UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

State of Ohio, *et al.*, *Plaintiffs*, –v– XAVIER BECERRA, *et al.*, *Defendants*.	**Case No. 1:21-cv-675** **Judge Timothy S. Black**

BRIEF OF THE NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION AS *AMICUS CURIAE* OPPOSING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST OF *AMICUS CURIAE*

The National Family Planning & Reproductive Health Association (NFPRHA) is a national, nonprofit membership organization dedicated to promoting and supporting the work of family planning providers and administrators, especially those in the safety net, to provide high-quality, client-centered, affordable family planning services. NFPRHA represents nearly 1,000 members—including more than 900 health care organizations—in all 50 states, the District of Columbia, and the territories. NFPRHA's members operate or administer thousands of health centers, many of which are or recently have been Title X grantees or subrecipients of Title X grants, serving millions of patients a year. NFPRHA's organizational members include state, county, and local health departments; private, nonprofit family planning organizations; family planning councils; hospital-based clinics; and federally qualified health centers.

As the leading national advocacy organization for family planning providers since 1971, NFPRHA submits this *amicus* brief to provide the Court with additional facts and perspective about (1) the history and administration of the Title X program; (2) the role of Title X and its providers in ensuring patient access to high-quality, affordable, voluntary, client-centered family planning services; and (3) how the Department of Health and Human Services' (HHS's) recent regulatory changes are necessary to restore the Title X network nationwide.[1] NFPRHA agrees with the legal arguments Defendants make in opposition to Plaintiffs' motion[2] and focuses this *amicus* brief on the impact of the 2021 rule on the Title X network and its patients.

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[1] *See* Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 Fed. Reg. 56,144 (Oct. 7, 2021).

[2] Defs.' Mem. Opp. Pls.' Mot. Prelim. Inj., ECF No. 27.

BACKGROUND

A. Congress Enacted Title X to Provide Low-Income Patients with High-Quality Family Planning Medical Care

For more than 50 years, the Title X program's grants to public and private nonprofit entities have served as the nation's only dedicated federal funding for family planning services.[3] By enacting Title X, Congress intended to provide patients with a nationwide network of high-quality family planning medical care, equal access to contraceptives, and the freedom to make decisions about whether and when to have children.[4]

Although Title X-funded projects provide services, supplies, and information to patients regardless of income, the statute requires that priority be given to low-income patients.[5] The Title X program disproportionately serves people with low incomes, young people, and people of color, and it provides a lifeline for a number of marginalized communities.[6] For example, a 2016 study found that 60 percent of the women who received contraceptive care from Title X-funded health centers had seen no other medical provider in the previous year.[7]

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[3] Family Planning Services & Population Research Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504 (1970) (*codified as amended at* 42 U.S.C. §§ 300 *et seq*. (2018)).

[4] *See id.*; S. Rep. No. 91-1004, at 4–12 (1970); H.R. Rep. No. 91-1472, at 6–11 (1970).

[5] 42 U.S.C. § 300; *see also* Christina Fowler et al., *Title X Family Planning Annual Report: 2020 National Summary*, OPA, 25 (Sept. 2021), https://opa.hhs.gov/sites/default/files/2021-09/title-x-fpar-2020-national-summary-sep-2021.pdf.

[6] In 2020, 66 percent of the patients Title X-funded providers served had incomes at or below the federal poverty level, *id.*, and 56 percent were under age 30, *id.* at ES-2. Twenty-six percent of patients self-identified as Black and 35 percent as Latino/a, *id.* at 16, compared to 14 percent and 19 percent of the nation, respectively, Nicholas Jones et al., *Improved Race and Ethnicity Measures Reveal U.S. Population Is Much More Multiracial*, Census Bureau (Aug. 12, 2021), https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html.

[7] Megan L. Kavanaugh et al., *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X-Funded Facilities in 2016*, 50 Perspectives on Sexual & Reproductive Health 101, 105 (Sept. 2018), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12061.

The Title X statute requires that funded projects "offer a broad range of acceptable and effective family planning methods and services."[8] Since its initial passage, Title X has also required that "[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning."[9]

A Title X "project" refers not to a physical space or entity but to a set of proposed family planning activities that are described in detail in a grantee's application for funding.[10] Within each Title X project, there are typically three levels: (1) the grantee, (2) the subrecipient (if any), and (3) individual health centers, also referred to as service sites, run by either grantees or subrecipients. Throughout the program's history, Title X-funded providers have operated like other outpatient medical providers, meaning that entities that also provide other health care services, including abortion care—without Title X funds and outside their Title X projects, though often under the same roof—have historically participated as grantees, subrecipients, and service sites in the Title X program.

The Office of Population Affairs (OPA) within HHS administers Title X; awards Title X service grants; and oversees grantees' compliance with the governing legal framework, program requirements, and national standards of clinical care.[11] Beginning in 2014, OPA's Title X

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[8] 42 U.S.C. § 300(a).

[9] 42 U.S.C. § 300a-6.

