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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

(Eugene Division)

STATE OF OREGON et al.,,

Plaintiffs,

v.

ALEX M. AZAR II et al.,,

Defendants.

Civil No. 6:19-cv-00317-MC (Lead Case)

MOTION TO APPEAR AS AMICUS CURIAE AND TO FILE MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

AMERICAN MEDICAL ASSOCIATION et al.,,

Plaintiffs,

v.

ALEX M. AZAR II et al.,,

Defendants.

Civil No. 6:19-cv-00318-MC (Trailing Case

MOTION TO APPEAR AS AMICUS CURIAE AND TO FILE MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

ORAL ARGUMENT DATE: April 23, 2019

UNOPPOSED MOTION TO APPEAR AS AMICUS CURIAE

A coalition of academics consisting of nine deans, seven department chairs, and forty-one scholars affiliated with public health institutions ("Academics") along with the American Public Health Association ("APHA") (collectively "Academics/AHPA") respectfully move to appear as amicus curiae and file the below memorandum in support of Plaintiffs' motions for preliminary injunction of Defendant's final rule, Compliance with Statutory Program Integrity Requirements, 84 Fed. Reg. 7714 (Mar. 4, 2019) (the "final rule"). Pursuant to Local Rule 7, Academics/APHA certifies that the parties jointly gave blanket consent to filing amicus briefs. Joint Notice of Blanket Consent (6:19-cv-317, ECF No. 72).

Academics are deans, department chairs, and faculty scholars who are affiliated with educational institutions that focus on matters of public health policy, spanning both policies that promote the health of individuals and populations as well as those that affect the accessibility and quality of care as well as the performance of the health care system.[1] Academics are among the nation's leading experts in the field of health policy. Many are considered to have particular

[1] A specific list of the nine deans, seven department chairs, and forty-one scholars is attached as Exhibit 1.

expertise in reproductive health and health care, and access to reproductive health and other health care services within medically underserved and by medically vulnerable populations. Academics seek to ensure the highest standard of sexual and reproductive health care for all people by promoting evidence-based policies and conducting research according to the highest standards of methodological rigor.

APHA is an organization that champions the health of all people and all communities, strengthens the public health profession, shares the latest research and information, promotes best practices, and advocates for evidence-based public health policies. Combining a nearly 150-year perspective and a broad-based membership working to improve the public's health, APHA has long recognized that access to the full range of reproductive health services, including abortion, is a fundamental right integral to both the health and well-being of individual women and the broader public's health. APHA opposes restrictions that, without valid medical reason, deny, delay, or impede access to reproductive health services. Such restrictions make reproductive health services unnecessarily difficult to obtain and increase physical and mental health risks.

MEMORANDUM

I. ARGUMENT

A. Introduction

The Centers for Disease Control and Prevention ("CDC") has identified family planning as one of the ten great public health achievements of the 20th century;[2] at stake in this case is nothing less than access to these essential services by millions of people. The threats flowing

[2] Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements--United States, 1900-1999*, 281 JAMA 1481 (1999).

from reduced access are gravest for at-risk, vulnerable low income women living in medically underserved communities. Family planning gives women and their partners the ability to control the timing and spacing of pregnancy, thereby lowering the risk of infant, child, and maternal mortality, along with lifelong childhood disability. Access is especially important for women with pre-existing health conditions that heighten risks associated with pregnancy and childbirth.[3] The use of barrier methods of contraception also lowers the risk of transmission of human immunodeficiency virus ("HIV") and other sexually transmitted infections that threaten health and life.[4]

Of profound importance, family planning is also associated with the dramatic decline in abortion rates, which are especially sensitive to the rate of unintended pregnancy. As the rate has declined steeply, so have abortion rates, which have reached record lows.[5]

Clinics funded through Title X of the Public Health Service Act account for much of this achievement. In 2014, the Title X clinic network accounted for half of a 1.3 million reduction in unintended pregnancies, which would have led to 619,000 unplanned births and 459,000

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[3] *See, e.g.*, Hal C. Lawrence, *Testimony Before the Institute of Medicine Committee on Preventive Services for Women*, at 11 (Jan. 12, 2011), http://www.nationalacademies.org/hmd/~/media/8BA65BAF76894E9EB8C768C01C84380E.ashx (offering expert testimony regarding the impact of unintended pregnancy on women with pre-existing conditions).

[4] Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements--United States, 1900-1999*, 281 JAMA 1481 (1999).

