" and "shrink and diminish the effectiveness of the Title X network"); Guttmacher Cmt 264420-23, 264426 (showing that "it is clear that by dissuading dedicated, high-quality family planning providers from participating in Title X, these [counseling] restrictions would make it more difficult for patients to receive the family planning care they need"); Minn Orgs Cmt 243781; AUCH Cmt 84165-66.

HHS arbitrarily did not factor in the high cost of losing many Title X providers for *all* program purposes once the Rule's counseling restrictions, including the ban on abortion referrals at patient request, took effect. *See Nat'l Lifeline Assoc.*, 921 F.3d at 1112-13 (agency arbitrarily failed to consider an important aspect of the problem under *State Farm* by not considering providers' unwillingness to offer services in program to aid low-income individuals and the impact on those vulnerable consumers when gaps in service therefore occurred).[7] The rulemaking record, however, exhaustively documented the harms to the Title X program and to the broader public health that these departures would cause. *See, e.g.*, AAN Cmt 107970-75; AAP Cmt 277787-89, 277794-95; ACOG Cmt

[7] HHS did engage in a cursory, irrational discussion of possible provider departures as a result of the physical separation requirements, *see, e.g.*, 84 FR at 7766, 7782; *infra* at 47-50, but did not address at all the provider exodus that the record indicated would occur even earlier—when the counseling scheme took effect.

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268837; Brindis Cmt 388053-66; TxPEP Cmt 269930-36; CAP Cmt 309216-17; HIVMA Cmt at 269714-15; CDIH Cmt at 20722-23; APIAHF Cmt 96231-32.

In adopting the Rule, HHS conceded that "cost is an important consideration in any rulemaking," but then immediately thereafter asserted that in this case, "compliance with statutory program integrity provisions is of greater importance[.]" 84 FR at 7783. That assertion is arbitrary and unreasoned (both for the counseling distortions alone and for the Rule as a whole), because the agency *inter alia* did not actually weigh any of the significant costs to Title X of these new counseling provisions and instead irrationally found "no cost" in proceeding with them, though the record shows widespread costs to patients, providers, and the program itself. *See Michigan v. EPA*, 135 S. Ct. at 2707 (reasoned decision-making requires paying attention to the costs as well as any benefits); *State Farm*, 463 U.S. at 43 (agency must examine the relevant data and rationally ground its choices there); *Make the Road*, 2019 WL 4738070 at *36 ("an agency cannot consider only the perceived shiny bright spots … [but] must *also* attempt to forecast the storm clouds that might be spawned if it adopts the proposed policy").

d. The Type-of-Clinician Restriction Further Adds Costs and Is Arbitrary

The new pregnancy counseling scheme includes yet another unreasoned and harmful distinction: Section 59.14(b)(1), without explanation, allows any Title X staff members to discuss with pregnant patients "maintaining the health of the mother and unborn child during pregnancy" (subpart (iv)) but requires that only "physicians or advanced practice providers" can give what the Rule calls "nondirective pregnancy counseling" (subpart (i)). Thus, under the Rule, even

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untrained or volunteer staff could undertake to provide pregnant women with information biased in favor of continuing their pregnancy, including by using non-medical terms such as "unborn child," *see* ACOG Cmt 268839, but the Rule insists that "nondirective" discussions must involve only the most highly credentialed and expensive Title X clinicians—though many types of trained staff are qualified to provide nondirective pregnancy counseling. HHS's rulemaking does not even attempt to rationalize or justify this distinction between subparts (i) and (iv).

Furthermore, the Rule's requirement that only what it defines as "Advanced Practice Providers (APPs)" or physicians can give "nondirective pregnancy counseling" ignored the comments that urged HHS to avoid supplanting state regulation of clinicians' scope of practice. *See, e.g.*, ASTHO Cmt 199042 ("Many state public health agencies regulate healthcare professions and their scope of practice. ASTHO believes that any healthcare provider permitted to provide this counseling should not be restricted, in any manner or form, from providing their scope of services."); ACOG Cmt 268840 ("arbitrarily limiting the providers" permitted to undertake some types of pregnancy counseling, especially in a time of workforce shortages, "erects an unnecessary and unsupported barrier to care"). Indeed, in the FPAR, OPA defers to "state-specific regulations" to define its category of "clinical service providers" able to handle *all* aspects of Title X care and recognizes that others, including registered nurses, health educators, and social workers, may appropriately participate in client counseling. AR406194. The Rule's APP definition replaces one arbitrary distinction set forth in the proposed rule (between physicians and all others), *see* 83 FR at 25,531, with another

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(between APPs, physicians, and all others) to restrict nondirective pregnancy counseling to an overly narrow set of trained Title X providers. Again, HHS acted without weighing important considerations, including cost, and without even attempting to explain this Rule's new line drawing as to counseling providers.

3. *Exaggeration of Purported Benefits*

While ignoring these many costs, HHS also irrationally portrayed and exaggerated purported benefits of the Rule's pregnancy counseling changes. For example, HHS contends without any explanation, evidence, or logic that the Rule's more complex pregnancy counseling scheme, including the new ban on abortion referrals and required prenatal referrals, will "reduce the regulatory burden associated with monitoring and regulating Title X providers for compliance," as compared with the 2000 regulations—which uniformly required nondirective information and patient-requested referrals, without any mandatory or banned referral steps. 84 FR at 7719. The elaborate guidance that HHS attempted to provide in the rulemaking and its own warnings about "monitoring and oversight," 84 FR at 7747-48 & n.77, 7780, however, make apparent that monitoring and regulatory burdens will likely be greater—and at minimum unchanged—for the pregnancy counseling aspects of the new Rule.

Similarly backwards is HHS's assertion that an increase in *providers*' expression of or decisions based on their *own* religious or moral beliefs would improve care for Title X patients. 84 FR at 7782-83. The QFP and the two references that HHS itself cites all underscore that each *patient*'s faith or spirituality, not the personal beliefs of clinicians, must be respected for quality

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health care to occur. *See* 84 FR at 7782-83 n.142-44; QFP at 2-3, 4, 13-14. All health care providers—and especially those in a federal program designed to serve vulnerable patients with limited resources wherever those patients happen to need care—must be effective *cross*-culturally, with understanding of and respect for *patient* beliefs and choices even when those are quite different than providers' own. *See id.*; AR407013 (providers ignoring *patients*' spirituality or *patients*' "parallel sets of beliefs" can be barriers to care); *supra* at n.4. Yet the Rule cedes control to providers' beliefs and preferences in every pregnancy counseling encounter, without regard to the individual patient's needs.

Finally, HHS characterized the Rule's counseling scheme as "reliev[ing] burdens on conscience" for providers and hypothesized that it "may" or "might" increase the number of providers seeking to participate in Title X as a result. 84 FR at 7719, 7780-81. Jumping from that speculation, HHS then asserted: "Ultimately, the Department believes that the final rule will result in more Title X applicants" and will "expand the number of entities interested in participating in Title X." 84 FR at 7777, 7781. But HHS's own statements and other evidence in the record contradicted these asserted benefits.

For one thing, HHS explicitly stated that since 2008 OPA "would not enforce" and "continues to conclude" that the 2000 regulations' requirement of abortion counseling (including referral upon request) "cannot be enforced against" those with conscience objections. 84 FR at 7746; *see also* ECF No. 85 (Notice claiming this "preexisting policy dating back at least to 2008"). If true, that is inconsistent with the assertion now that there was a burden on conscience.

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Moreover, the rulemaking record contains only conclusory assertions that new entities might seek to join Title X. HHS references "one comment" describing an online survey of "faith-based medical professionals," but that survey in no way measures interest in participating in Title X or even mentions the program. 85 FR at 7780-81 & n.138-139; AR406939-40. Though the record contains the bare assertion that the Rule will "open the door" to new providers, Imbody Cmt 69736, it lacks any evidence that the counseling changes or any other part of the new Rule will actually generate new applicants and increase the number of providers of Title X care. HHS, Title X grantees, and health care advocates have worked hard to establish and expand a nationwide network offering Title X care for almost five decades. The agency has not pointed to *any* untapped reservoir of qualified health care professionals with the capacity and interest to become Title X providers. Indeed, HHS has not identified a single commenter that stated the Rule would cause it to apply to participate in the program for the first time.[8] Even

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[8] Plaintiffs identified one entity, the Human Coalition, that *had* applied before to no avail and that objected not only to the 2000 counseling regulations, but also to assisting clients in obtaining contraception that has "an abortifacient effect." Human Coal. Cmt 268384. The Coalition targets "abortion-determined women" to make abortion "unthinkable." https://www.humancoalition.org/donate/save-a-child/. Its comments and a number of similar ones told HHS that the Rule was still "deficient" and did not go far enough to address "culture of life" concerns. *See, e.g.*, Human Coal. Cmt 268383-84; PRI Cmt at 243344, 243346-49, 243355.

