Case No. 21-4235

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

STATE OF OHIO, e*t al.*,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, *et al.*,

Defendants-Appellees.

On Appeal From the United States District Court
For the Southern District of Ohio

THE NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION'S BRIEF AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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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 that 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 per year. NFPRHA's 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[1] 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,

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), NFPRHA states that no party's counsel authored the brief in whole or in part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person outside of NFPRHA, its members, or its counsel contributed money intended to fund preparing or submitting this brief. Plaintiffs-Appellants and Defendants-Appellees have consented to the filing of this brief.

affordable, voluntary, client-centered family planning services; (3) how the Department of Health and Human Services' (HHS's) recent regulatory changes[2] are necessary to restore the Title X network nationwide; and (4) why an injunction would harm public health and curtail patient access to family planning services.

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 serve patients regardless of income, the statute requires that priority be given to low-income

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

[3] *See* 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).

patients.[5] The Title X program disproportionately serves people with low incomes, young people, and people of color.[6] For many women, Title X-funded health centers are their only source of medical care.[7]

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

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[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, Fowler et al., *supra* note 5, at 25, and 56 percent were under age 30, *id.* at 12. 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] For example, a study found that 60 percent of women who received contraceptive services from a Title X-funded health center in 2016 had no other source of medical care in the prior year. Megan L. Kavanaugh et al., *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X-Funded Facilities in 2016*, 50 Pers. on Sexual & Reprod. Health 101, 105 (Sept. 2018), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12061.

[8] 42 U.S.C. § 300(a).

[9] 42 U.S.C. § 300a-6.

HHS's Office of Population Affairs (OPA) administers Title X,[10] including overseeing grantees' compliance with the program's requirements. Beginning in 2014, OPA's program guidelines incorporated U.S. clinical standards for family planning (the "QFP," short for quality family planning), developed by OPA and the Centers for Disease Control and Prevention (CDC).[11] 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 HHS issued new Title X regulations in 2019, OPA used the QFP to monitor and evaluate Title X grantees.

A Title X "project" or "program"[12] refers not to a physical space or entity but to a set of proposed family planning activities that are described in detail in a

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[10] Angela Napili, Cong. Research Serv., RL33644, *Title X (Public Health Service Act) Family Planning Program*, 22 (2017), https://sgp.fas.org/crs/misc/RL33644.pdf.

[11] *See Program Requirements for Title X Funded Family Planning Projects*, OPA, 5 (Apr. 2014), https://opa.hhs.gov/sites/default/files/2021-03/title-x-program-requirements-april-2014.pdf. The CDC and OPA updated the QFP in 2016 and 2017. *See* Loretta Gavin et al., *Update: Providing Quality Family Planning Services—Recommendations from CDC and the US Office of Population Affairs, 2015*, 65(9) MMWR 231 (Mar. 11, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf; Loretta Gavin et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, 63(4) MMWR 1 (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf, *updated*, 66(50) MMWR 1383 (Dec. 22, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6650a4-H.pdf.

[12] The terms "project" and "program" may be used interchangeably. *See* Order, RE 50, Page ID # 661–62; 42 U.S.C. § 300a-4.

grantee's application for funding.[13] A Title X project includes the (1) grantee, (2) subrecipients (if any), and (3) individual health centers, also referred to as service sites, run by either grantees or subrecipients. Title X-funded providers operate like other outpatient medical providers, and as such, entities that also provide other health care services, including abortion care—without Title X funds and outside their Title X-funded projects, though sometimes under the same roof—have participated in Title X as grantees, subrecipients, and service sites throughout its history.

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

For almost the entirety of the program's existence, HHS has directed Title X-funded projects to offer nondirective pregnancy counseling and, when requested, referrals for abortion-related services.[14] Before 2019, the only time HHS strayed from this longstanding framework was in 1988, when it issued regulations (known

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[13] *See, e.g.*, *Notice of Funding Opportunity: Title X Family Planning Services Grants*, OPA, 40, https://www.grantsolutions.gov/gs/preaward/previewPublicAnnouncement.do?id=95156 (last visited Mar. 31, 2022) (grantees "may only use award funds to support activities outlined in the approved project plan").