[5] Joerg Dreweke, *U.S. Abortion Rate Reaches Record Low Amidst Looming Onslaught Against Reproductive Health and Rights*, 20 Guttmacher Pol'y Rev. 15 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2001517.pdf; Joerg Dreweke, *New Clarity for the U.S. Abortion Debate: A Steep Drop in Unintended Pregnancy Is Driving Recent Abortion Declines*, 19 Guttmacher Pol'y Rev. 16 (2016), https://www.guttmacher.org/sites/default/files/article_files/gpr1901916.pdf.

abortions."[6] Without this network, the rates of unintended pregnancies, unplanned births and abortions would have been 33% higher."[7]

The consequences of unintended pregnancy are grave. They include delayed initiation of prenatal care, increased risk of maternal depression and physical violence during pregnancy, and maternal mortality.[8] Unintended pregnancies also significantly elevate health threats to children. Without a planned pregnancy, which improves the ability to initiate prenatal care early in pregnancy, women and their children lose the benefits of prenatal counseling and patient support for healthy births.[9]

B. By Radically Altering the title X Provider Network, The Final Rule Undermines Access To Effective Care

1. Mandatory Referrals for Maternity Care Amount to a "Gag Rule" That Will Undermine Providers' Willingness to Participate

The final rule[10] threatens the continued participation of highly qualified providers while discouraging others from participating in the Title X program. As such, the rule presents significant patient risks. Given defendants' virtually nonexistent impact analysis, none of these risks has been given meaningful consideration, even though extensive evidence of the potential

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[6] Jennifer J. Frost et al., *Contraceptive Needs and Services: 2014 Update*, GUTTMACHER INSTITUTE (2016), https://www.guttmacher.org/sites/default/files/report_pdf/contraceptive-needs-and-services-2014_1.pdf.

[7] Mia R. Zolna & Jennifer J. Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, GUTTMACHER INSTITUTE (2016), https://www.guttmacher.org/sites/default/files/report_pdf/publicly-funded-family-planning-clinic-survey-2015_1.pdf.

[8] *Family Planning*, HEALTHY PEOPLE 2020 (2019), https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning.

[9] Adam Sonfield et al., *Moving Forward: Family Planning in the Era of Health Reform*, GUTTMACHER INSTITUTE (2014), https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

[10] 84 Fed. Reg. 7714.

for adverse impact exists, including evidence from a highly similar effort by Texas, discussed below, to eliminate Planned Parenthood ("PP") from its own state-funded family planning program.

In the world as it would look were the final rule to take effect, Title X programs would be authorized to offer family planning that falls short of the most effective care. Post-conception care would be fundamentally altered, since providers would be *required* to refer all pregnant patients for maternity care regardless of personal choice and preference. Nondirective post-conception counseling – a core element of reproductive health practice guidelines published by the CDC in 2013[11] – would be reduced to mere health care options, contradicting the non-directive counseling provision of the 1996 appropriations legislation[12] and the access to therapies provisions of the Patient Protection and Affordable Care Act ("ACA").[13] The rule's prenatal care referral mandate, 42 C.F.R. § 59.14, coupled with its demand that providers withhold material information from their patients, together operate as a "gag rule" that inevitably will push the most qualified providers away from program participation.

The rule utterly fails to account for the access impact caused by the amount of time needed to rebuild a competent Title X provider network, even assuming that qualified providers can be convinced to participate in a program riddled with both legal and ethical risks. Years of experience with the development of health care capacity in medically underserved rural and

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[11] *See* Loretta Gavin et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, CTRS. FOR DISEASE CONTROL & PREVENTION: MORBIDITY & MORTALITY WEEKLY REPORT (2014), 14, https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf (Appendix A) (providing guidelines for women with a positive pregnancy test).

[12] Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, sec. 104, 110 Stat. 1321 (1996) (''Omnibus Appropriations Act 1996'') ("[A]ll pregnancy counseling shall be nondirective . . . ").

[13] Pub. L. No. 111-148, § 1554, 124 Stat. 259 (codified at 42 U.S.C. § 18114).

urban areas underscores the complexity of such an undertaking. The Title X network has evolved over decades, and yet even today many communities remain inadequately served. Nowhere is this reality accounted for in the rule, despite clear evidence readily available from the Texas experience, as well as the federal government's own experience in the expansion of health care capacity.