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if one hypothesizes that some such providers may exist, however, the rulemaking record documented that specific existing providers would depart on a large scale and that professional standards would trigger others to do the same, while also militating against any new health care providers joining Title X. *See supra* at 24-27. HHS's contention of *more* total providers under the new Rule was implausible and contrary to the record before it. Even HHS's own rulemaking description reveals a slight of hand from "might" to "will" that defies logic. 84 FR at 7780-81.

Thus, HHS repeatedly offered conclusory assertions that the Rule "will contribute to more clients being served, gaps in services being closed, and improved client care," *see, e.g.*, 84 FR at 7766, despite the rulemaking's lack of foundation for those asserted justifications. HHS unequivocally claimed one benefit of the Rule would be an "[e]xpanded number of entities interested in participating in Title X, including" by virtue of the pregnancy counseling changes, 84 FR at 7777, when the record overwhelmingly showed the contrary.

Now, as a litigation strategy, HHS ignores that it promulgated the Rule by relying on such overstatements.[9] It attempts to retroactively scale back the

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[9] HHS's briefing also invokes the phrase "predictive judgments" to attempt to shield its rulemaking suppositions that defied the record and logic, and instead amounted to wishful thinking. DOJ Br. at 39. The case law has used the phrase "predictive judgment" on occasion to describe an agency's exercise of technical expertise after "thoughtful, comprehensive" consideration of the record and the problem before it. *See, e.g., Trout Unlimited v. Lohn*, 559 F.3d 946, 958-59 (9th

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"benefits" of the Rule, focusing on operating the program through prior applicants and aiming not for an increase but only to avoid a "decrease in the overall number of facilities offering services." DOJ Br. at 38-39. Even measured against this diminished re-characterization, however, HHS's representations to this Court that its rulemaking predictions have "borne out," *id*., are plainly incorrect.

4. *HHS's Improper Resort to Subsequent Events Supports Plaintiffs*

HHS admits that once the Rule's Pregnancy Counseling Distortions took effect last summer, it was beset by "departing providers[.]" DOJ Br. at 38. Despite numerous comments warning this would occur, HHS had predicted no departures, at "no cost," and had even considered the possibility of such departures only when the physical separation rules later apply. *See supra* 24-27 & n.7. Since these immediate departures, moreover, HHS has not sought out any prior "competing applicants" or possible new Title X participants, but has only funneled additional funds to the existing providers that remain in a now gap-ridden network.

HHS's directory of Title X participants and sites as of October 2019 shows *more than 900 fewer service sites* than the Title X program had just prior to HHS's

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Cir. 2009); *see also BNSF Railway Co. v. Surface Transp. Bd.*, 526 F.3d 770, 774, 780-81 (D.C. Cir. 2008) (recognizing agency expertise in the tradeoffs of railroad rate-setting, and upholding new methodology that reflected "reasoned predictions about technical issues"). HHS's rulemaking here bears no resemblance to the decision-making in those cases—cases that reinforce the requirement of reasoned justifications rooted in the record, instead of unfounded speculation.

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initial implementation of the Rule, with five states today having not a single Title X site.[10] Eight other states have lost 50-99% of their previous network. Some entities are no longer participating in at least 32 states. *See* Data Note (analysis of HHS data) https://www.kff.org/womens-health-policy/issue-brief/data-note-is-the-supplemental-title-x-funding-awarded-by-hhs-filling-in-the-gaps-in-the-program/. The program has lost more than 200 subrecipients. *See supra* n.10.

Most harmfully, these network losses mean that sites serving almost half of the Title X patient population in recent years are no longer available for Title X services. *See, e.g.*, Guttmacher Cmt 264424-26; NYAG Cmt 269294. Without any Title X program in multiple states and with network gaps in at least 32, HHS has no conceivable basis for its September 2019 press release assertion that it nonetheless expects its diminished set of '"grantees to come close to—if not exceed—prior Title X patient coverage.'" DOJ Br. at 38 (quoting release).

Likewise, HHS cannot claim the Obria organization as a "new network of providers" that emerged in response to the Rule. *Cf.* DOJ Br. at 39. The Obria organization had applied for Title X funding in 2018 and 2019, and under the 2000 regulations HHS awarded it one of the FY 2019 grants that began on April 1, 2019. *See* https://www.hhs.gov/opa/grants-and-funding/recent-grant-awards/index.html. OPA addressed Obria's conscience objections through its prior policies, not via the Rule. ECF No. 85 (Notice to this Court). According to the October 2019 Title X

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[10] *Compare* October 2019 and June 2019 Title X Directories, available at https://www.hhs.gov/opa/title-x-family-planning/title-x-grantees/index.html.

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Directory, Obria is funded to provide Title X services only in California—at just five Obria locations and three "RealOptions" sites, for a total of eight. When the Pregnancy Counseling Distortions took effect, California lost more than 125 sites. *See* Directories, *supra* n.10. Contrary to DOJ's arguments, its *post hoc* invocation of Obria falls far short of showing that HHS's rulemaking assumptions about an intact network, without any "decrease in the overall number of facilities offering services," have been borne out. *Cf.* DOJ Br. at 38-39.

More fundamentally, HHS cannot rely on its supplemental funding to existing grantees in September 2019, its press statement then, or Obria's suit in May 2019 to attempt to counter the arbitrariness of the Rule. A court may uphold agency action based only on the reasoning and record the agency relied upon at the time it made the decision. *See Michigan v. EPA*, 135 S. Ct. at 2710 (it is a "foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action") (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)). This Court can thus disregard HHS's subsequent information. To the extent subsequent events are considered, however, they only add to the already-overwhelming record evidence of HHS's failure to rationally assess the Rule's costs and only underscore the arbitrariness of its rulemaking.

* * *

HHS left the record far behind in adopting the Pregnancy Counseling Distortions, failing at every juncture to ground its decision-making in the record's evidence and instead putting an impermissible "thumb on the scale" to achieve its

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desired end. *Ctr. for Biologic Diversity*, 538 F.3d at 1198; *see also Sorenson Comms. Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) (rejecting rulemaking that "[r]elied on one unsubstantiated conclusion heaped on top of another"). This new counseling scheme is not supported by the detailed, reasoned explanation grounded in the facts that the APA requires, especially for an agency reversal of its own previous factual findings. *State Farm*; *Encino Motorcars*.

C. HHS Arbitrarily Adopted a Physical Separation Requirement and Infrastructure Limits

The Rule also creates a new physical separation mandate, imposed through Sections 59.15 and its use of Sections 59.13, 59.14, and 59.16 (collectively, the "Physical Separation Requirement"). And the Rule in Section 59.18 erects a related bar on infrastructure spending for "prohibited purposes," as well as requires funds to be used only in "direct implementation" of Title X projects, with "the majority of grant funds to provide direct services" (the "Infrastructure Limits"). HHS's promulgation of these restrictions was just as arbitrary as its imposition of the Pregnancy Counseling Distortions, for all the reasons described below.

1. *Failure to Rationally Explain Conflicts with Prior Findings and Reliance*

a. HHS's Factual Findings in 2000

HHS's adoption of the 2000 regulations clarified how grantees and their sub-recipients should organize their Title X projects and rejected a "physical separation" requirement. The agency emphasized that it "has traditionally viewed a grant project as consisting of an identified set of activities," not a physical structure. 65 FR at 41276. HHS made clear in 2000 that it saw "physical

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separation" as of "little relevance" to the Title X program and not "likely ever to result in an enforceable compliance policy that is consistent with the efficient and cost-effective delivery of family planning services." *Id*. HHS specifically found that earlier attempts to require physical separation had been vague, "unenforceable" and "never implemented on a national basis." *Id*. HHS found that in the 1988 physical separation regulation, the "fundamental measure of compliance" had "remained ambiguous;" that revealed the "practical difficulties of line-drawing in this area." *Id*. HHS also concluded that the 1988 physical separation rule gave no apparent "additional statutory protection" with regard to Section 1008, beyond the Title X program's already-strict financial separation. *Id*.

Alongside the 2000 regulations, HHS also published guidance "to promote uniform administration of the program and facilitate grantee compliance," including with regard to separating project *activities* from non-project abortion-related *activities*. 65 FR at 41281. In that 2000 guidance, HHS found that, in addition to financial separation (including properly pro-rated cost allocations), grantees "may demonstrate that prohibited abortion-related activities are not part of the Title X project" by means "including counseling and service protocols, intake and referral procedures," and other administrative procedures. 65 FR at 41282.

b. Grantees', Other Title X Providers', and Patients' Longstanding Reliance

In addition, Title X providers have relied for decades on the pre-Rule Title X parameters to effectively locate, structure, and operate their facilities that offer Title X services, and their patients have relied on those locations as access points for ongoing care. The 2000 regulations importantly preserved the program's

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essential character and functioning since its inception: Congress specified that Title X's grants were to assist in the "establishment and operation" of family planning projects. 42 U.S.C. § 300(a). Congress's explicitly stated Title X purposes include enabling "public and nonprofit private entities to plan and develop comprehensive programs of family planning services," and to develop materials, "trained manpower," and other assets for such programs. 84 Stat. 1504.