[10] *See, e.g.*, Off. of Population Affs., Off. of the Assistant Sec'y for Health, HHS, *Notice of Funding Opportunity: Title X Family Planning Services Grants*, 40 (Oct. 27, 2021), available at https://www.grantsolutions.gov/gs/preaward/previewPublicAnnouncement.do?id=95156 (grantees "may only use award funds to support activities outlined in the approved project plan").

[11] Safeguards to ensure compliance include "(1) careful review of grant applications to ensure that the applicant understands the requirements and has the capacity to comply with all requirements; (2) independent financial audits to examine whether there is a system to account for program-funded activities and nonallowable program activities; (3) yearly comprehensive reviews of the grantees' financial status and budget report; and (4) periodic and comprehensive

program guidelines incorporated the "QFP" (short for quality family planning), the US clinical standards for family planning developed in partnership by the Centers for Disease Control and Prevention (CDC) and OPA.[12] The QFP defines core family planning services and other preventive health services that promote reproductive health and specifies the optimal approach to care no matter the provider, payer, or setting. Before 2019, OPA used the QFP to monitor and evaluate Title X grantees.

B. Title X's Regulatory Framework Operated Effectively for Almost 50 Years

For the five decades the program has existed, the statutory and regulatory framework governing Title X has remained remarkably consistent. Over that time, Congress has acted primarily to protect certain of Title X's key elements, including that "all pregnancy counseling [in Title X-funded projects] shall be nondirective," which Congress has included in every HHS appropriations enactment since 1996.[13] And before 2019, the executive branch only once tried to institute fundamental changes to Title X.

During the 1970s, Title X-funded providers were permitted to offer pregnant patients nondirective counseling on all their options, including referrals for such options upon request.[14]

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program reviews and site visits by OPA regional offices." Angela Napili, Congressional Research Service, *Title X (Public Health Service Act) Family Planning Program*, 22 (Aug. 31, 2017), https://sgp.fas.org/crs/misc/RL33644.pdf.

[12] *See Program Requirements for Title X Funded Family Planning Projects*, OPA, 5 (Apr. 2014), https://www.nationalfamilyplanning.org/document.doc?id=1462; *see also* Loretta Gavin, PhD, et al., *Proving Quality Family Planning Services: Recommendations of CDC and the US Office of Population Affairs*, CDC, 63(4) MMWR (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

[13] *See, e.g.*, Further Consolidated Appropriations Act, 2020, Pub. L. 116-94, 133 Stat. 2534, 2558 (2019).

[14] *See* Mem. from Carol C. Conrad, Off. of the Gen. Couns., Dep't of Health, Educ. & Welfare, to Elsie Sullivan, Assistant for Info. & Educ., Off. of Family Planning, BCHS (Apr. 14, 1978) ("[T]he provision of information concerning abortion services, mere referral of an individual to another provider of services for an abortion, and the collection of statistical data and information

In 1981, HHS issued Title X Program Guidelines directing Title X projects to offer nondirective pregnancy counseling and referrals for abortion-related services if requested.[15] In 1988, however, HHS issued regulations that prohibited offering any abortion-related information or referrals, regardless of a patient's wishes.[16] This so-called "Gag Rule" further required Title X-funded providers to refer all pregnant patients for prenatal care, regardless of their wishes, and imposed new, strict physical-separation requirements between Title X-funded activities and any abortion-related activities.[17]

The Gag Rule was never implemented nationwide.[18] After lower courts enjoined the rule, the Supreme Court in 1991 upheld the Gag Rule as a "permissible construction of Title X."[19] But confusion remained about the regulations governing the Title X program, and the Gag Rule continued to be litigated. In 1992, Congress attempted to clarify that pregnant Title X patients must receive nondirective counseling and referrals for all options upon request, but President Bush vetoed the legislation.[20]

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regarding abortion are not considered to be proscribed by § 1008.") (cited by *Family Planning Ass'n of Me. v. HHS*, 404 F. Supp. 3d 286, 292 n.7 (D. Me. 2019)).

[15] *See* Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7464, 7464 (Feb. 5, 1993).

[16] Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects, 53 Fed. Reg. 2922, 2927 (Feb. 2, 1988).

[17] *Id.*

[18] *See* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,271 (July 3, 2000).

[19] *Rust v. Sullivan*, 500 U.S. 173, 203 (1991). The Supreme Court first determined the statute is ambiguous and that HHS's "construction of Title X may not be disturbed as an abuse of discretion if it reflects a plausible construction of the plain language of the statute and does not otherwise conflict with Congress' expressed intent." *Id.* at 184; *see also id.* at 185 ("holding that the legislative history is [also] ambiguous" because "[a]t no time did Congress directly address the issues of abortion counseling, referral, or advocacy").

[20] S. Doc. No. 102-28 (1992).