By effectively excluding full-spectrum reproductive health providers that cannot meet its physical and financial separation requirements, the final rule triggers major access risks, with results that are predictable based on past experience. These effects, are, in fact, on full view as a result of events that transpired in Texas following that state's exclusion of PP and other full spectrum reproductive health providers from its state-funded women's health program. Despite readily available, extensively documented evidence from this experience, the administration has made no effort to determine the effects of its own rule, including the immediate loss of access in affected communities, the difficulties in recruiting new qualified providers, or the problems facing remaining providers as they struggle to offset the loss of access. The health, health care, and cost consequence effects of the Texas policy have included reduced access to care, a falloff in use of the most effective contraceptive methods, escalating unintended pregnancy rates, and escalating teen birth rates. Unintended pregnancy and teen births are associated with higher health risks to women and children.[14]

[14] Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 New England J. Med. 843 (2016), https://www.nejm.org/doi/10.1056/NEJMsa1506575.

The Texas case is a stark one. Established in the wake of the Obama Administration's refusal to permit Texas to exclude PP from its special Medicaid family planning program, Texas' state-funded program purported to replicate previous levels of access.[15]

Between the program's establishment in 2011 and 2016, enrollment in Texas' program fell by 26% from 127,536 to 94,851 women. Furthermore, enrollees receiving heath care services declined even more severely, falling 39%, from 115,226 in FY 2011 to 70,336 in FY 2016 – a signal of severe problems with provider capacity. Those providers that remained simply could not compensate for the loss of network capacity. Whereas 90% of all women enrolled in the predecessor program received care in FY 2011, by FY 2016, only 74% of women enrolled in the Texas Women's Health Program/Healthy Texas Women obtained care. In other words, by FY 2016, one in four women enrolled in Texas' program failed to receive covered family planning services.[16]

Importantly, the exclusion of a trusted provider such as PP carried consequences for comprehensive primary care providers such as community health centers, which are obligated to meet the needs of community residents of all ages and which faced serious barriers to expansion of services and full integration of reproductive and sexual health care. Community health centers that previously offered only limited family planning services owing to the availability of alternative sources of care often would have lacked the training needed to offer the most effective long-acting reversible contraception ("LARC") methods and have tended to be less

[15] Texas Health and Human Services Commission, *Final Report of the Former Texas Women's Health Program: Fiscal Year 2015 Savings and Performance* (Mar. 2017) https://hhs.texas.gov/reports/2017/03/former-texas-womens-health-program-fiscal-year-2015-savings-performance.

[16] *Excluding Planned Parenthood has been Terrible for Texas Women*, CENTER FOR PUBLIC POLICY PRIORITIES (Aug. 2017), https://forabettertexas.org/images/HW_2017_08_PlannedParenthoodExclusion.pdf.

consistently skilled and experienced in the family planning counseling patients require.[17] Evidence shows that general primary care providers in fact tend to have more limited capacity and skills than those specializing in reproductive health care.[18]

The Texas experience underscores these problems. Use of LARC fell by 35%, while use of effective injectable contraception decreased from 60% to 38% in counties previously served by PP clinics; birth rates climbed among former PP patients who relied on injectable contraceptives. Between 2011 and 2014, the number of births to women receiving care at publicly funded clinics and insured by Medicaid increased by 27%.[19] Landmark research published in 2016 in the New England Journal of Medicine and examining access under the Texas program found that counties losing access to PP reported an increase in Medicaid-insured pregnancies while those unaffected by the exclusion did not. This, according to researchers, established a causal connection.[20] A separate study found that reduced access to family planning services in Texas led to a 3.4% increase in teen births over four years with effects concentrated 2–3 years after the initial cuts."[21]

In sum, defendants failed completely to consider readily available evidence crucial to reasoned agency decision making regarding dramatic changes to existing provider networks.

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[17] Kari White et al., *Providing Family Planning Services at Primary Care Organizations after the Exclusion of Planned Parenthood from Publicly Funded Programs in Texas: Early Qualitative Evidence*, 53 Health Servs. Res. 2770 (2018).
[18] Zolna & Frost, *supra* note 6, at 11-12.
[19] Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, 374 New England J. Med. 853 (2016); Zolna & Frost, *supra* note 6, at 11-12.
[20] Stevenson et al., *supra* note 18.
[21] Analisa Packham, *Family Planning Funding Cuts and Teen Childbearing*, 55 J. Health Econ. 168 (2017).

2. The Final Rule's Restriction on Providers that Elect to Engage in Non-Directive Counseling Contradicts Federal Law and Threatens to Undermine Title X Participation by Highly Qualified Providers

The prohibitions in the final rule are inconsistent with the language of the 1996 appropriations statute, *supra*, as well as the access to therapies provision of the ACA. Furthermore, as reflected in extensive public comments in the rulemaking record, the rule will undermine the willingness of highly qualified providers to participate in Title X because of the liability risks it creates as a result of the degree to which it undermines professional ethics and the professional standard of care. In the final rule, however, the Department fails to consider these potential consequences of its policies for Title X provider participation, health care access, and health outcomes.