Thus, Title X has never functioned as an insurance program like Medicaid, which focuses on reimbursement for services rendered, but rather is a means for building, investing in, and supporting care in a nationwide, high-quality network for family planning. AR406795-801.[11] In its rulemaking, HHS describes (using Guttmacher Institute reports) how Title X funds '"the *essential* infrastructure support that enables'" sites to provide care, 84 FR at 7773 (emphasis added), including physical facilities and equipment, information technology, bulk

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[11] Title X grants rely on Medicaid funding for projects' overall budgets, which HHS reviews and approves ahead of time. *See* OPA, FY 2019 Funding Opportunity Announcement, https://www.hhs.gov/opa/sites/default/files/FY2019-FOA-FP-services-amended.pdf (2019 FOA) at 17-18. Under requirements that the Rule does not alter, Title X providers must seek reimbursement from third-party insurance, both public and private, to help fund Title X projects. *See* 42 U.S.C. § 300a-4(c)(2); 42 C.F.R. §§ 59.5(a)(7), (9). But this does not "free up" funds for any unexpected use, *cf.* 84 FR at 7773; it is part of HHS's structuring of Title X grants and projects in the first place.

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purchasing of contraceptives, and staff training, and enables '"indispensable'" outreach for connecting patients with Title X care, 84 FR at 7774.

Moreover, there have always been Title X providers that also, separate from Title X activities and with non-Title X funds, provide abortion care—including in the same building, with shared staff and the same administrative systems. *See* PPFA Cmt 316426. These are typically reproductive health-focused providers that have historically offered the most comprehensive, high-quality family planning care. Guttmacher Cmt 264423-27 (also describing that, overall, 72% of Title X sites are reproductive health-focused practices); NACCHO Cmt 294044-45.

Until the Rule took effect, Title X grantees and subrecipients consistently structured and planned their programs under the 2000 regulations and 2000 guidance on abortion-related activity. VTDOH Cmt 198208 (relying on those regulations, the Title X network has been enhancing its infrastructure and opening new facilities); APHA Cmt 239895-96. This included all applications, work plans, and budgets submitted as recently as January 2019, *see* 2019 FOA, to secure the three-year Title X project grants that HHS made for jurisdictions nationwide in March, with initial funding that began on April 1, 2019. *See supra* at 34.

In building their Title X projects over the last decades, grantees routinely sought out additional health care providers and worked to establish Title X care where it would best respond to patient need. Before the Rule, Title X-funded providers existed in more than 2000 counties, with approximately 650 Title X sites in counties where there was no other access to such safety-net health care. Guttmacher Cmt. 264428, 264439-40. Patients using Title X-funded sites counted

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on them and their clinicians for continuing care. The West Virginia Department of Health Comments illustrated this important consideration of patient reliance:

> The [2000] rule allows for clear separation of Title X services from non-Title X services. This rule is greatly respected and regarded in the highest capacity but requiring full physical separation would hinder access for clients, many of which have the most need. Both facilities in WV [that would be subject to physical separation from abortion care under the Rule] are in high need impoverished areas. One site is in a rural location and is able to offer expanded hours of operation for family planning services, an invaluable service for clients whose schedule [requires that]. The other site is located in the most populous area in WV and provides extended hours of operation that service sites in close proximity cannot match. This urban site takes on a Title X client load, on average, 3 times the size of nearby sites. In order to maintain access and prevent barriers to essential family planning services, these facilities need to be able to continue their mission to help women and men plan the timing and spacing of their families.

WVDH Cmt 280811; *see also* AM Cmt 256449 (among 22 subrecipients, the three agencies with co-located abortion services provided 61% of grantee's Title X contraception services in 2017); MSAHC Cmt 106750-51 (describing negative impact on patients from disruption to physical locations, email addresses, shared outreach efforts, and the Mount Sinai integrated electronic health records system); PPFA Cmt 316477-78. In the face of a nationwide network of effective Title X sites, built in compliance with longstanding Title X regulations, and the patients who have relied on trusted Title X locations and clinicians, HHS has not rationally explained why the physical separation and infrastructure changes should upend this elaborate structure. *See, e.g.*, NFPRHA Cmt 308024-29; WAAG Cmt 278573-76; NYAG Cmt 269299-300; NCSD Cmt 106828; NIRH Cmt 106463-64; CCHHS Cmt 305263.

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Contrary to HHS's litigation assertion, DOJ Br. at 37, its rulemaking *never* "discussed and considered the reliance interests" of existing Title X grantees, other providers, or patients. For this reason alone, among the many others demonstrated here, HHS's adoption of the Physical Separation Requirement and Infrastructure Limits was insufficiently reasoned and arbitrary. *Encino Motorcars*, 136 S. Ct. at 2125-27.

c. HHS Compounds, Rather Than Refutes, Its Earlier Findings of an Unworkable, Arbitrary Regulatory Approach

Likewise, HHS did not address and attempt to explain its abandonment of the factual findings that underlay the 2000 rulemaking, again acting arbitrarily and contrary to the essential requirements for reasoned agency action. *Id*.; *see also FCC v. Fox Television*, 556 U.S. at 515-16. Instead, it modeled the Physical Separation Requirement on a 1988 provision that had never been implemented across the network and the contours of which had never been determined. 65 FR at 41276. HHS in 2000 found that approach uncertain, without a "fundamental measure of compliance," and lacking in notice to grantees. *Id*. HHS concluded in 2000 that attempting to impose a "physical separation" standard is "not likely ever to result in an enforceable compliance policy" consistent with Title X's aims. *Id*. HHS now ignores all of the 2000 findings, and tries to revert to 1988 without rationally explaining rejection of its more recent 2000 analysis.

In addition, the new details HHS has added in 2019 to the 1988 idea have only exacerbated its lack of clarity, subjectivity, and interference with "the efficient and cost-effective delivery of family planning services," 65 FR at 41276.

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Title X projects now must be concerned with separation of back-office support systems, such as electronic health record systems, as a matter of "physical separation" (and under the new Infrastructure Limits). Sections 59.15 & 59.18; 84 FR at 7774; *cf*. 53 FR 2938-41, 2945. Separation factors have been extended beyond treatment areas to "office entrances and exits," though that was rejected as too onerous in 1988. *Id*. The Secretary of HHS will be the lone arbiter of compliance, addressing each entity (and each one of their locations) away from public view, with no discernible, objective benchmark by which all providers can know the "physical separation" requirements and whether they are being treated equally (or more restrictively) than others. Section 59.15.

HHS "encourages grantees to contact the program office" to discuss possible ways to accomplish physical separation, 84 FR at 7766, thereby triggering an elaborate back-and-forth process for grantees and their subrecipients to even begin to attempt to comply. Likewise, for the newly required differentiation among improper infrastructure spending, "direct implementation," and "direct services" under Section 59.18, this rulemaking provides no objective guideposts for grantees and subrecipients. Such new labels are especially confusing because all Title X activities "directly implement" grantees' HHS-approved projects and accomplish "direct services." These ambiguous parts of the Rule necessarily divert attention and resources from family planning and are inconsistent with "the efficient and cost-effective delivery of family planning services," as foreshadowed in 2000. 65 FR at 41276. Yet HHS avoids these implementation issues. As discussed below,

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this is only the start of HHS's inadequate and unreasoned assessment of these new regulations' disadvantages.

2. *Failure to Rationally Consider the High and Widespread Costs*

a. HHS Pulled the Initial Expense of Physical Separation Out of Thin Air

To finalize this Rule, HHS baldly asserted that only "an average of between $20,000 and $40,000, with a central estimate of $30,000 would be incurred" per site—counting only 15% of sites—to accomplish the "physical separation" changes needed. 84 FR at 7781-82. HHS provided *no* substantiation for its dollar figures, nor did it explain what actions, materials, or any other items it was purportedly estimating. HHS said only that it slightly increased the estimate of between $10,000 and $30,000 given with the proposed rule. *Id*. At both the proposed and final stages, however, HHS apparently pulled those financial cost numbers to achieve physical separation out of thin air.

This is the antithesis of reasoned decision-making. That is particularly so because comments to the agency and HHS's own records detailing many years of Title X project costs—which HHS did *not* consult for this rulemaking, as the administrative record reveals—indicated exponentially higher financial costs to accomplish the physical, staff, and systems separation imposed by Section 59.15.