In February 1993, HHS issued an interim rule suspending the Gag Rule and announcing that "the agency's [pre-1988] nonregulatory compliance standards" would be used to administer the Title X program.[21] The agency simultaneously issued a notice of proposed rulemaking (NPRM), formally proposing to revoke the Gag Rule and return the Title X program to the regulations and compliance standards that existed prior to 1988.[22] When HHS finalized those regulations in 2000 (the 2000 rule),[23] it concluded that the 1988 physical separation model was unworkable, of "little relevance" to Title X, not "likely ever to result in an enforceable compliance policy" consistent with "the efficient and cost-effective delivery of family planning services," and "ambiguous."[24] HHS also formalized in 2000 the interpretations and policies that had been in place for much of the program's history relating to Title X's statutory prohibition on the use of Title X funds "in programs where abortion is a method of family planning."[25]

[21] Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7462, 7462 (Feb. 5, 1993).

[22] 58 Fed. Reg. 7464.

[23] 65 Fed. Reg. 41,270.

[24] *Id.* at 41,276.

[25] 42 U.S.C. § 300a-6; *see also* Provision of Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,281 (July 3, 2000). For example, the "prohibition does not apply to all the activities of a Title X grantee, but only to those within the Title X project." 65 Fed. Reg. at 41,281. HHS further detailed requirements for adequate separation between Title X-funded services and abortion-related services. *See, e.g.*, *id.* at 41,282 ("Certain kinds of shared facilities are permissible, so long as it is possible to distinguish between the Title X supported activities and non-Title X abortion-related activities: (a) A common waiting room is permissible, as long as the costs [are] properly pro-rated; (b) common staff is permissible, so long as salaries are properly allocated and all abortion related activities of the staff members are performed in a program which is entirely separate from the Title X project.").

C. Regulatory Changes in 2019 Significantly Damaged the Title X Network

On June 1, 2018, HHS issued an NPRM proposing not only to reinstate the majority of the 1988 Gag Rule, but also to add new requirements and restrictions.[26] Over the vigorous objections of leading medical, family planning, reproductive health, evidence-based research, reproductive justice, and civil rights organizations, among others,[27] HHS published a final rule on March 4, 2019 (the 2019 rule), without significant changes.[28]

More than twenty states, NFPRHA, the American Medical Association, Planned Parenthood Federation of America, and multiple Title X grantees immediately challenged the 2019 rule,[29] but it went into effect nationwide as of July 15, 2019.[30] In response, many grantees began to withdraw from Title X rather than be forced to comply with the 2019 rule's requirements. Although enjoined in Maryland since February 2020,[31] the 2019 rule was in effect

[26] Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (June 1, 2018).

[27] *See* Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7714, 7722–77 (Mar. 4, 2019).

[28] *See generally id.*

[29] *Washington v. Azar*, Nos. 1:19-cv-3040-SAB, 1:19-cv-3045-SAB (E.D. Wash.), No. 19-35394 (9th Cir.); *Oregon v. Azar*, Nos. 6:19-cv-317-MC, 6:19-cv-318-MC (D. Or.), No. 19-35386 (9th Cir.); *California ex rel. Becerra v. Azar*, Nos. 19-cv-1184-EMC, 19-cv-1195-EMC (N.D. Cal.), Nos. 19-15974, 19-15979 (9th Cir.); *Mayor of Baltimore v. Azar*, No. RDB-19-1103 (D. Md.), Nos. 19-1614, 20-1215 (4th Cir.); *Family Planning Ass'n of Me. v. Azar*, No. 1:19-cv-100-LEW (D. Me.), No. 20-1781 (1st Cir.).

[30] *See* Order on Mots. for Stay Pending Appeal, *California ex rel. Becerra v. Azar*, 927 F.3d 1068 (9th Cir. 2019) (per curiam); Order, *Mayor of Baltimore v. Azar*, 778 F. App'x 212 (4th Cir. 2019); *see also California ex rel. Becerra v. Azar*, 950 F.3d 1067, 1074 (9th Cir. 2020) (en banc) (vacating preliminary injunctions).

[31] *See Mayor of Baltimore v. Azar*, 973 F.3d 258, 266 (4th Cir. 2020) (en banc) (upholding lower court's injunction).

throughout the rest of the country until new regulations (challenged here) went into effect on November 8, 2021.[32]

The 2019 rule imposed numerous harmful restrictions and requirements. Most relevant here, the 2019 rule (1) replaced the requirement that Title X-funded providers offer nondirective counseling to pregnant patients on all options with provisions allowing providers to withhold information about abortion-related services,[33] prohibiting providers from giving patients referrals for abortion services,[34] and requiring providers to refer all pregnant patients for prenatal care, regardless of the patients' expressed wishes;[35] and (2) mandated that Title X-funded providers "maintain physical and financial separation from locations which provide abortion as a method of family planning."[36]

The 2019 rule thus interfered with the provider-patient relationship by mandating which options must be provided and which may not, regardless of patients' needs. It also imposed a demanding—and often impossible—requirement that Title X-funded projects "not share any infrastructure with abortion-related activities," no matter the cost to providers of making required changes.[37] To determine whether "objective integrity and independence" existed between Title X-funded projects and "prohibited activities," the 2019 rule granted HHS broad discretion to consider such factors as whether there were separate "treatment, consultation, examination and

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[32] Although the Supreme Court granted certiorari with respect to various challenges to the 2019 rule, the parties later agreed to dismiss the cases. *See Oregon v. Becerra*, 141 S. Ct. 2621 (2021).