Mandatory referral for prenatal care is a basic element of the rule. While the rule permits nondirective post-conception counseling, it also bars clinical providers from making appropriate referrals to qualified community providers for those patients who do constitutionally elect to terminate their pregnancies. Because counseling and referral practices are program integrity requirements, a likely result is that providers will drop out of Title X or refuse to participate altogether rather than subject themselves to ongoing intensive monitoring of their patient communications.

The defendants' counseling and speech restrictions violate professional norms by requiring physicians to deliberately withhold information material to a reasonable patient's ability to make an informed choice. In such cases, the fact that a payer's instructions fall below

the professional standard of care is no defense in a subsequent action for medical liability.[22] Such restrictions thus not only defeat patients' compelling interest in receiving fully appropriate medical advice but are fundamentally at odds with the responsibility of individual health professionals to use their best medical judgment in counseling patients with diagnosed health conditions. Defendants' rulemaking record is replete with public comments on this issue. Both the American College of Obstetricians and Gynecologists ("ACOG") and the American Academy of Pediatrics ("AAP") offered extensive commentary on this matter, explicitly pointing to the *Wickline* problem created by the rule.[23] Both organizations drew particular attention to liability risks arising from withholding material information from patients at the point of diagnosis, a matter of especially great concern.[24] The Guttmacher Institute also raised serious professional ethics issues.[25] Indeed, defendants have ample evidence regarding the ethical problems their rule would cause, given the massive medical resistance to a virtually identical rule published 30 years ago.[26]

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[22] *Wickline v State of California*, 183 Cal. App. 3d 1175 (1986).
[23] Am. College of Obstetricians & Gynecologists, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements (July 31, 2018), https://www.regulations.gov/document?D=HHS-OS-2018-0008-179339 [hereinafter ACOG Comment Letter] (citing Sara Rosenbaum et al., *The Title X Family Planning Proposed Rule: What's At Stake for Community Health Centers?*, HEALTH AFFAIRS BLOG (June 25, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180621.675764/full/).
[24] *Id.* (citing Andrea M. Carpentieri et al., *Overview of the 2015 American Congress of Obstetricians and Gynecologists' Survey on Professional Liability* (Nov. 2015), https://www.acog.org/-/media/Departments/Professional-Liability/2015PLSurveyNationalSummary11315.pdf?dmc=1&ts=20180718T1957354993); ACOG Comment Letter, at 6.
[25] Guttmacher Institute, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements, at 12 (July 31, 2018), https://www.guttmacher.org/sites/default/files/article_files/guttmacher_letter_to_hhs_on_proposed_title_x_changes.pdf [hereinafter Guttmacher Comment Letter].
[26] *See Rust v. Sullivan*, 500 U.S. 173 (1991).

Given Title X's role in creating access in medically underserved communities, a key area of concern with the potential deterrent effect of the rule has to do with its impact on community health centers, nonprofit clinics funded under § 330 of the Public Health Service Act to furnish comprehensive primary care to residents of all ages. Family planning is a required service, and approximately 1 in 4 health centers has expanded the services it offers beyond a minimum required level by participating in Title X.[27] At various points in the Preamble accompanying the final rule, the administration appears to assume that more community health centers will become Title X participants in order to expand capacity.[28] However the administration offers no evidence on which to base this conclusory assumption; indeed, the percentage of health centers participating in Title X has remained unchanged for years.[29] Indeed, all evidence points in the opposite direction. In Texas, for example, despite their best efforts, health centers were able to make only modest expansions.[30] Indeed, a nationwide study of health centers and family

[27] *See* Susan Wood et al., *Health Centers and Family Planning: Results of a Nationwide Study*, The George Washington University School of Public Health & Health Services Department of Health Policy (2013), https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1059&context=sphhs_policy_facpubs

[28] *See, e.g.*, 84 Fed. Reg. 7714, 7754 ("and to allow for grantees such as community health centers . . ."); *see also* 84 Fed. Reg. at 7727.