It is apparent that hiring and paying even one new front desk staff member and a single clinician to staff newly separate facilities would quickly cost multiples of $30,000, *see* CRR Cmt 315994, before even counting additional costs for obtaining the physical space, configuring it, furnishing it, and setting up electronic systems—yet all of those components are part of "physical separation" under the

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Rule. Many commenters, including those with experience in setting up and equipping Title X and other health care facilities, emphasized to HHS that its numbers were drastically too low. *See, e.g.*, FPCI Cmt 279362 ("it typically costs hundreds of thousands, or even millions, of dollars to locate and open any health care facilities (and would also cost much more than $10,000-30,000 to establish even an extremely simple and limited office), staff it, purchase separate workstations, set up record-keeping systems, etc."); FPAM Cmt 239562; PPFA Cmt 316485-87; Drexel Cmt 293840; NFPRHA Cmt 308046-47.

Commenters provided specific evidence to substantiate the inadequacy of HHS's random number. *See, e.g.*, CRR Cmt 315994 n.144 (cost of EHR system alone over $160,000 for small practice); FPCI Cmt 279362 (Title X subrecipient's additional physical site cost $85,000 in March 2018); FPAM Cmt 239562 (explaining $300,000-$450,000 in facilities cost for relocating an abortion-providing site); PPFA Cmt. 316485-87 (describing health center construction or renovation costs in detail); Brown Cmt 245854-56 (same). And many called on HHS to undertake an actual assessment of the cost components of "physical separation" under Section 59.15. *See, e.g.*, FAPP Cmt 305102, 305108-09 (urging HHS to "calculate the inclusive costs," including by consulting with "medical practitioners, Title X providers and health economists"); ACP Cmt 281208 (ACP "calls on HHS to analyze the financial, time, and quality of care impacts" of physical separation); EAH Cmt 245494; JIWH Cmt 239149; IPI Cmt 308569-70;

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LV Cmt 310404. But HHS failed to do so.[12] It simply finalized the Rule based on its bare assertion about a critical cost number that was irrational and contrary to the record evidence. This alone requires the Physical Separation Requirement to be vacated and set aside.

b. HHS Totally Omits Other Financial Costs and the Majority of Sites

In addition to arbitrarily picking a far-too-low cost for Title X providers' initial physical separation from abortion care, HHS erroneously downplayed financial cost by: (i) considering the cost of separation for only 15% of providers, 84 FR at 7781, when all Title X providers at the time of the Rule's implementation had activities, materials, and systems subject to the physical separation requirements; (ii) ignoring the ongoing costs of duplicate locations, staff, and systems after initial separation; and (iii) offering no estimate at all for the costs to providers of Title X's new limitations on infrastructure spending, which now hamper projects' ability to function and to do so cost-effectively. All of these costs were brought to the attention of HHS during the comment period, yet it completely ignored them in finalizing the Rule. *See*, *e.g.*, NFPRHA Cmt 308046-47; PPFA Cmt 316428-44; NCSD Cmt 106827; ASTHO Cmt 199040.

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[12] HHS's nebulous rulemaking statements, such as "entities will usually choose the lowest cost method to come into compliance," 84 FR at 7781, are meaningless, because HHS has not provided any calculation of, explanation of, or basis for actually estimating the "lowest cost method" for complying with Section 59.15.

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HHS wrote Section 59.15 to require what it terms "physical separation" from all "activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 of these regulations[.]" Sections 59.14 and 59.16 address counseling, advocacy, and other activities that might support patient access to abortion, but that do not involve direct abortion care. Though HHS has explicitly imposed this broad physical separation mandate, it has irrationally calculated financial costs as if Title X providers need to separate only from abortion care, and not from all the other (and more common) abortion-related activities like referral, education, or other patient support that are included within Section 59.15. *See* 84 FR at 7781 (discussing only physical separation by abortion providers and asserting that only 20% of Title X providers will need to even consider whether they are in compliance with Section 59.15). *Each* Title X provider will have to evaluate their structures, staff, resources, and administrative systems under Section 59.15 and then physically separate from, for example, abortion referral (including by, e.g., gynecological specialists or primary care practitioners working under the same roof); EHR systems that overlap with abortion-related activities; electronic or hard copy libraries that contain "material referencing" abortion; etc., to remain in the Title X network. Yet HHS considered none of these compliance costs.

Similarly, the Rule in Section 59.18 introduces new restrictions on the "use of Title X funds for infrastructure purposes," apparently mandating that "Title X projects would not share any infrastructure with abortion-related activities." 84 FR at 7774. HHS itself explained, however, that federal funds cannot support 100% of a Title X project's costs and that this new limit on infrastructure spending would

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diminish the flexibility projects have previously had to use Title X funds for the critical building blocks that keep them operating—such as utilities, staff training, office systems, bulk purchasing, and outreach activities. 84 FR at 7773-74. Yet HHS attributed no cost at all to foregoing these previously-approved types of Title X expenditures, and failed to consider how much these new Infrastructure Limits would negatively impact the existence and functioning of Title X sites.

c. HHS Again Irrationally Ignores Provider Exits and Program Disruption

After vastly underestimating the financial costs that the Rule's Physical Separation Requirement and Infrastructure Limits impose, the rulemaking then refused to acknowledge that such major costs will push providers from the Title X network and discourage other providers from joining it. But comments repeatedly called attention to this byproduct of Sections 59.15's and 59.18's unreasonable costs, unnecessary duplication, and irrational limits on modern, effective means of providing health care: the Rule makes "it financially impractical, if not impossible, to continue" participation in Title X. PPFA Cmt 316432; *see also* AMA Cmt 369333 (these provisions "appear[] designed to make it extremely difficult, if not impossible, for specialized reproductive health providers" to continue in Title X); FAPP Cmt 305102 ("Title X sites … are already underfunded and financially struggling"; these requirements will in some cases "force Title X site closures altogether and, in others, would cause a decrease or dilution in the provision of quality family planning services"); Drexel Cmt 293840 (physical separation and infrastructure costs "will be more than many Title X projects can bear … and will undoubtedly lead to providers leaving Title X for economic

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reasons alone"); MOFHC Cmt 268688; Johns Hopkins Cmt 285354. HHS itself conceded that these aspects of the Rule may change providers' decisions about participating in Title X or "the viability of their applications," 84 FR at 7782, but declined to factor into its decision-making any Title X network disruption.

Contrary to the record evidence, HHS refused to "anticipate future turnover" in providers because any "calculations would be purely speculative[.]" 84 FR at 7782. This is yet another arbitrary aspect of the rulemaking. An agency cannot point to uncertainty as a sufficient reason to ignore a serious impact that evidence in the record and logical inference indicate will occur. *See Ctr. for Biological Diversity v. Zinke*, 900 F.2d 1053, 1072 (9th Cir. 2018) (agency cannot disclaim the need for projection by declaring effects "too speculative"); *State Farm*, 463 U.S. at 52 ("substantial uncertainty" not a sufficient justification; agency must explain available evidence and rationally rest choices on facts found). By significantly raising the cost of providing Title X care, forbidding important infrastructure expenditures, and requiring unnecessary duplication, HHS is obviously creating obstacles to providers remaining in the program. Any rational rulemaking would take those serious disincentives and their harmful impact on Title X's operation into account, even if the ultimate magnitude is uncertain.

d. HHS Irrationally Counts the Impact on Current Patients as "Zero"

HHS also engaged in the same wishful thinking seen elsewhere in the rulemaking to proffer that, while providers "may relocate" some facilities because of "physical separation," there would be no overall decrease in the number of facilities and a "net impact" of "zero" on patients seeking services; HHS asserted,

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moreover, that new grantees were "likely" to expand coverage for patients. 84 FR at 7782. These unfounded assertions ignore readily apparent harms to patients.

For example, HHS considers only travel time to moved facilities as a potential impact on patients, reasoning without any factual support that for those needing Title X services, any change in location of Title X sites will be a wash. 84 FR at 7782 ("some seeking services will have shorter travel times and others … will have longer travel times," resulting in the "net impact on those seeking services" of zero). The record, however, contained no basis for assuming that providers would move facilities instead of pulling them from Title X completely; and if there were moves, HHS had no basis to guess that the distance of provider moves would somehow equal out for affected Title X patient populations. Moreover, if an existing Title X facility moves, patients may encounter difficulty finding that new facility and may not be able to travel to it at all. Staff changes, in light of the "physical separation" factors and limits on infrastructure spending, may also mean that a trusted clinician is no longer available to existing patients. As discussed above, the record indicates that patients will suffer from providers and sites disappearing, not merely from moves. Again, HHS sweeps aside these negative impacts and considers "no cost" to patients in promulgating the physical separation and infrastructure provisions. 84 FR at 7718, 7766, 7777, 7782.