[33] *See* 84 Fed. Reg. at 7724 (provider "*may* provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options") (emphasis added).

[34] *Id.* at 7762.

[35] *Id.* at 7747–78, 7788–89.

[36] *Id.* at 7715.

[37] *Id.* at 7774.

waiting rooms, office entrances and exits, . . . and websites," as well as "separate personnel, electronic or paper-based health care records, and workstations."[38]

Contrary to Plaintiffs' allegations and largely because of the changes outlined above, the 2019 rule had a damaging effect, creating significant gaps in the previously robust nationwide Title X network and leaving many patients around the country without access to Title X-funded services. The Title X program lost 19 grantees immediately and nearly 1,000 health centers overall due to the 2019 rule, or about one quarter of all Title X service sites.[39] Six states were left entirely without a Title X-funded provider network.[40] In California, the single-largest Title X project in the nation (before the 2019 rule) had 128, or 36 percent, of its service sites withdraw from the program, leaving more than 700,000 patients without access to Title X-funded care.[41] In New York, the number of Title X-funded service sites dropped from 174 to just two, leaving more than 300,000 patients without Title X-funded care.[42] All Planned Parenthood affiliates—

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[38] *Id.* at 7789.

[39] *See* Fowler et al., *supra* note 5, ES-5; *see also* Mia Zolna et al., *Estimating the impact of changes in the Title X network on patient capacity*, Guttmacher Inst., 2 (Feb. 5, 2020), https://www.guttmacher.org/sites/default/files/article_files/estimating_the_impact_of_changes_in_the_title_x_network_on_patient_capacity_2.pdf.

[40] Fowler et al., *supra* note 5, ES-5 (Hawaii, Maine, Oregon, Utah, Vermont, and Washington).

[41] *See Impact of the Title X Rule in California*, NFPRHA (July 2020), https://www.nationalfamilyplanning.org/file/2020-state-one-pagers-new/Impact-of-the-Title-X-Rule-in-California.pdf; Press Release, Cal. Att'y Gen. Xavier Becerra, *Attorney General Becerra Leads Coalition Seeking Supreme Court Review Against Trump-Pence Administration's Title X Family Planning Rule* (Oct. 6, 2020), https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-coalition-seeking-supreme-court-review-against; *compare* Fowler et al., *supra* note 5, B-4, *with* Christina Fowler et al., *Title X Family Planning Annual Report: 2018 National Summary*, OPA, B-4 (Aug. 2019), https://opa.hhs.gov/sites/default/files/2020-07/title-x-fpar-2018-national-summary.pdf.

[42] *See Impact of the Title X Rule in New York*, NFPRHA (July 2020), https://www.nationalfamilyplanning.org/file/2020-state-one-pagers-new/Impact-of-the-Title-X-Rule-in-New-York.pdf; *compare* Fowler et al., *supra* note 5, B-4, *with* Fowler et al., *supra* note 41, B-4.

which in 2015 had served 41 percent of all contraceptive clients at Title-X funded health centers[43]—withdrew from Title X due to the 2019 rule.

Ultimately, the 2019 rule caused approximately 1.5 million patients to lose access to Title X-funded services.[44] Despite the claim that the 2019 rule would lead new entities to apply for Title X funding and result in "more clients being served,"[45] the reality was far different, and HHS struggled to recruit additional grantees. In September 2019, HHS announced $33.6 million in supplemental awards to 50 Title X grantees, to be drawn from funds relinquished by withdrawn grantees.[46] At that time, HHS asserted that "the supplemental awards will enable grantees to come close to—if not exceed—prior Title X patient coverage,"[47] presumably during the six-month duration of the awards. But by the end of 2019, after the 2019 rule had been in effect for about five months and halfway through the supplemental funding period, Title X had served 21 percent *fewer* users (*i.e.*, people), a decrease of more than 844,000—and those numbers continued to decrease in 2020.[48]

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[43] Jennifer J. Frost et al., *Publicly Funded Contraceptive Services at US Clinics, 2015*, Guttmacher Inst., 1, 18 (Apr. 2017), https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf.

[44] Fowler et al., *supra* note 5, ES-4. Of the 2.4 million fewer patients Title X-funded providers saw between 2018 and 2020, OPA attributes the remaining decrease of 877,354 patients to the COVID-19 pandemic. *Id.* at ES-6, D-5.

[45] 84 Fed. Reg. at 7723.

[46] Press Release, HHS, *HHS Issues Supplemental Grant Awards to Title X Recipients* (Sept. 30, 2019), https://opa.hhs.gov/about/news/grant-award-announcements/hhs-issues-supplemental-grant-awards-title-x-recipients.

[47] *Id.*

[48] *See* Christina Fowler et al., *Title X Family Planning Annual Report: 2019 National Summary*, OPA, 9 (Sept. 2020), https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf; Fowler et al., *supra* note 5, ES-4. OPA distinguishes between "family planning user[s]," *i.e.*, the individuals served, and "family planning encounters," *i.e.*, the number of times an individual was served. *See, e.g.*, Fowler et al., *supra* note 5, 54.