[29] For years 2013 and 2018, 26% of FQHCs that responded to a nationwide survey reported participating in the Title X program. *See* Susan Wood et al., *Health Centers and Family Planning: Results of a Nationwide Study*, The George Washington University School of Public Health & Health Services Department of Health Policy (2013), https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1059&context=sphhs_policy_facpubs; and Susan Wood et al., *Community Health Centers and Family Planning in an Era of Policy Uncertainty*, Kaiser Family Foundation (2018), https://www.kff.org/womens-health-policy/report/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty/

[30] Leighton Ku et al., *Deteriorating Access to Women's Health Services in Texas: Potential Effects of the Women's Health Program Affiliate Rule*, Policy Research Brief No. 31, GEIGER GIBSON / RCHN COMMUNITY HEALTH FOUNDATION RESEARCH COLLABORATIVE (Oct. 2012), https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1000&context=sphhs_policy_ggrchn.

planning found that in 2018, only six percent of all health centers reported an ability to increase their capacity by 50 percent or more.[31] In its comments, ACOG pointed out that health centers would be unable to absorb the approximately 2 million contraceptive patients who would lose access to care, noting that while the average community health center site serves 320 contraceptive clients annually, the comparable average figure for a PP clinic site is 2,950.[32] The Guttmacher Institute commented that other providers in 13 states would have to double their contraceptive client caseloads to maintain current provider access.[33]

Furthermore, federal health center requirements under § 330 actually militate against any participation in Title X given the rule's bar against adherence to evidence-based practice for post-conception care.[34] Defendants completely failed to consider the requirements of § 330 itself. Like other medical providers, community health centers must consider medical liability issues, and in the case of community health centers, this consideration is a matter of federal law. The Health Resources and Services Administration ("HRSA"), the federal HHS agency that administers the health centers program, maintains a Health Center Program Compliance Manual that specifies that under § 330(k)(3)(C) of the Public Health Service Act, compliance requires "adhering to current evidence-based clinical guidelines, standards of care, and standards of

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[31] Susan Wood et al., *Community Health Centers and Family Planning in an Era of Policy Uncertainty*, Kaiser Family Foundation (2018), https://www.kff.org/womens-health-policy/report/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty/

[32] ACOG Comment Letter, at 12 (citing Kinsey Hasstedt, *Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net*, 20 Guttmacher Pol'y Rev. 67 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2006717_0.pdf)

[33] Guttmacher Comment Letter, at 10 (citing Jennifer J. Frost & Mia R. Zolna, *Memo to Sen. Patty Murray Regarding Response to Inquiry Concerning the Impact on Other Safety-Net Family Planning Providers of "Defunding" Planned Parenthood*, GUTTMACHER INSTITUTE (June 14, 2017), https://www.guttmacher.org/sites/default/files/article_files/guttmacher-murray-memo-2017_1.pdf).

[34] Section 330 of the Public Health Service Act (42 U.S.C. § 254b) provides the statutory basis for DHHS/HRSA grants to federally qualified community health centers.

practice. . . ."[35] Where family planning is concerned, the evidence-based standard is the CDC family planning guideline, which was developed with full participation of HRSA in anticipation of their applicability to health centers. These guidelines require nondirective counseling.[36] Furthermore, not only does eligibility for federal grant funding turn on compliance with evidence-based practice standards; so does health centers' professional medical liability coverage. Unlike private providers, federally funded community health centers obtain medical liability protection through the Federal Tort Claims Act ("FTCA").[37] FTCA coverage, in turn, depends on adherence to all § 330 grant funding rules. In effect, therefore, the final family planning rule creates a legal Hobson's choice for community health centers: provide substandard patient counseling and care management in accordance with the final rule and risk violation of requirements applicable to their § 330 operating grants (which account for nearly 20% of all health center revenue)[38] or cease participation in Title X.[39] Defendants have given no consideration to this problem in their final rule.

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[35] *Health Center Program Compliance Manual*, HRSA, 44 (Aug. 2018), https://bphc.hrsa.gov/sites/default/files/bphc/programrequirements/pdf/hc-compliance-manual.pdf.

[36] These guidelines encompass both preconception care and pregnancy testing and counseling. Gavin et al., *supra* note 10.

[37] *About the Federal Tort Claims Act (FTCA)*, HRSA, https://bphc.hrsa.gov/ftca/about/index.html.

[38] Sara Rosenbaum et al., *Community Health Center Financing: The Role of Medicaid and Section 330 Grant Funding Explained*, KAISER FAMILY FOUNDATION (Mar. 26, 2019), https://www.kff.org/medicaid/issue-brief/community-health-center-financing-the-role-of-medicaid-and-section-330-grant-funding-explained/.