HHS claims, without foundation in the record, that if these new restrictions drive grantees and subrecipients from Title X, HHS "will be in a position to" operate this national program with "entities that will comply." 84 FR at 7766. Even if that were a rational conclusion consistent with the record (which it is not),

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such change in grantees and subrecipients would impose significant cost on the Title X patients who had come to rely on the previous providers, and would deprive all potential Title X patients of access points to the program in those communities during the many months (at minimum) it would take to accomplish any transition. *See* 2019 FOA at 1, 49-52, 67 (applications, competitive processes, risk screening, and final awards to new grantees take months to accomplish).

HHS arbitrarily did not consider any costs at all to patients from the provider and facility disruption and the diminished family planning resources that the new physical separation and infrastructure rules will cause. It is not an "extraordinary position," DOJ Br. at 39, but a matter of practical reality, to acknowledge that the federal government cannot operate its social service programs effectively without willing providers. *See Nat'l Lifelines*, 921 F.2d at 1111-15 (agency irrationality failed to consider providers' unwillingness to participate in program and relied on unsupported assertions of purported incentives to do so). And rational rulemaking must take into account not only the changes' impacts on providers, but what those impacts mean for the program's recipients and its larger public purpose. *Nat'l Lifelines*, 921 F.2d at 1111-14 (agency acted arbitrarily by ignoring reliance and the impacts on beneficiaries' access in light of provider unwillingness).

3. *Failure to Rationally Weigh Purported Benefits and Asserted Needs*

At the same time as HHS ignored many costs of its decision to impose the Physical Separation Requirement and Infrastructure Limits, it exaggerated the purported benefits of and need for such restrictions. Again, it impermissibly "put a thumb on the scale." *Ctr. for Biological Diversity*, 538 F.3d at 1198.

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First, the rulemaking misleads in claiming a "particularly acute concern" based on "recent evidence that abortions are increasingly performed" at nonspecialized clinics offering abortion that "could be recipients of Title X funds." 84 FR at 7765. HHS used percentages to paint a deceptive picture, but at the end of its discussion concedes that "the number of nonspecialized clinics performing abortions *remained stable*" from 2008 to 2014, the most recent years it considered. 84 FR at 7765 (emphasis added). Thus, HHS conceded there had been *no increase* in the potential co-location of abortion care with Title X care, HHS's asserted target for regulation here. *See also* AR406746. The total number of U.S. abortions, meanwhile, has been steadily declining for years. *Id*.

Second, the rulemaking similarly distorts in claiming that commenters' objections to the increased cost imposed by physical separation "only confirms the need" for it. 84 FR at 7766. Physical separation as described in the Rule requires *duplicate* locations, staff, equipment, and systems that Title X providers would otherwise not need, and that is the Rule's driver of their huge "increase[d] cost of doing business." *Id*. Moreover, even if a Title X provider experienced "economies of scale" in its initial location, by occupying that location alongside abortion or other health care provision, such economies do *not* mean that Title X funds are paying for non-Title X care. Title X grants, which by regulation cover less than the amount necessary to support even the entirety of the Title X project, have always been reserved for Title X expenses, whether those are cost-effectively reduced by economies of scale or not. "None of the funds appropriated" for Title X are "used in programs where abortion is a method of family planning," 42

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U.S.C. § 300a-6, when a Title X project uses federal funds to pay *its own* expenses. *Cf.* DOJ Br. at 37. Contrary to HHS's depiction, economies of scale do not mean "comingling of funds." 84 FR at 7766.

Third, HHS asserted a need for the physical separation and infrastructure regulations based on "a risk of intentional or unintentional misuse of Title X funds" and a "risk for public confusion over the scope of Title X services." 84 FR at 7715, 7765. HHS, however, offers no evidence that any misuse of Title X funds to pay for abortion or confusion about the limits of Title X has manifested over the almost two decades of operation under the 2000 regulations, such that major new interventions were warranted. This long, stable history undermines the rationality of HHS's asserted need for any new rule. *See also* WA SJ Br. Part B(4).

Similarly, HHS claimed as a benefit of the new physical separation and infrastructure provisions that it "expect[ed] the quality of Title X services to improve as Title X funds are focused and prioritized." 84 FR at 7718. But HHS did not explain any aspect of Title X services where quality would improve, or where quality had suffered in the past, or how any such improvement would occur.[13] Instead, the rulemaking's own descriptions made clear that investments in

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[13] HHS also asserted that its imposition of Section 59.18 relied on the fact that "the number of Americans at or below the poverty line has increased," 84 FR 7774, when federal determinations show that 2018 instead saw the fourth consecutive annual *decline* in that number. *See* U.S. Census Bureau, *Income and Poverty in the U.S.: 2018*, https://www.census.gov/library/publications/2019/demo/p60-266.html.

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Title X infrastructure, such as its outreach programs, and in cost-effective purchases, such as bulk contraceptives, had been important to its success, but those would apparently be scaled back under Section 59.18 of the Rule. 84 FR at 7773-74. And reproductive health-focused providers have served the most patients within Title X historically, with comprehensive and up-to-date programs, *see supra* at 3, 39, yet the physical separation requirements would either push such providers out of Title X or impose exorbitant new costs on their providing Title X family planning services. Thus, HHS claimed this "quality improvement" benefit, but the provisions of the Rule, the administrative record, and HHS's own rulemaking discussions do not plausibly indicate that any quality improvement will be achieved—the opposite will occur. *See* FPCI Cmt 279356-57; Guttmacher Cmt 264423-34; NACCHO Cmt 294044-46; VTDOH Cmt 198208; Prine Cmt 5457.

* * *

HHS repeatedly expressed that it seeks to bring about "enhanced implementation" of and compliance with Section 1008 by adding the physical separation and infrastructure provisions here, though neither of those matters is addressed or otherwise required by the text of Section 1008. *See*, *e.g.*, 84 FR at 7715, 7764. HHS sought to advance what it calls a "better interpretation." 84 FR at 7723. Even if HHS's interpretation of that one section is a "permissible" one, however, 84 FR at 7764, the agency must still engage in reasoned decision-making to determine whether its interpretation and these changes make sense for the Title X program overall, given the record facts; they do not. Simply stating that HHS

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prefers this implementation of Section 1008 does not answer Plaintiffs' arbitrary and capricious claims nor justify HHS's rulemaking. *Cf.* DOJ Br. at 37.

Instead, what this record shows is HHS's failure to see the forest for the trees. With its sights fixated on Section 1008 and on greatly expanding that compliance provision to address risks that had not materialized, HHS adopted physical separation and infrastructure rules that harm Title X's effectiveness, sap precious family planning funds, and magnify "enforcement" to ravage this public health program. Again, at every turn, HHS's failed to engage in reasoned decision-making and these provisions must be set aside. 5 U.S.C. § 706(2)(A).

D. The Rulemaking in Other Ways Arbitrarily Interferes with an Effective Title X Network for Quality Family Planning Care

Sections 59.5 and 59.7, along with the Definitions in Section 59.2 and other intertwined pieces of the Rule, contain other harmful changes resulting from HHS's arbitrary rulemaking. These changes alter the Title X program to the detriment of patients based on irrational purported reasoning and HHS's deflecting of commenters' well-founded objections.

1. *Section 59.5(a)(12) Irrationality Reduces Isolated Title X Sites*

First, the Rule blocks Title X providers without primary care on site or nearby, and thereby hampers Title X in order to try to expand a type of health care that falls beyond this program. Section 59.5 defines the programmatic "requirements" for Title X family planning projects. The 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

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> providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

42 C.F.R. § 59.5(a); 84 FR at 7787-88 (new subsection (a)(12)).

Commenters alerted HHS that this 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. E.g., Guttmacher Cmt 264426-29; PPFA Cmt 316468-70; ACP Cmt 281210-11; *see also* CAAG Cmt 245699. Moreover, commenters 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." *Id*. Title X providers *already* had long worked to establish referral relationships with primary care providers for their patients and made such referrals as patients needed. *See*, e.g., 65 FR at 41279 (2000 §§ 59.5(b)(1) & (8)). Thus, this new subsection merely confuses and creates a barrier to Title X family planning clinics in the very areas 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 provision would interfere with health departments maintaining or opening Title X sites. ASTHO Cmt 199037. ASTHO emphasized that "most state and local health agencies do not provide direct primary care," and that HHS failed to define "close physical proximity" or "robust referral linkages." *Id*.

The West Virginia Department of Health 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

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comprehensive services." WVDH Cmt 280808; *see also* PPFA Cmt 316415 ("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 Cmt 280808; *see also* ACOG Cmt 268848; TWHC Cmt 306447. HHS failed to acknowledge these concerns, to create an exception, or even to attempt to clarify.