HHS then released two competitive funding announcements for "areas of high need" in May 2020, intending to provide approximately $18 million through an estimated 10 grants to provide services in areas left without any Title X-funded services.[49] However, HHS was able to fund only $8.5 million to five grantees, four of which already were grantees with current projects and none of which provided services in the states that lost their entire Title X-funded network due to the 2019 rule.[50]

DISCUSSION

Seeking to reverse the 2019 rule's damage and reestablish a robust Title X network nationwide, HHS finalized new regulations on October 7, 2021 (the 2021 rule).[51] Before doing so, HHS considered extensive comments and decades' worth of evidence concerning the Title X program. Based on this considered process, the 2021 rule returns Title X to the regulatory framework that had facilitated the successful provision of high-quality, patient-centered family planning services for almost all of the program's 50-year history, with a few improvements and clarifications.

Contrary to Plaintiffs' assertions, Title X-funded providers operated effectively and in compliance with statutory requirements for decades before the 2019 rule, and the 2021 rule is essential to restoring nationwide access to Title X services for all patients no matter where they

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[49] *See* Grants Notice, HHS, *PA-FPH-20-001, FY2020 Title X Services Grants: Providing Publicly-Funded Family Planning Services in Areas of High Need* (May 29, 2020), https://www.grants.gov/web/grants/view-opportunity.html?oppId=323353; Grants Notice, HHS, *PA-FPH-20-002, FY2020 Title X Service Grants: Providing Publicly-Funded Family Planning Services in Areas of High Need—Maryland Service Area Only* (May 29, 2020), https://www.grants.gov/web/grants/view-opportunity.html?oppId=327358.

[50] *See* Press Release, OPA, *OPA Awards $8.5 Million in Grants to Family Planning Services in Unserved & Undeserved Areas* (Sept. 18, 2020), https://opa.hhs.gov/about/news/grant-award-announcements/opa-awards-85-million-grants-family-planning-services-unserved.

[51] 86 Fed. Reg. at 56,144.

live—especially low-income patients. HHS properly reached this conclusion, and the Court should deny Plaintiffs' motion to enjoin the 2021 rule.

A. The 2021 Rule Reinstates Regulations that Ensure Patients Receive Equal Access to High-Quality Care

Recognizing that the harms caused by the 2019 rule "must be rectified with urgency in the interest of public health and equity,"[52] HHS drew on decades of experience and expertise administering the Title X program to issue the 2021 rule. HHS "essentially readopt[ed] the 2000 regulations . . . [, which] were consistent with applicable statutory commands, were widely accepted by grantees, enabled the Title X program to operate successfully, and led to no litigation over their permissibility."[53]

The 2021 rule thus restores Title X's commitment to ensuring patients' equal access to high-quality family planning medical services. At base, the 2021 rule removes unnecessary, inefficient, and cost-prohibitive separation requirements for Title X-funded providers; restores patients' access to nondirective pregnancy counseling, a core family planning service; allows Title X-funded providers to respond appropriately to each patient's individual needs and questions; and prohibits providers from directing patients toward information and services that are not welcome.

1. *Eliminating the 2019 Rule's Strict Physical- and Financial-Separation Requirements Will Allow Title X Grantees to Operate Effectively and Restore the Robust Title X Network Nationwide*

In promulgating the 2021 rule, HHS reviewed decades of evidence showing that the 2019 rule's burdensome separation requirements were a solution in search of a problem.[54] "[T]he 2019

[52] *Id.* at 56,148.

[53] *Id.*

[54] *See id.* at 56,145.

rule could point to no significant compliance issues related to the diversion of Title X grant funds," and "close oversight of Title X grantees for almost two decades under the 2000 rule uncovered no misallocation of Title X funds by grantees" and no improper co-mingling of funds with prohibited activities.[55]

The 2021 rule will allow former and new grantees to fill the gaps in Title X coverage caused by the 2019 rule's unnecessary separation requirements. The 2019 rule imposed enormous compliance costs on grantees—such as needing to build separate facilities, hire new personnel, and create and maintain separate health records[56]—but also created significant uncertainty regarding what would satisfy the requirements. In a comment responding to the 2021 NPRM, NFPRHA explained that under the 2019 rule, "those charged with implementation—both inside and outside HHS—had no clear, discernable standard that could be readily summarized, consistently applied, and objectively enforced," and "[i]ndeed, when grantees inquired of HHS, they were sometimes given different answers to the same implementation

[55] *Id.* at 56,150. OPA only "identif[ied] occasional instances over the years where grantees needed to update their written policies to clearly reflect the Title X statutory language." *Id.*