[14] *See* Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7464, 7464 (Feb. 5, 1993) (reinstating 1981 guidelines requiring nondirective counseling for abortion services upon patient request). Before 1981, HHS permitted rather than required such counseling and referrals. *See* Mem. from Carol C. Conrad, Office of the Gen. Counsel, Dep't of Health, Educ. & Welfare, to Elsie Sullivan, Assistant for Info. & Educ., Office of Family Planning, Bureau of Cmty. Health Servs. (Apr. 14, 1978) (cited by *Family Planning Ass'n of Me. v. HHS*, 404 F. Supp. 3d 286, 292 n.7 (D. Me. 2019)); *see also* Order, RE 50, Page ID # 647–48.

as the "Gag Rule") that prohibited offering abortion-related information or referrals, regardless of a patient's wishes, and imposed strict physical-separation requirements between Title X-funded projects and any abortion-related activities.[15] Although the Supreme Court in 1991 upheld the Gag Rule as a "permissible construction of Title X,"[16] it was never implemented nationwide.[17]

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.[18] HHS simultaneously issued a notice of proposed rulemaking (NPRM) to revoke the Gag Rule and return to the pre-1988 regulations and compliance standards.[19] When HHS finalized those regulations in 2000 (the 2000 rule), it also formalized its previous interpretation that

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[15] 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).

[16] *Rust v. Sullivan*, 500 U.S. 173, 203 (1991).

[17] Although the *Rust* Court upheld the Gag Rule, confusion remained about the regulations governing the Title X program, and the Gag Rule continued to be litigated. *See* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,271 (July 3, 2000). 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. S. Doc. No. 102-28 (1992).

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

[19] 58 Fed. Reg. at 7464.

the prohibition against using Title X funds "in programs where abortion is a method of family planning" applied only to activities within a Title X project and not to the provider generally.[20] Additionally, in every annual HHS appropriations act since 1996, Congress has directed that "amounts provided to [Title X] projects . . . shall not be expended for abortions, [and] all pregnancy counseling shall be *nondirective*."[21] Consistent with Title X, the appropriations riders, and the 2000 rule, Title X grantees have for almost the entirety of the program offered patients "complete, accurate and unbiased information on all pregnancy options—including parenting, adoption and abortion—and [provided] referrals for additional services as needed,"[22] but have not used Title X funds to provide abortion services.

C. The 2019 Regulatory Changes Devastated the Title X Network

Although the 2000 rule "w[as] consistent with applicable statutory commands, w[as] widely accepted by grantees, enabled the Title X program to operate successfully, and led to no litigation over [its] permissibility" for more than

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[20] 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).

[21] *See, e.g.*, Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321, 1321–221 (Apr. 26, 1996) (emphasis added); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182, 1570 (Dec. 27, 2020).

[22] Kinsey Hasstedt, *Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care*, 21 Guttmacher Pol'y Rev. 1 (Jan. 10, 2018), https://www.guttmacher.org/sites/default/files/article_files/gpr2100118.pdf.

18 years,[23] in 2019, HHS reinstated the majority of the 1988 Gag Rule, along with additional burdensome and unnecessary requirements and restrictions (the 2019 rule).[24] HHS enacted the 2019 rule over "the ethical concerns of literally every major medical organization in the country"[25] and other vigorous objections from leading medical, family planning, reproductive health, evidence-based research, reproductive justice, and civil rights organizations, among others.[26]

More than twenty states, NFPRHA, the American Medical Association, Planned Parenthood Federation of America, and multiple Title X grantees immediately challenged the 2019 rule,[27] but it went into effect nationwide as of July 15, 2019.[28] In response, a number of grantees and service sites began to withdraw

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[23] 86 Fed. Reg. at 56,148; *see also* Order, RE 50, Page ID # 651.

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

[25] *Mayor of Baltimore v. Azar*, 973 F.3d 258, 266 (4th Cir. 2020) (en banc).

[26] *See* 84 Fed. Reg. at 7722–77.

[27] *See 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.).

[28] *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).

from Title X rather than comply with the 2019 rule's requirements. Although enjoined in Maryland beginning in February 2020,[29] the 2019 rule was in effect throughout the rest of the country until new regulations (which Appellants challenge here) went into effect on November 8, 2021.[30]

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,[31] prohibiting providers from referring patients for abortion services,[32] and requiring providers to refer all pregnant patients for prenatal care, regardless of the patients' expressed wishes;[33] and (2) mandated that Title X-funded providers "maintain physical and financial separation from locations which provide abortion as a method of family planning."[34]

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[29] *See Mayor of Baltimore*, 973 F.3d at 266 (upholding lower court's injunction).

[30] 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).

[31] *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).

[32] *Id.* at 7762.

[33] *Id.* at 7747–78, 7788–89.

[34] *Id.* at 7715.