[39] Note the following from a Washington, DC lawyer specializing in health centers and the FTCA:

> The Federally Supported Health Centers Assistance Act requires that in order to be deemed, the Secretary must determine that the health center: "has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health related functions performed by the

3. The Final Rule Undermines the Availability of Effective Family Planning Services

The final rule deprioritizes the awarding of funds to project sponsors willing and able to offer the most effective modern medical contraceptive technologies. Since *Rust v Sullivan*[40] was decided in 1991, contraception science has advanced considerably through the development of prescribed LARC.[41] Yet the final rule strikes the term "medically" from the requirement that grantees offer contraception, while explicitly calling out for far less effective "natural family planning or other fertility awareness-based methods" – a clear effort to telegraph agency priorities where the scope of available care is concerned. Despite the extensive scientific evidence regarding the safety and effectiveness of LARC, the rule effectively de-emphasizes prescribed contraception while openly encouraging project participation by greater numbers of entities that elect to offer only "natural family planning" methods. This could stimulate the growth of greater numbers of Title X project grantees with only limited ability to furnish the most effective contraception, a particular concern for rural states in which patients must either

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> covered entity" (42 U.S.C. § 233(h)(1)). * * *. If health centers put themselves in a position where they are forced by federal rules to give incomplete information to a patient regarding clinical referrals it could be construed as inconsistent with the above requirement. If they comply with the Title X rule they may not be compliant with Section 233(h)(1); if they fully comply with Section 233(h)(1), they violate the Title X rule. The consequence for failing to adhere to Section 233(h)(1) could be denial of a deeming application (i.e., deemed to be compliant for Section 330 health center grant purposes). (Martin Bree, Feldesman Tucker Leifer and Fidell).

[40] *Sullivan*, 500 U.S. 173.
[41] *ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician-Gynecologists*, ACOG (Nov. 2017), https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Gynecology/Long-Acting-Reversible-Contraception-Implants-and-Intrauterine-Devices?IsMobileSet=false.

endure large travel distances to reach a provider where choice is possible or pay out-of-pocket for effective contraception no longer available at their nearby Title X-funded project site. Defendants make no effort to assess the access and health impact of relaxing the previous regulatory medical effectiveness standard.

The rule goes beyond simply degrading the quality of care, of course. By requiring physical and financial separation, the rule effectively excludes providers offering full-spectrum care or affiliated with providers that do offer such care, such as PP. In 13 states, PP clinics were the site of care for more than 40% of all women receiving publicly funded family planning services.[42]

All of these policies aimed at excluding current network providers and degrading the level of care available come together in another provision of the rule[43] that empowers the agency to exclude Title X project applicants before their applications reach the competitive review stage, thereby applying a highly politicized filter to the funding award process in order to favor projects that offer limited contraceptive access and engage only in highly directive counseling in accordance with defendants' clearly stated preferences.

4. The Financial and Physical Separation Requirement will Exclude Highly Qualified Providers

The financial and physical separation requirements of the proposed rule, *Maintenance of Physical and Financial Separation*, 42 C.F.R. § 59.15, will severely undermine the ability of Title X grantees to provide family planning services. Indeed, the physical and financial

[42] Laurie Sobel et al., *Proposed Changes to Title X: Implications for Women and Family Planning Providers*, KAISER FAMILY FOUNDATION (Nov. 21, 2018), https://www.kff.org/womens-health-policy/issue-brief/proposed-changes-to-title-x-implications-for-women-and-family-planning-providers/.
[43] *See* 42 C.F.R. § 59.7.

separation requirements in the final rule will make Title X participation prohibitively costly, potentially causing many Title X provider entities to forgo numerous types of constitutionally protected activity altogether.[44] Multiple professional medical organizations expressed these views, for example, the American Medical Association ("AMA") noted the impact of the rule on continued participation by specialized reproductive health providers, such as PP, "[45] as did ACOG[46] and the National Family Planning and Reproductive Health Association ("NFPRHA"). Indeed, *Rust v Sullivan* underscores the extent to which qualified providers objected to this requirement. Yet defendants fail to consider the impact of such a requirement on the size and scope of the Title X network, and therefore, on access.[47]

Exacerbating the circumstances for family planning providers, the final rule does not issue clear guidance on what constitutes sufficient "separation." Instead, the final rule calls for a subjective "facts and circumstances" test that, without further definition, will consider accounting practices, physical separation down to entrances and exits, shared phone numbers and email addresses, websites, and separate personnel and health care records. *See* 42 C.F.R. § 59.15. Any applicant or grantee that cannot pass the facts and circumstances test – not just for provision of abortion, but for promoting or referring for abortion as a method of family planning

[44] Nat'l Fam. Plan. & Reprod. Health Ass'n, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements, at 16-17 (July 31, 2018), https://www.nationalfamilyplanning.org/file/NFPRHA-Comments_07312018_FINAL.pdf [hereinafter NFPRHA Comment Letter].
[45] Am. Med. Ass'n, Comment Letter on Proposed Rule Regarding Compliance with Statutory Program Integrity Requirements, at 4 (July 31, 2018), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-7-31-Letter-to-Azar-re-Title-X-Comments.pdf.
[46] ACOG Comment Letter, at 11.
[47] NFPRHA Comment Letter, at 37.