[56] Although HHS estimated that "it would cost between $10,000 and $30,000 per site 'to come into compliance with physical separation requirements in the first year,'" these projections severely underestimated the actual costs of adjusting to the 2019 rule. Letter from Clare Coleman, President & CEO, NFPRHA, to Diane Foley, Deputy Assistant Secretary, OPA, 37 (July 31, 2018), https://www.nationalfamilyplanning.org/file/NFPRHA-Comments_07312018_FINAL.pdf. In fact, as NFPRHA explained in a comment to the 2018 NPRM, "[i]t would cost hundreds of thousands of dollars or more to locate and open a facility, staff it, purchase separate workstations, set up separate record-keeping systems, etc. . . . This physical transformation, moreover, does not include staffing and other operational costs, such as utilities and other overhead. Furthermore, [the analysis] ignores the ongoing, annual cost to entities to continue maintaining a separate facility, with its separate staffing and other numerous ongoing costs." *Id.*; *see also Mayor of Baltimore*, 973 F.3d at 282 ("[I]n some cases the physical separation provision would require clinics to hire new staff, engage in construction, and set up new bookkeeping methods, all of which would easily cost multiples of $30,000.").

questions, even when the facts and circumstances presented to HHS were the same."[57] The great costs of compliance and accompanying uncertainty were a significant part of why the 2019 rule resulted in the Title X program losing nearly one quarter of all service sites.

By eliminating the 2019 rule's unnecessary, onerous separation requirements that resulted not in increased compliance with section 1008 (particularly given the lack of noncompliance) but instead in a mass exodus of Title X providers from the program, the 2021 rule will help restore a robust Title X network.

2. *Reinstating the Requirement of Nondirective Counseling and Referrals for Requested Services Better Serves Patients*

By reinstating the requirement that providers offer pregnant patients nondirective counseling on all their options, including referrals for such options upon request, and by eliminating the 2019 rule's requirement that providers refer *all* pregnant patients for prenatal services, regardless of their wishes, the 2021 rule recenters the patient in Title X. The 2019 rule directly contradicted Congress's requirements that family planning services in Title X "shall be voluntary"[58] and that pregnancy counseling "shall be nondirective,"[59] and also countermanded HHS's own Title X program guidelines, including the QFP. The 2021 rule realigns Title X with those directives.

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[57] Letter from Clare Coleman, President & CEO, NFPRHA, to OPA, 3 (May 17, 2021), https://www.nationalfamilyplanning.org/file/2021-Title-X-NPRM-NFPRHA-comments-FINAL.pdf. NFPRHA had warned of just this problem in its comment to the 2018 NPRM. Specifically, because the separation requirements were subjective, left to the interpretation of whatever Secretary was serving at any particular time, and based on a non-exhaustive list of factors, NFPRHA explained that the 2019 rule would "push effective family planning providers out of the Title X program, diminish patient access, and greatly destabilize what is now vital safety-net care." Letter from Clare Coleman, President & CEO, NFPRHA, to Diane Foley, Deputy Assistant Secretary, OPA, 14 (July 31, 2018).

[58] 42 U.S.C. § 300a-5.

[59] *See, e.g.*, 133 Stat. 2534, 2558.

The 2019 rule forced Title X-funded providers to choose between remaining in the program—but being required to provide incomplete care and counseling inconsistent with congressional and professional mandates—or forgoing Title X funds. The 2021 rule restores Title X's focus on health care quality and health equity, reflecting both federal law and clinical standards of care. As NFPRHA stated in its comments to the NPRM, the 2021 rule "puts patients' own stated needs at the heart of pregnancy counseling. It does not mandate the type of counseling, information, or referral pregnant people receive; rather, it ensures that pregnant people are provided the opportunity to receive counseling on all of their options, have their questions answered, and receive information relevant to whatever options they might choose, as well as receiving any referral they request."[60]

B. The 2021 Rule Is Necessary to Remedy the Public Health Harms Wrought by the 2019 Rule

HHS finalized the 2021 Rule in full compliance with statutory mandates and through a well-reasoned administrative process in which it considered extensive comments and evidence and came to sound conclusions regarding the 2019 rule's negative public health consequences and the 2021 rule's expected benefits. Plaintiffs' attempts to dismiss the data underlying HHS's conclusions should be rejected.

1. *HHS Properly Determined that the 2019 Rule Devastated the Title X Network and Harmed Patients*

Whether the 1.5 million patients who lost access to Title X-funded services because of the 2019 rule "simply transferred their care from a Title X provider to a non-Title X provider,"[61]

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[60] Letter from Clare Coleman, President & CEO, NFPRHA, to OPA, 13 (May 17, 2021).

[61] Combined Mot. Prelim. Inj. & Mem. Supp. Mot. (Pls.' Mot.) iii, ECF No. 2. Changing providers is often not a "simple" endeavor for any patient, let alone patients with low incomes. *See, e.g.*, Teresa A. Coughlin et al., *Many Insured Adults Report Problems Trying to Find New Health Care Providers*, Urban Inst. (Aug. 14, 2020), https://www.urban.org/urban-wire/many-

"are forgoing care altogether,"[62] or continued to receive services from the same (former Title X) provider, HHS's findings that the 2019 rule negatively impacted both the Title X program and public health are sound.