The 2019 rule interfered with the provider-patient relationship by mandating which options must be provided and which may not, regardless of patients' wishes and 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.[35] 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 waiting rooms, office entrances and exits, . . . and websites," as well as "separate personnel, electronic or paper-based health care records, and workstations."[36]

Largely because of the changes outlined above, the 2019 rule had a devastating effect, creating significant gaps in the previously robust Title X network and leaving many patients around the country without access to Title X-funded services. The Title X program lost 19 grantees and nearly 1,000 health centers overall due to the 2019 rule, or about one quarter of all Title X service sites.[37] Six

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[35] *Id.* at 7774.

[36] *Id.* at 7789.

[37] *See* Fowler et al., *supra* note 5, at 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.

states were left entirely without a Title X-funded provider network.[38] 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 in California without access to Title X-funded care.[39] 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.[40] All Planned Parenthood affiliates—which in

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[38] Fowler et al., *supra* note 5, at ES-5 (Hawaii, Maine, Oregon, Utah, Vermont, and Washington). Five of these states joined an *amicus* brief filed in the district court in support of HHS and in opposition to Appellants' motion for a preliminary injunction. *See* Brief for the States of California, New York, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, and Wisconsin, and the District of Columbia as Amici Curiae in Support of Defendants and in Opposition to Plaintiffs' Motion for a Preliminary Injunction, RE 28-1, Page ID # 370–98 (hereinafter "States' Amicus Br. Opp. Mot. Prelim. Inj.").

[39] *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, at 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. California joined the states' *amicus* brief filed in the district court supporting HHS and opposing Appellants' motion for a preliminary injunction. *See* States' Amicus Br. Opp. Mot. Prelim. Inj, RE 28-1, Page ID # 370–98.

[40] *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, at B-4,

2015 had served 41 percent of all contraceptive clients at Title-X funded health centers[41]—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.[42] Despite the claim that the 2019 rule would lead new entities to apply for Title X funding and result in "more clients being served,"[43] the reality was far different, and HHS struggled to recruit additional grantees.[44] 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.[45] At that time, HHS asserted that "the supplemental awards will enable grantees to come close to—if not exceed—prior Title X patient coverage,"[46] presumably during the six-month duration of the awards. But by the end of 2019, after the 2019 rule had been

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with Fowler et al., *supra* note 39, at B-4. New York joined the states' *amicus* brief filed in the district court supporting HHS and opposing Appellants' motion for a preliminary injunction. *See* States' Amicus Br. Opp. Mot. Prelim. Inj., RE 28-1, Page ID # 370–98.

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

[42] Fowler et al., *supra* note 5, at ES-4.

[43] 84 Fed. Reg. at 7723.

[44] Order, RE 50, Page ID # 653.

[45] 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.

[46] *Id.*

in effect for about five months and halfway through the supplemental funding period, Title X had served 21 percent *fewer* users (*i.e.*, people[47]), a decrease of more than 844,000—and those numbers continued to decrease in 2020.[48]

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 were already 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]

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[47] OPA distinguishes between "family planning user[s]," *i.e.*, the individuals served, and "family planning encounters," *i.e.*, the occasions individuals were served. *See, e.g.*, Fowler et al., *supra* note 5, at 54.

[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, at ES-4.

[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.

D. In 2021 HHS Reinstated the Previous Regulatory Framework to Undo the 2019 Rule's Damage

To reverse the 2019 rule's harm and reestablish patient access to a robust network providing high-quality family planning services nationwide, HHS finalized new regulations on October 7, 2021 (the 2021 rule),[51] which were largely modeled on the 2000 rule.[52] The 2021 rule, which has been in effect since November 8, reinstates the regulatory framework that had facilitated the successful provision of patient-centered family planning care for almost all of Title X's 50-year history, with a few improvements and clarifications.

Though Appellants never challenged the implementation of almost identical provisions in the 2000 rule,[53] they filed the instant lawsuit and moved to preliminarily enjoin the 2021 rule.[54] Finding that Appellants were unlikely to succeed on the merits of their claims and that they would not be irreparably harmed in the absence of a preliminary injunction, the district court denied Appellants' motion.[55] Likewise, a panel of this Court denied Appellants' motion to enjoin the 2021 rule pending this appeal on the grounds that Appellants failed to demonstrate

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

[52] *Id.*

[53] *See* Order, RE 50, Page ID # 651.

[54] *See* Compl., RE 1; Mot. Prelim. Inj., RE 2.