Instead, HHS simply asserted that onsite or close linkages to primary care should take precedence, 84 FR at 7749-50, regardless of the negative impact on the reach of Title X care into underserved communities. But that reasoning impermissibly prioritizes expanding primary care—which is not Title X care—over access to 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 not considering 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 rationally explain their rejection).

Moreover, this provision asking Title X providers to offer primary care on site is inconsistent with the Rule's mandates that Title X providers physically separate from and not share any infrastructure with abortion-related activities. Primary care providers, like family planning providers, often have patients who are pregnant and seek pregnancy counseling from them. *See* QFP at 3. Primary care providers, following clinical standards, offer information about pregnancy options,

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including abortion, and referral to abortion upon request as a regular part of their routine care. QFP at 13-14. So while Section 59.5(a)(12) tries to pull primary care and Title X care together in the same sites, Sections 59.15 and 59.18 tell Title X providers not to engage in such co-location. Similarly, HHS contends with regard to Section 59.5(a)(12) that Title X projects do not "subsidize" primary care if the two are co-located, whereas the agency reasons (erroneously) that a Title X project subsidizes a co-located provider of abortion care. *Compare* 84 FR at 7750 *with* 84 FR at 7766. These unexplained inconsistencies further underscore the arbitrary nature of all of these aspects of HHS's rulemaking. *Kake*, 795 F.3d at 966.

2. *The Rule Irrationally Reduces Patient Access to Contraception Options*

Congress sought with Title X to open access to "a broad range" of family planning methods for low-income patients throughout the country, so that they could afford modern medical advances and have truly free choice in making contraceptive decisions. 42 U.S.C. § 300; *see also* S. Rep. No. 91-1004 at 9-10; H.R. Rep. No. 91-1472 at 6. 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 FR at 25,526; 84 FR at 7743; (ii) has removed the phrase "medically approved" from Section

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59.5(a)(1), after HHS's history of 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 at service sites, "as long as the entire project offers a broad range of methods and services." Section 59.5(a)(1). *Cf.* ACOG Cmt 268843-46 (opposing these changes, stressing lack of safeguards for all patients' access to the contraceptive choice that will work best for them); AMA Cmt 269332-33 (changes will "undermine the quality and standard of care upon which millions of women depend"); APHA Cmt 239897; Guttmacher Cmt 264429; Dehlendorf Cmt 251841-42 (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 can 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, under the Rule such sites do 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—do not have to ensure that patients have ready access to full-service Title X sources of care. *See* ACLU Cmt 305735; 84 FR at 7741 ("patients [will] struggle to find providers that offer desired services"); *cf.* Pub. L.

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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 to commenters raising these important considerations, 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 FR 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 at 1072-73, 1075 (agency acted arbitrarily by failing to consider "additive" and "synergistic" effects). HHS cited the asserted benefit of allowing patients access to "specialized expertise in certain methods" and patients' greater likelihood of "visit[ing] clinics that respect their views and beliefs," but both those interests were already served by the status quo of the 2000 regulations and the QFP standards of care. 84 FR at 7743.

The record establishes that the new providers sought by HHS and its changes to Section 59.5(a)(1) would combine to limit, rather than expand, choice for Title X patients, contrary to HHS's bare assertions. These changes "protect the ability of health care providers" with objections to severely circumscribe the range of contraceptive care they offer with Title X funds, 84 FR 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; LCCHR Cmt 306347-48; BWW Cmt 248194-96; NHCHC Cmt 308420-21. HHS got to this extraordinary result through arbitrary, unfounded rulemaking.

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3. *HHS Arbitrarily Changed Its Title X Grant-Making Process*

As with so many other aspects of this rulemaking, HHS also jumbled its prior Title X grant-making criteria and imposed a sweeping, subjective new eligibility hurdle for grant applications without rationally considering the costs and with exaggerated assertions of benefit. The new application hurdle, moreover, is inconsistent with the eligibility threshold set in the Title X statute and with HHS's own general standards for grant-making. HHS deflected commenters' objections without reasoned explanation and impermissibly finalized Section 59.7, the altered grant-making section.

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 expert outside reviewers. *See* 45 C.F.R. § 75.200-18, App. I; HHS, *Grants Policy Statement*, https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/hhsgps107.pdf. 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"). If a grant program uses other eligibility (or "go-no-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 FR at 7755: "The intent is to make the application process

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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 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. It ignores Title X's requirement that "[l]ocal and regional entities shall be assured the right to apply for direct grants … and the Secretary shall by regulation fully provide for and protect that right." 42 U.S.C. § 300(a). The Rule instead imposes a new, all-encompassing eligibility determination to be made by the HHS Secretary before an application can be considered. This new Section 59.7(b) piles vagueness upon vagueness by asking applicants to "clearly address" 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 (separate "integrity and independence"), and 59.18 (unclear infrastructure and "direct implementation" restrictions). And then the Rule empowers the Secretary to subjectively decide if an application is not "clear" or "affirmative" enough in its statements about any part and, if so, to reject consideration of its family planning proposal out of hand. That occurs without regard to the statutory criteria for grant-making in Section 59.7(c), the application's programmatic merits, its proposed project area's needs, or whether there is any competing application to serve that area.

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Such a subjective, all-encompassing threshold requirement pushes applicants to interpret each of the new Rule's components, including Section 59.16 and the physical separation and infrastructure provisions, for example, at their most extreme and to constrain possible projects accordingly, because if they do not, they risk rejection before any merits consideration at all. It also creates a burdensome new requirement of elaborate description and documentation of future plans for compliance before any application review, *see* 84 FR at 7754-55, when the regulations themselves already require that *all* Title X projects, if selected and funded, must comply with all Title X rules once those projects go forward.

HHS's rulemaking failed to acknowledge the inconsistency of Section 59.7(b) with Title X and with the agency's general system for grant-making. Likewise, HHS failed to acknowledge the significant pre-project costs and unpredictability for applicants that this new step generates, as well as the costs for the Title X program in the applications it may discourage. *See, e.g.*, FPCA Cmt 385034-35 (objecting to expanded "power to prevent applications from even reaching the objective review process" and the possibility it introduces for hidden, subjective, more political considerations); FPAM Cmt 239559-60 (Section 59.7(b) has no transparency and "pre-empts the review and assessment process employed by objective review committees"); CRR Cmt 315989 (Section 59.7(b) imposes "an inappropriately subjective compliance check prior to advancing applications to the objective review stage, and establishes a scheme that could be subject to abuse"); NFPRHA Cmt 308041 (this provision works against wide competition, "evades objective review, [and] makes fair and transparent competition impossible"); PPFA

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Cmt 316449-55 (discussing lack of clarity and considerable regulatory burden imposed, without reasoned justification and contrary to statute); MADPH Cmt 91193 (this new "disqualification criteria" may "eliminate[e] applications" with "significant strengths and thereby weaken[] the Title X provider network").

Commenters raised these significant objections, but HHS attempted to sweep all concerns aside with conclusory assertions of benefit. Its rulemaking assertions, however, do not rationally explain why this pre-application discussion of plans will purportedly ensure compliance and "prevent misuse of funds" beyond that accomplished by the regulations themselves. 84 FR at 7754. Nor do they rationally explain how this significant *added step* for HHS would "increase the efficiency" or diminish the Department resources necessary for selecting grantees, especially since competitive review panels will have to be impaneled in any event. 84 FR at 7755.

In addition, Section 59.7(c) then mashes together what were formerly seven distinct grant-making factors and creates fewer, jumbled grant-making criteria that include internal inconsistencies and new, arbitrary considerations. HHS failed to offer a reasoned explanation for these altered terms' asserted benefits, and instead made only implausible conclusory statements to attempt to justify them.

For example, one part of Section 59.7(c)(2) apparently means that grant applicants that plan to use subrecipients will be scored on an "ability to procure a broad range of diverse subrecipients," including "those who are nontraditional," 84 FR at 7754, but grantees that will directly serve patients will not need any analogous diversity, leaving unclear how competition between the two types of

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applicants could occur in an objective and fair way. Moreover, HHS did not rationally connect seeking a broad diversity of subrecipients for one type of grantee with its claimed benefit of expanded overall Title X patient coverage; the record facts instead make it highly *unlikely* that encouraging an altered mix of subrecipients for some grantees will achieve expanded coverage. *Cf.* 84 FR at 7756. Under the previous criteria, HHS for almost five decades has already sought any grantees and subrecipients throughout the country that can effectively use Title X funds to meet local needs, serve low-income patients, and leverage other resources in their communities for maximum impact. *See* 42 U.S.C. § 300(b); 65 FR 41280 (2000 § 59.7(a)). In fact, it has been the most common type of provider that has served the most patients and expanded the Title X network into isolated areas not serve by any other safety-net resources. *See supra* at 25, 39-40, 55-56.[14]

Similarly, HHS's mere mixing up of Title X's historical criteria with the addition of the word "innovative" and a reference to "more sparsely populated areas" in Sections 59.7(c)(3) & (4) does not indicate that any new providers are available, are interested in participating in Title X, and will emerge to actually expand overall coverage under the Rule. HHS has consistently encouraged innovation, and existing grantees or new applicants have always been free to

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[14] HHS provides no record support for its bald contention that the criteria that governed the program for almost five decades skewed the grant-making process for Title X projects "in favor of heavily populated areas." 84 FR at 7723.