First, not all family planning care is equal: for example, a joint HHS-CDC study showed that Title X-funded health centers consistently outperform other publicly-funded providers in the provision of family planning care.[63] Compared with non-Title X-funded health care providers, Title X-funded sites provide higher quality care and are better able to help patients start and effectively use their chosen method of family planning.[64] These providers are more likely to provide the full range of FDA-approved contraceptives, including intrauterine devices (IUDs) and contraceptive implants, onsite.[65] In addition, many patients prefer accessing care through a

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insured-adults-report-problems-trying-find-new-health-care-providers (finding that, in 2019, even among adults with health insurance, "more than one in seven (15.5 percent) . . . reported difficulty finding a health care provider who would see them in the previous 12 months"); Off. of Disease Prevention & Health Promotion, HHS, *Family Planning*, https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning (outlining barriers to accessing family planning services, including "[c]ost of services," "clinic locations and hours that are not convenient for clients," and "[n]o or limited transportation").

[62] Pls.' Mot. 25.

[63] Marion W. Carter et al., *Four Aspects of the Scope and Quality of Family Planning Services in U.S. Health Centers: Results from a Survey of Health Center Administrators*, 94(4) J. Contraception 340, 340 (Oct. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6742436/.

[64] *See, e.g.*, Kinsey Hasstedt, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, 20 Guttmacher Pol'y Rev. 20, 21–22 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2002017.pdf; Kinsey Hasstedt, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net*, 20 Guttmacher Pol'y Rev. 12, 12–13 (2017), https://www.guttmacher.org/gpr/2017/01/understandingplanned-parenthoods-critical-role-nations-family-planning-safety-net.

[65] *See, e.g.*, Heike Thiel de Bocanegra et al., *Onsite Provision of Specialized Contraceptive Services: Does Title X Funding Enhance Access?*, 23(5) J. Women's Health 428, 431–32 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4011460/; *see also* Mia R. Zolna & Jennifer J. Frost, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, Guttmacher Inst. (Nov. 2016), https://www.guttmacher.org/sites/default/files/report_pdf/publicly-funded-family-planning-clinic-survey-2015_1.pdf.

specialized Title X provider.[66] HHS thus properly concluded that 1.5 million patients losing access to Title X-funded services constituted a negative impact to the program and public health.

Additionally, when Congress enacted Title X, it sought specifically to make high-quality medical services readily available throughout the country to low-income patients.[67] For example, Title X guarantees that patients with incomes at or below 100 percent of the federal poverty level receive services at no cost to them, and patients with incomes at or below 250 percent of the federal poverty level receive services at reduced cost.[68] By decreasing access to affordable, Title X-funded services, the 2019 rule undermined congressional intent and the purpose of Title X.

Finally, at least some patients who lost access to Title X-funded services because of the 2019 rule did *not* receive equivalent family planning services from the same or other providers. Grantees that withdrew from Title X due to the 2019 rule face a funding crisis as they try to continue providing quality care for low-income patients. While supplemental state and private funds were able to mitigate some of the impact of losing Title X funding for some former grantees, those grantees cannot rely on the continued availability of substitute funding.[69] And even where supplemental funds were available, the 2019 rule forced family planning facilities to scale back.[70] Nationwide, patients have experienced a reduction in services and hours, and providers have had to reduce staff and pass on costs, all of which negatively impact patient

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[66] Jennifer J. Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22(6) J. Women's Health Issues e519, e525 (Sept. 6, 2012), https://www.whijournal.com/action/showPdf?pii=S1049-3867%2812%2900073-4.

[67] H.R. Rep. No. 91-1472, at 10 (1970); 84 Stat. 1504.

[68] 42 U.S.C. § 300a-4; 42 C.F.R. §§ 59.5(a)(7), (a)(8). The 2021 federal poverty level is $12,880 in annual income for an individual and $21,960 for a family of three. Annual Update of the HHS Poverty Guidelines, 86 Fed. Reg. 7732, 7733 (Feb. 1, 2021).

[69] 86 Fed. Reg. at 56,169, 56,174.

[70] *Id.* at 56,174.

access to care.[71] As HHS explained, "the loss of Title X funding meant that organizations had to adjust their fee schedules and push more costs for services to the clients. As a result, organizations saw more clients forgoing recommended tests, lab work, [sexually transmitted infection (STI)] testing, clinical breast exams, and pap tests."[72] Some organizations also saw patients choosing less effective birth control methods due to the rising costs of care.[73]