– runs the risk of a program integrity violation, a risk that may lead many qualified providers to exit the program altogether. Yet defendants offer no impact assessment.

Furthermore, impact estimates published to date grossly underestimate the costs of compliance with the final rule to the point of disregarding them. Existing estimates are confined to the technical costs of compliance and do not consider the cost impact of creating required separate networks, renting separate space, maintaining separate personnel and patient records, or building duplicate program administration infrastructure. Nor does the rule account for the provider exodus that could ensue as a result of the increasing operational and cost strain it will introduce.

C. The Final Rule will Lead to Decreased Access to Health Care

Contrary to the purpose of Title X, the final rule will decrease, rather than improve, access to essential health care. Title X enables access, not only to the most effective forms of family planning but also to critical preventive services related to family planning, such as screening and counseling for sexually-transmitted infections and HIV, preventive cancer screenings, and counseling and referrals for other needed care. Access to a constellation of services is thus at risk.

1. Decreased Access to Effective Contraceptive Threatens a Rise in Unplanned Pregnancies

By adopting policies that effectively exclude certain qualified providers and deter participation by others, the rule can be expected to rapidly shrink the Title X network, just as the Texas experience illustrated. With reduced network size comes reduced access to care. Abundant scientific evidence (especially the Texas example) shows, reduced access to the most effective types of family planning carries with it enormous health, economic, and social

consequences. By providing millions of patients with access to affordable and medically effective contraception, publicly funded family planning in 2010 helped women to avoid 2.2 million unintended pregnancies. The rule fundamentally threatens this track record; without such access, the rates of unintended pregnancy, unplanned births, and abortion would be 66% higher than they currently are.[48]

2. Decreased Access to Testing for Sexually Transmitted Infections Will Lead to More Preventable Illnesses

By quickly downsizing the Title X network, the rule also can be expected to impair access to a range of family planning-related services, such as testing for sexually transmitted infections. In 2017, STI testing and treatment represented nearly half of the services (48.7%) performed at PP clinics.[49] Overall, Title X program providers performed nearly 6.5 million screening tests for STIs in 2017.[50] These services are particularly crucial for low-income women, who experience both higher rates of STIs and lower access to care.[51] Defendants make no attempt to assess the impact of a downgraded network on untreated STI rates.

Disrupting STI screening and treatment inevitably will contribute to a rise in preventable conditions that impair the health of both people who experience infection and children born to infected women. Such a result comes at a particularly pivotal moment for STI treatment and

[48] Sonfield et al., *supra* note 8.
[49] *2017-2018 Annual Report*, PLANNED PARENTHOOD, 23 (2018), https://www.plannedparenthood.org/uploads/filer_public/4a/0f/4a0f3969-cf71-4ec3-8a90-733c01ee8148/190124-annualreport18-p03.pdf.
[50] Dep't of Health & Hum. Servs., *Title X Family Planning Annual Report 2017 Summary*, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/fpar-2017/index-text-only.html.
[51] Usha Ranji et al., *Financing Family Planning Services for Low-Income Women: The Role of Public Programs*, KAISER FAMILY FOUNDATION (May 11, 2017), https://www.kff.org/womens-health-policy/issue-brief/financing-family-planning-services-for-low-income-women-the-role-of-public-programs/.

prevention: according to the CDC, the number of new cases of STIs has been growing steadily since 2013.[52] CDC reported 2.3 million new cases of chlamydia, gonorrhea, and syphilis in 2017, surpassing the 2016 all-time high by more than 200,000 cases.[53] Defendants have completely failed to consider this even though the Texas experience showed precisely these results, with chlamydia and congenital syphilis infection rates well above the national average,[54] along with newly diagnosed cases of HIV.[55]

3. Decreased Access to Cancer Screenings Will Lead to Delayed Cancer Diagnosis

Nor have defendants considered the impact of radically configuring the Title X provider network on access to critical primary and preventive services such as screenings for cervical cancer and clinical breast exams.[56] These services are a basic feature of the current Title X network,[57] as called for in the CDC's family planning guidelines.[58] In 2017 alone, the existing network provided pap testing to 18% (649,266) female family planning patients; 14% led to an