[55] *See* Order, RE 50. The district court also denied in a notation order Appellants' motion for an injunction pending appeal.

irreparable harm.[56] Now, Appellants challenge the district court's ruling, and in an attempt to avoid having to meet their burden of proving irreparable harm, invite this Court to usurp the district court's role and consider the merits of their claim for a permanent injunction of the 2021 rule.[57] For the reasons set forth in Appellees' brief,[58] this invitation should be declined, and for the reasons set forth in Appellees' brief and below, the Court should affirm the district court's denial of a preliminary injunction.

DISCUSSION

In issuing and finalizing the 2021 rule, HHS considered more than 500,000 comments and decades of evidence concerning Title X.[59] Based on this considered process, the 2021 rule returns Title X to the regulatory framework that had facilitated the successful and effective 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. The 2021 rule thus restores Title X's commitment to ensuring patients' equal access to high-quality family planning medical services. All in compliance with the Title X statute, the rule removes unnecessary, inefficient, and cost-prohibitive separation requirements for Title X-funded providers; restores

[56] Order 3, ECF No. 45-2.

[57] *See* Br. of Appellants 31, ECF No. 47.

[58] *See* Br. of Appellees 45–47, ECF No. 51.

[59] *See* 84 Fed. Reg. at 7722.

patients' access to nondirective pregnancy counseling, a core family planning service; allows Title X-funded providers to respond appropriately to each patient's needs and questions; and prohibits providers from directing patients toward information and services that are not welcome.

Continued implementation of the 2021 rule is critical to restore patient access to high-quality family planning services nationwide.[60] Enjoining the rule would again wreak havoc on the Title X program, and Appellants' assertions to the contrary are premised on fundamental mischaracterizations of the statute, the rule, and the 2019 rule's impact.

A. Continued Implementation of the 2021 Rule Is Essential to Restore the Title X Network and High-Quality Services Nationwide

In promulgating the 2021 rule, HHS reviewed decades of evidence showing that the 2019 rule's separation requirements were a solution in search of a problem.[61] "[T]he 2019 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

[60] *See* 86 Fed. Reg. at 56,148 (explaining that healthcare inequities "would be exacerbated by continuing to allow limited or delayed healthcare choices and biased or insufficient healthcare information" contemplated by the 2019 rule).

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

grantees" and no improper commingling of funds with prohibited activities.[62]

HHS thus appropriately determined that the 2019 rule unnecessarily imposed enormous compliance costs on grantees—such as needing to build separate facilities, hire new personnel, and create and maintain separate health records.[63] Further,

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[62] *Id.* at 56,150, 56,152. 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.* at 56,152. There is also no evidence to suggest significant compliance issues prior to the 1988 Gag Rule, despite Appellants' assertion that the Gag Rule responded to a 1982 HHS Office of the Inspector General (OIG) report finding "that grantees had insufficient guidance regarding what they could do or not" pursuant to section 1008 of Title X. Br. of Appellants 8–9 (citing Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion Is a Method of Family Planning; Standard of Compliance for Family Planning Services Project, 52 Fed. Reg. 33,210, 33,210 (Sept. 1, 1987)). Although the OIG report concluded that there was some "confusion" and "variations in practice by grantees," it did not directly find noncompliance with the Title X statute. *See* 52 Fed. Reg. at 33,210.

[63] Although HHS, in issuing the 2019 rule, 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," those projections severely underestimated the actual costs of adjusting to the 2019 rule. Letter from Clare Coleman, President & CEO, NFPRHA, to Diane Foley, Deputy Assistant Sec'y, 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.").

because the 2019 rule granted HHS broad discretion in evaluating the adequacy of projects' separation from abortion services,[64] it created significant uncertainty regarding what would satisfy the requirements.[65] 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 questions, even when the facts and circumstances presented to HHS were the same."[66] These unnecessary requirements did nothing but help cause an exodus of qualified providers from the Title X program.

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[64] 84 Fed. Reg. at 7789 (listing factors such as separate "treatment, consultation, examination and waiting rooms, office entrances and exits, . . . websites . . . [,] personnel, electronic or paper-based health care records, and workstations").

[65] *See* 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 (explaining that "those charged with implementation—both inside and outside HHS—had no clear, discernable standard that could be readily summarized, consistently applied, and objectively enforced").

[66] *Id.* 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, *supra* note 63, at 14.

By restoring the requirement that providers offer pregnant patients nondirective counseling on all their options and referrals on 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. As NFPRHA stated in its comments to the NPRM, the 2021 rule "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*."[67] The 2021 rule also fully re-implements the QFP, the nationally recognized standards of care for the provision of family planning services, to govern the Title X program, ensuring that providers offer medical services in line with best practices.