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explore new avenues and service areas.[15] And for all the reasons discussed elsewhere in this brief, the Rule as a whole makes keeping even the same number and reach of providers, particularly those with the capacity to serve large numbers of patients and geographic areas, much more difficult. *See supra*; *see also Stewart v. Azar*, 366 F. Supp. 3d 125, 142 (D.D.C. 2019) (rejecting generalities, without reasoned basis or evidence, as to incentives for increased health care).

Section 59.7(c)'s fewer, jumbled, and more complex grant-making criteria mean that, overall, they are less clear, less distinct, and less amenable to comparative scoring by merits review panels, reducing the role of their expertise and the process's supposed objectivity. *See, e.g.*, NFPRHA Cmt 308038-40; ACLU Cmt 305731; CRR Cmt 315987-88; PPFA Cmt 316451-55. Yet HHS irrationally made the unreasoned, unsupported assertion that these criteria will "increase competition and rigor" and better "ensure the selection of quality applicants." 84 FR at 7718.

4. *The Rule's Definitions Draw Other Unreasoned Distinctions*

HHS also acted arbitrarily in altering other, key Section 59.2 definitions, bending them beyond rationality to the detriment of equal access to Title X for those who most need its services.

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[15] *See, e.g.*, 2019 FOA at 4 (seeking applicants with "innovative strategies" to increase clients served or improve the quality or breadth of services); 2018 FOA, https://www.hhs.gov/opa/sites/default/files/FY18-Title-X-Services-FOA-Final-Signed.pdf at 4 (same); *see also* 42 U.S.C. § 300(b); 65 FR at 41280 (2000 § 59.7).

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a. The Rule's Unequal Treatment Harms Minors Who Seek Free Services

The Rule subjects minors who seek to access Title X's confidential services for free, based on their own income qualifications, to an unequal, too-stringent requirement of encouraging family participation in the minor's family planning care, while the Rule applies a different standard to minors who can afford to self-pay or otherwise access Title X services. It does so without any proffered justification for that differential treatment.

Title X explicitly requires that its services be provided to adolescents. 42 U.S.C. § 300(a). This access has long been protected by the Title X definition of "low income family," which in part requires that all "unemancipated minors who wish to receive services on a confidential basis must be considered [for "low income" free services] on the basis of their own resources" as individuals and not based on their family's resources. Section 59.2. Now, however, the Rule tells Title X projects that for minors seeking to qualify for free or reduced-fee care based on their own income, the provider must encourage involvement of the minor's parents or guardian, regardless of the specifics of the minor's family circumstances, the minor's best interests, and what is practicable. The only exception is if the provider suspects "child abuse or incest," has already "reported the situation to relevant" state or local authorities, and documents that reporting in the medical record. Section 59.2 (part 1 of "low income family").

The Rule, by contrast, sets a less exacting requirement for encouraging family involvement if the minor is *not* seeking free or subsidized services based upon their own income level. In that circumstance, Section 59.5(a)(14) gives

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providers the option of documenting *any* "specific reason why … family participation was not encouraged," and allows a broader factual context and the clinician's professional judgment to operate. 84 FR at 7788. As commenters to HHS explained, this better accommodates other circumstances that may make pushing a minor to involve parents or other family members dangerous or otherwise harmful for the minor patient. *See, e.g.*, CHN Cmt 294155-56 (noting risk to some minors of being evicted from home or suffering newly-initiated violence *if* their sexual health care disclosed to family members); NFPRHA Cmt 308031-32. Yet the much larger group of minors who seek free services based on their own income qualification must be encouraged to involve their family except in the very narrow circumstances of already-reported child abuse or incest. The Rule's different requirements based on minors' ability to pay has no plausible basis and is contrary to Title X's explicit focus on low-income patients and adolescents.

b. The Rule Offsets Income When an Employer Invokes Conscience

The Rule's definition of "low income family" also introduces a second arbitrary, unexplained, and unjustified distinction. TNDOH Cmt 102527. "For … payment for contraceptive services only," that definition describes in part (2) a special process for assessing income eligibility for women who have "health insurance through an employer that does not provide the contraceptive services sought by the woman because the employer has a" religious or moral objection to that coverage. 84 Fed. Reg. at 7787. For those women, part (2) allows Title X projects to "consider her annual income as being reduced by the total annual out-

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of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs, or estimate them at $600." *Id.*

In all other instances, however, a Title X patient's actual annual income is considered in assessing whether the patient is eligible for free or reduced cost care. The Rule does not adjust other patients' incomes, for purposes of comparing those against federal poverty levels, by the annual cost of family planning services they "use[] or seek[] to use." Id. at 7737, 7787. The Rule's unique offset for Title X contraceptive patients whose employers have a religious objection to providing insurance coverage for contraceptives was not set out in the proposed rule, is unexplained and unjustified, and is yet another arbitrary part of this rulemaking. It stems from HHS's desire to allow exemptions from the contraceptive coverage obligations under the ACA. *See* AM Cmt 256452-53; ACOG Cmt 268849-50; NWLC Cmt 280768. This highlights the degree to which HHS promulgated the Rule to serve conscience objectors, even beyond the confines of the Title X program, rather than to aid the efficient, effective functioning of this program.[16]

E. The Rule as a Whole Results from Arbitrary Balancing and Undermines Title X's Fundamental Purpose

HHS's rulemaking power does not extend to decisions that interfere with a public program's fundamental purpose. Courts cannot "rubber stamp … administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Bureau of Alcohol,*

[16] The NFPRHA Plaintiffs also incorporate by reference Washington's arguments as to parts of the Rule that are not a logical outgrowth of HHS's proposed rule.

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Tobacco & Firearms v. Fed. Labor Relations Auth., 464 U.S. 89, 97-98 (1983) (*ATF*); *Bresgal v. Brock*, 843 F.2d 1163, 1168 (9th Cir. 1987). An administrative interpretation 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). The Court of Appeals emphasized in *Center for Biological Diversity v. NTSB* that, while federal agencies are often empowered to balance relevant factors, they cannot do so to "undermine the fundamental purpose" of the statutory scheme under which the agency is acting. 538 F.3d at 1195; *see also id*. at 1197.

As established above, HHS at every turn in this rulemaking ignored its provisions' negative impact on patients seeking family planning care, the entities that have provided that care, and the functioning of the Title X program overall. In addition, HHS also used the Rule to add layers upon layers of compliance requirements where no lack of compliance had been shown, further burdening Title X projects with administrative tasks and regulatory steps that siphon off resources from their family planning purpose. *E.g.*, NIRH Cmt 10644-65; ACP Cmt 281204.

The Rule veered in this counterproductive direction not only with its major components, but also with sections like 59.5(a)(13), 59.17, and 59.18(c). For example, grantees have always been required to disclose their subrecipients and all service sites to HHS, as shown by the directories that HHS frequently publishes, *see* AM Cmt 256452; *supra* at 34 n.10; likewise, grantees have always been responsible for the oversight of their subrecipients to ensure that they properly carry out Title X services and requirements, ECF No. 19-1 (Program Requirements) at 11-12. With the Rule, however, Section 59.5(a)(13) now

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requires elaborate information gathering and submission not only in grant applications but also in every single required report (which occur at least quarterly) to HHS, which must provide the specifics of all subrecipients' *and* out-of-project referral providers' "expertise and services provided," "[d]etailed descriptions of the extent of collaboration with subrecipients, referral agencies, [and other referral providers] … in order to demonstrate a seamless continuum of care" beyond Title X services, etc. Though numerous commenters alerted HHS that these new reporting and information gathering requirements would impose high unnecessary costs and discourage wide referral networks, among other negative impacts, HHS adopted this section based only on bare assertions of "necessity," an asserted lack of any "inappropriate administrative burden," and other conclusory statements that were contrary to the record before it. HHS's rulemaking seemed oblivious to the fact that grantees typically operate through dozens if not hundreds of subrecipient sites and with vast networks of referral providers—referral resources that receive no compensation through Title X and do not have the means for periodically providing detailed information to Title X grantees. Essential Access Health (EAH), the largest Title X grantee prior to the Rule, emphasized to HHS that it operated through nearly 60 subrecipient health care organizations at more than 350 sites. EAH warned, as did others, of the "particularly onerous and burdensome requirements" under Section 59.5(a)(13) that create a disincentive for large subrecipient and referral networks and represent harmful overreach by HHS. EAH Cmt 245493-94.