[52] Ctrs. for Disease Control & Prevention, *New CDC Analysis Shows Steep and Sustained Increases in STDs in Recent Years*, CDC NEWSROOM (Aug. 28, 2018), https://www.cdc.gov/media/releases/2018/p0828-increases-in-stds.html.
[53] *Id.*
[54] Kinsey Hasstedt, *The State of Sexual and Reproductive Health and Rights In the State of Texas: A Cautionary Tale*, 17 Guttmacher Pol'y Rev. 14 (2014), available at https://www.guttmacher.org/gpr/2014/03/state-sexual-and-reproductive-health-and-rights-state-texas-cautionary-tale; *Sexually Transmitted Disease Surveillance 2017*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 2018), https://www.cdc.gov/std/stats17/2017-STD-Surveillance-Report_CDC-clearance-9.10.18.pdf.
[55] *Diagnoses of HIV Infection in the United States and Dependent Areas*, CTRS. FOR DISEASE CONTROL & PREVENTION, 114 (Nov. 2018), https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf.
[56] C. I. Fowler et al., *Family Planning Annual Report: 2017 National Summary*, OFFICE OF POPULATION AFFAIRS, 41 (Aug. 2018), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.
[57] *Title X: The Nation's Program for Affordable Birth Control and Reproductive Health Care*, PLANNED PARENTHOOD, https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x.
[58] Fowler, *supra* note 55, at 41.

indeterminate or abnormal result requiring additional evaluation or treatment.[59] Likewise, the existing network performed more than 878,000 clinical breast exams (25% (878,491) of female patients); one in 20 (5% - 41,766 cases) led to a referral for further evaluation and ultimately, lifesaving care if needed.[60] In addition to cervical and breast cancer screenings, many members of the current Title X network also provide colon cancer screenings, including 57 percent of all PP clinics compared to only 19 percent of health department clinics.[61]

As the final rule causes a downward spiral in the size and robustness of the Title X network, access to these related services will also decline and diagnoses and treatment will be delayed with potentially irreversible consequences for medically underserved communities. None of the obvious health and health care results flowing from the major impact on the existing Title X network that this rule will produce are reflected in defendants' regulatory impact assessments despite having the failures of the earlier Texas example available to them.

4. Reduced Access to Care Will Significantly Increase Medicaid Expenditures

Although the final rule can be expected to have a major impact on both federal and state Medicaid spending, defendants made no effort to analyze these costs. The primary and preventive health care delivered by the existing Title X network significantly lowers Medicaid outlays by reducing unplanned pregnancies, preventing the spread of disease, and reducing the health impact of conditions that can be detected and treated early. In 2010, for each dollar invested in publicly funded family planning programs like Title X, the government saved $7.09

[59] *Id.*
[60] *Id.*
[61] Zolna & Frost, *supra* note 6, at 12.

in Medicaid-related costs.[62] Moreover, the gross public savings in 2010 was approximately $15.8 billion, including $15.7 billion in savings from preventing unplanned births, $123 million from STI/HIV testing, and $23 million from pap and HPV testing and vaccines.[63] By subtracting $2.2 billion in total public costs to provide family planning services in 2010, state and federal governments saved $13.6 billion in 2010 from publicly funded family planning programs, including $7 billion from Title X-funded providers.[64]

The rule will reduce access to effective and cost effective care, thereby elevating both the severity of conditions and the cost of treatment.[65] Reduced access to contraceptive services will also likely increase unplanned pregnancies with their significant Medicaid-associated costs. Research shows that contraceptive services can reduce Medicaid-associated maternity and infant care costs dramatically.[66] By severely reducing Title X network capacity in communities, the final rule reverses these gains.[67]

II. CONCLUSION

The weight of evidence regarding the likely impact of the final rule is substantial. The final rule will rapidly and dramatically shrink the Title X network, while deterring other qualified providers from participating. The health care, health, economic, and social consequences flowing from the rule are potentially enormous, yet defendants have failed to

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[62] Jennifer J. Frost et al., *Return on Investment: A Fuller Assessment of Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 *The Milbank Quarterly* 667, 668 (2014), https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/MQ-Frost_1468-0009.12080.pdf [hereinafter Frost et al., *Return on Investment*] ; *Title X: The Nation's Program for Affordable Birth Control and Reproductive Health Care*, PLANNED PARENTHOOD, https://www.plannedparenthoodaction.org/issues/health-care-equity/title-x.

[63] Frost et al., *Return on Investment*, *supra* note 61, at 668.

[64] *Id.* at 696.

[65] *Id.* at 680.

[66] *Id.* at 696.

[67] Stevenson et al., *supra* note 18.

consider these issues at all. By adopting a final rule so bereft of any effort to assess impact – and especially considering the vast rulemaking record pointing to precisely these types of impact – defendants have acted arbitrarily and capriciously, in violation of the Administrative Procedure Act.

The Court should grant plaintiffs' motions for preliminary injunction.

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