The 2021 rule therefore restores the purpose and promise of the Title X program. Enjoining it would harm public health, be inconsistent with national best practices for quality family planning services, and directly violate Congress's requirements that Title X-funded services "shall be voluntary"[68] and that pregnancy counseling "shall be nondirective."[69] Regressing to lower standards of care would

[67] Letter from Clare Coleman, *supra* note 65, at 13 (emphasis added).

[68] 42 U.S.C. § 300a-5.

[69] *See, e.g.*, 134 Stat. at 1570.

prevent patients from accessing appropriate, individualized care and perpetuate the extensive public health harms of the 2019 rule.

B. Enjoining the 2021 Rule Would Perpetuate the 2019 Rule's Harms to Public Health

An injunction of the 2021 rule would cause significant harm to public health by perpetuating the decimation of the Title X network under the 2019 rule. Not all family planning care is equal, and HHS properly concluded that 1.5 million patients losing access to Title X-funded services under the 2019 rule constituted a negative impact to the program and to public health. For example, a joint HHS-CDC study conducted prior to the issuance of the 2019 rule showed that Title X-funded health centers consistently outperform other publicly-funded providers in the provision of family planning care.[70] Compared with health care providers not funded by Title X, Title X-funded health centers are better able to help patients start and effectively use their chosen method of family planning.[71] For example, these providers are more

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[70] Marion W. Carter et al., *Four Aspects of the Scope and Quality of Family Planning Services in US Publicly Funded 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/.

[71] *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/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program; 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/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

likely to provide the full range of FDA-approved contraceptives, including intrauterine devices (IUDs) and contraceptive implants, onsite.[72] In addition, many patients prefer accessing care through a specialized Title X provider.[73]

Additionally, by decreasing access to affordable, Title X-funded services, the 2019 rule undermined congressional intent and the purpose of Title X. When Congress enacted Title X, it sought specifically to make high-quality medical services readily available throughout the country to low-income patients.[74] 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

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[72] *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.

[73] 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.

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

reduced cost.[75] Accordingly, the loss of access to Title X-funded services caused by the 2019 rule was particularly harmful to the low-income patients that Congress intended to help through Title X.

Finally, grantees that withdrew from the program because of the 2019 rule faced a funding crisis as they tried to continue providing quality care. 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.[76] In Washington, for example, although former grantees received state subsidies to remain operational, those funds quickly dwindled, leaving family planning providers in peril.[77] In an effort to keep providing the same level of care to patients, some former grantees and subrecipients have been forced to draw from their own operating budgets or reserves to cover shortfalls.[78]

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[75] 42 U.S.C. § 300a-4; 42 C.F.R. §§ 59.5(a)(7), (a)(8). The 2022 federal poverty level for the 48 contiguous states and the District of Columbia is $13,590 in annual income for an individual and $23,030 for a family of three. Annual Update of the HHS Poverty Guidelines, 87 Fed. Reg. 3315, 3316 (Jan. 21, 2022).

[76] 86 Fed. Reg. at 56,169, 56,174.

[77] 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/.

[78] *See* 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/.

And even where supplemental funds were available, the 2019 rule forced family planning facilities to scale back.[79] Nationwide, patients have experienced a reduction in services and hours, and some providers have had to reduce staff and pass on costs, all of which negatively impact patient access to care.[80] As HHS explained when issuing the 2021 rule, "the loss of Title X funding meant that organizations had to adjust their fee schedules and push more costs for services to

[79] 86 Fed. Reg. at 56,174.

[80] *See, e.g.*, 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."); 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-waitsafter-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.").

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."[81] Some organizations also saw patients choosing less effective birth control methods due to the rising costs of care.[82]

CONCLUSION

For the foregoing reasons and those outlined in Appellees' brief, the Court should affirm the district court's denial of Appellants' motion for a preliminary injunction of the 2021 rule.

[81] 86 Fed. Reg. at 56,147.

[82] *Id.*

Dated: March 31, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies, in accordance with Rule 32(g)(1) of the Federal Rules of Appellate Procedure, that this amicus brief complies with the type-volume requirements and contains 5,952 words. *See* Fed. R. App. P. 29(a)(5).

The undersigned further certifies that this brief complies with the typeface requirements of Federal Rule 32(a)(5) and the type-style requirements of Federal Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

/s Alyssa M. Howard
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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 31st day of March 2022.

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