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[71] *See, e.g.*, Marie Solis, *Financially reeling from Trump's Title X rules, abortion clinics won't see relief anytime soon*, Fortune (Mar. 23, 2021), https://fortune.com/2021/03/23/title-x-rules-trump-abortion-clinics-financial-relief/; Rebecca Anzel, *Aunt Martha's, Illinois' only Title X provider, awarded additional federal family planning dollars*, The Southern Illinoisan (updated Nov. 22, 2019), https://thesouthern.com/news/local/govt-and-politics/aunt-martha-s-illinois-only-title-x-provider-awarded-additional-federal-family-planning-dollars/article_95ca3ec6-dd16-5dfe-a332-513f123c8fb7.html ("Even with the increased grant [one provider] was awarded, Illinois family planning facilities are receiving $6.7 million less than they otherwise would have received in federal dollars."); Nakisa B. Sadeghi & Leana S. Wen, *After Title X Regulation Changes: Difficult Questions For Policymakers & Providers*, Health Affairs (Sept. 24, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190923.813004/full/ ("Two Planned Parenthood health centers in Cincinnati closed this month. In Minnesota, . . . a provider that serves patients in rural areas of the state[] is facing a 50 percent staff reduction. Some health centers opting out of Title X have said that they will make up the lost revenue through charging patients additional fees and limiting hours, barriers that could deter care."); Karen Pinchin, *With Planned Parenthood Out of Title X, Clinics Face "A Terrible Choice,"* WETA (Aug. 27, 2019), https://www.pbs.org/wgbh/frontline/article/with-planned-parenthood-out-of-title-x-clinics-face-a-terrible-choice/ ("For now, Washington's Title X-supported clinics are being funded from state coffers. Based on predictions by the state's health department, Washington projects it can maintain its current level of service until March 2020. After that, they're going to start considering reducing eligibility or narrowing the list of Title X-eligible services, which currently includes mammograms and testing for sexually transmitted infections."); Ariana Eunjung Cha & Sheila Regan, *Patients face higher fees and longer waits after Planned Parenthood quits federal program*, Wash. Post (Aug. 24, 2019), https://www.washingtonpost.com/business/2019/08/24/patients-face-higher-fees-longer-waits-after-planned-parenthood-quits-federal-program/ ("At the Planned Parenthood in Vienna, W.Va., employees boxed up various supplies, including birth control shots that had been purchased with Title X funds to be given to clients at no or low cost. In some cases, the clinic has had to write prescriptions that are now filled elsewhere, often at a significant cost to patients. Those able to wait have been rescheduled while the clinic tries to find other ways to get the supplies.").

[72] 86 Fed. Reg. at 56,147.

[73] *Id.*

2. *HHS Properly Determined that the 2019 Rule—Not the COVID-19 Pandemic—Primarily Caused the Harm to the Title X Network*

While Plaintiffs acknowledge the losses to the Title X network following the 2019 rule, they contend that HHS failed to adequately account for the COVID-19 pandemic's role in driving those losses.[74] This is also incorrect: HHS expressly considered the pandemic's impact and confirmed that the 2019 rule was the leading cause of the gaps in Title X coverage. Indeed, even before the pandemic began, 19 grantees withdrew from the Title X program, and nearly all (94%) of the decrease in Title X users between 2018 and 2019 is attributable to the 2019 rule's decimation of the Title X network.[75]

3. *HHS Properly Found that New and Existing Grantees Could Not Fill the Gaps in Coverage Caused by the 2019 Rule*

As previously detailed, HHS's attempts to recruit new Title X grantees under the 2019 rule were unsuccessful.[76] Despite the issuance of supplemental funding in 2019, most states did not see increases in the number of their Title X service sites. Indeed, under the 2019 rule, which governed for less than half of 2019, Title X providers still saw a decrease in patients in every region in the country except for what is called Region IV, which saw only a one percent increase in patients from 2018 to 2019.[77]

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[74] Pls.' Mot. 29.

[75] 86 Fed. Reg. at 56,146.

[76] *See supra* notes 46–50.

[77] Fowler et al., *supra* note 48, 9. In seven of the nine remaining regions, which saw decreases in patients, those losses were severe—between 20 and 36 percent. *Id.* Region IV, which saw an increase of 6,375 users from 2018 to 2019, consists of Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. *Id.* at 3, 9.

4. *HHS Properly Considered the Benefits and Harms of Both the 2019 and 2021 Rules to Determine that the 2021 Rule Will Improve Patient Access and Public Health Outcomes*

Plaintiffs further claim that HHS failed to quantify the public health *benefits* of the 2019 rule, as well as the harms threatened by the 2021 rule.[78] Again, not so. In fact, Plaintiffs do not identify any specific, non-speculative benefits of the 2019 rule for which HHS failed to account.[79] And the only specific public health harm that Plaintiffs allege will result from the 2021 rule is that "providing Title X services through abortion providers might have encouraged riskier sexual behavior that was bad for public health," based on a study from the CDC showing that sexually transmitted infections peaked in the United States in 2018.[80] However, without any causal evidence linking the 2000 rule to this statistic, Plaintiffs' speculative assertion does not reasonably demonstrate that the 2021 rule threatens increased rates of STIs.

CONCLUSION

For the foregoing reasons and those outlined in HHS's opposition, the Court should deny Plaintiffs' motion to enjoin the 2021 rule.

Dated: November 29, 2021

Respectfully submitted,

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[78] Pls.' Mot. 27.

[79] *See id.*

[80] *Id.* at 28.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and accurate copy of the foregoing has been served on all parties via their counsel of record through the Court's ECF system this 29th day of November 2021.

/s/ Lisa Pierce Reisz
Lisa Pierce Reisz