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Likewise, all Title X health care providers are already bound by all state and local laws in their jurisdictions that require notification or reporting of child abuse, sexual violence, or human trafficking. Federal law already made explicit that Title X providers are not exempt from any such state or local reporting laws. Pub. L. 115-245, § 208, 132 Stat. 2981, 3090. Without any showing of need or assessment of its non-financial or financial costs, HHS in Section 59.17 of the Rule has now imposed a whole new layer of federal oversight regarding state and local obligations, by adding a vague "preliminary screening" of any minor seeking Title X services, expanding federal record-keeping requirements, and emphasizing the record review powers of HHS. The agency did so despite many commenters warning that these new forays into enforcing state or local law would interfere with Title X services and divert Title X family planning resources away from their purpose. *See*, *e.g.*, NFPRHA Cmt 308032-34; EAH Cmt 245490-91.

These subsidiary provisions are each indicative of the overall Rule's shift of OPA toward a law enforcement, compliance, and "enhanced transparency" office, policing Title X providers for hypothetical risks and enforcing new, immense compliance burdens under an altered legal framework for Title X that had *already* been transparent and been successful in using Title X funds properly. In this rulemaking, HHS arbitrarily took its focus off the public health mission that Congress charged OPA to implement: That is, running a unique, safety-net health care program, where appropriated funds should be used to support an effective national network of state-of-the-art family planning health care. HHS promulgated the Rule arbitrarily and contrary to the statue's purpose, rendering it unlawful in its

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entirety. *See Nat'l Lifelines*, 921 F.3d at 1114 (setting aside action that abandoned prior findings and upended reliance without reasoned explanation and failed to weigh key impacts on providers, low-income clients, and public program).

II. The Rule Is Contrary to Multiple Federal Laws

A. The Rule as a Whole Is Contrary to Title X; the Counseling Scheme Also Violates the Statutory Voluntariness Requirement

As just discussed, the Rule is contrary to Title X because it subverts this program's central purpose, wastes Title X's unique resources, and pulls apart national, quality family planning care rather than furthering it—to the detriment of individual and public health. Whether viewed as arbitrary, impermissible rulemaking or simply contrary to the statute, *see ATF*, 464 U.S. at 97-98, *Bresgal*, 843 F.3d at 1168, all of the ways in which this Rule fundamentally is at odds with Congress's public aims for Title X render it unlawful under 5 U.S.C. § 706(2)(A).

HHS is mistaken in its assertions that Section 1008 or *Rust* contradicts this claim. DOJ Br. at 32-33. No similar claim was litigated in *Rust*, and HHS's fixation on Section 1008 only shines a light on the essence of the problem: This Rule is so thoroughly caught up in attacking a non-existent compliance issue related to one section of Title X that HHS has sabotaged the larger statutory purpose, driven experienced providers from the program, and erected serious professional and financial obstacles to Title X's continued effective operation.

In addition, the new pregnancy counseling provisions violate Title X's explicit protection for patients' voluntary control over the services and information they might receive from this program. Section 1007 requires that "[t]he acceptance

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by any individual" of services or "information (including educational materials) provided through financial assistance under this subchapter … shall be voluntary." 42 U.S.C. § 300a-5. The Rule violates Section 1007 because it puts providers, not patients, in charge and compels all Title X projects to force pregnant patients to *in*voluntarily receive information, including the new mandatory prenatal referral. Section 59.14 (b); *see also* HHS Guidance, 84 FR at 7747.

Moreover, the new Section 59.18 limits the use of Title X funds in ways contrary to the Title X statute and the new Section 59.5(a)(12) endeavors to advance primary care, but that care is beyond the scope of Title X. The NFPRHA Plaintiffs also adopt Washington's arguments that the Rule violates Title X.

B. The Rule's Pregnancy Counseling Scheme Violates the Nondirective Mandate

The Rule is also contrary to law due to the myriad ways it violates the Nondirective Mandate. Every year from 1996 to the present, Congress has required that in Title X, "all pregnancy counseling shall be nondirective." Pub. L. 115-245, 132 Stat. 2981, 3070-71 (for fiscal year 2019). HHS concedes that "[n]ondirective counseling is designed to assist the patient in making a free and informed decision" about a pregnancy. 84 FR at 7747. Yet in the Rule, HHS departs from its own 2014 clinical standards for such pregnancy counseling and jettisons the 2000 regulations' proper implementation of that clinical concept.

Instead of ensuring that all pregnancy counseling in the Title X program is nondirective, the Rule: (1) mandates referrals for prenatal care, even if a patient has decided on an abortion; (2) requires the provision of information about

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continuing the pregnancy, even if a patient has decided on an abortion; (3) allows providers to withhold all information about abortion, regardless of the patient's questions or wishes; (4) allows providers to press information about adoption or preserving the health of the "unborn child" on patients, regardless of patient interest; and (5) bars referrals for abortion, even when explicitly requested by a patient. 84 FR at 7788-89. Each of these aspects of the Rule is contrary to the Nondirective Mandate, which forbids *any* directive aspect at all.

To avoid duplication, the NFPRHA Plaintiffs incorporate by reference the additional Washington arguments on violations of the Nondirective Mandate.

C. The Rule Violates Section 1554's Limits on HHS Rulemaking

The Rule is also not in accordance with law because it violates Section 1554 of the ACA. 42 U.S.C. § 18114. As described above, the Pregnancy Counseling Distortions prevent Title X clinicians from disclosing "all relevant information to patients making health care decisions" and "interfere[] with communications" about the "full range of treatment options," 42 U.S.C. § 18114(3)-(4). The Rule creates "unreasonable barriers" and "impedes timely access" (*id.* § 18114(1)-(2)) by, e.g., referring patients seeking an abortion referral to prenatal care instead and requiring separate space, personnel, and health care records from abortion-related activity. Sections 59.14-59.16. The Rule impedes timely access to contraceptive care by preventing it immediately following an abortion, *see*, *e.g.*, Prine Cmt 5457, and erecting its other new constraints on full family planning care. And the Rule's counseling provisions "violate the principles of informed consent and the ethical standards of health care professionals," id. § 18114(5). *See supra* at 9-72.

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To avoid duplication, the NFPRHA Plaintiffs incorporate by reference the additional Washington arguments on the Rule's violations of Section 1554.

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

The Court need not reach Plaintiffs' constitutional claims, because the statutory claims discussed above, including HHS's arbitrary and capricious rulemaking, alone necessitate vacatur of the Rule. *See Iturribarria v. INS*, 321 F.3d 889, 895 (9th Cir. 2003) ("We decline to decide cases on constitutional grounds when other grounds on which to base our decision are available.").

To the extent the Court examines the claims, the NFPRHA Plaintiffs also incorporate and adopt Washington's constitutional arguments.

IV. Vacatur Is the Correct Remedy

The APA requires courts to "hold unlawful and set aside" agency actions that are arbitrary and capricious, not in accordance with law, in excess of statutory authority, or adopted without proper procedure. 5 U.S.C. §§ 706(2)(A) -(D). HHS's 2019 rulemaking was shot through with arbitrariness, and oblivious to the serious costs and Title X program disruption it would impose. The resulting Rule, moreover, violates in multiple ways the statutory constraints under which HHS must operate Title X. The proper remedy is vacatur of the Rule in its entirety.

CONCLUSION

For all the foregoing reasons, the Court should enter summary judgment in favor of the NFPRHA Plaintiffs and vacate the Rule. HHS's motion to dismiss or for summary judgment should be denied in all respects.

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DATED: November 20, 2019

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CERTIFICATE OF SERVICE

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

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

/s/ *Emily Chiang*
Emily Chiang

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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.

Nos. 1:19-cv-3040-SAB

[PROPOSED] ORDER

Upon consideration of the National Family Planning & Reproductive Health Association Plaintiffs' Opposition to Defendants' Motion to Dismiss or for

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Summary Judgment and Cross-Motion for Summary Judgment, the State of Washington's Opposition to Defendants' Motion to Dismiss and Cross-Motion for Summary Judgment, Defendants' Motion to Dismiss or for Summary Judgment, and the full briefing and record submitted on these motions, IT IS HEREBY ORDERED that Plaintiffs' motions are GRANTED, and Defendants' motion is DENIED. Accordingly, the challenged rule, promulgated in Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 *et seq.* (2019), is VACATED and set aside in its entirety.

SO ORDERED.

Dated: _____

_____
Stanley A. Bastian
U.S. District Court Judge

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