Case No. 21-4235

IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

STATE OF OHIO, et 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 OPPOSING APPELLANTS' MOTION FOR INJUNCTION PENDING APPEAL

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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 a 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* brief¹ 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; (3) how the

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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.

Department of Health and Human Services' (HHS's) recent regulatory changes are necessary to restore the Title X network nationwide;² 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 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 Although Title X-funded projects serve patients regardless of income, the statute requires that priority be given to low-income patients.⁴ The Title X program disproportionately serves people with low incomes, young people, and people of color.⁵

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 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.

⁵ Fowler et al., *supra* note 4, at 25; 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.

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

HHS's Office of Population Affairs (OPA) administers Title X,⁸ including overseeing grantees' compliance with statutory requirements and national standards of clinical care. Beginning in 2014, OPA's program guidelines incorporated US clinical standards for family planning (the "QFP," short for quality family planning), developed by OPA and the Centers for Disease Control and Prevention (CDC).⁹ 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.

⁶ 42 U.S.C. § 300(a).

⁷ *Id.* § 300a-6.

⁸ Angela Napili, CRS, *Title X (Public Health Service Act) Family Planning Program*, 22 (Aug. 31, 2017), https://sgp.fas.org/crs/misc/RL33644.pdf.

⁹ 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., 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.

A Title X "project" or "program" 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. A Title X project typically includes the (1) grantee, (2) subrecipient (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 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 referrals for abortion-related services when requested. Before 2019, the only time HHS strayed

 $^{^{10}}$ The terms "project" and "program" may be used interchangeably. See Order, RE 50, Page ID # 661–62; 42 U.S.C. \S 300a-4.

¹¹ See, e.g., Notice of Funding Opportunity: Title X Family Planning Services Grants, OPA, 40, https://www.grantsolutions.gov/gs/preaward/previewPublicAnno uncement.do?id=95156 (last visited Jan. 19, 2022) (grantees "may only use award funds to support activities outlined in the approved project plan").

¹² 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. &

from this longstanding framework was in 1988, when it issued regulations (known as the "Gag Rule") that prohibited offering abortion-related information or referrals, regardless of a patient's wishes,¹³ and imposed strict physical-separation requirements between Title X-funded projects and any abortion-related activities.¹⁴ Although the Supreme Court in 1991 upheld the Gag Rule as a "permissible construction of Title X,"¹⁵ it was never implemented nationwide.¹⁶

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.¹⁷ HHS simultaneously issued a notice of proposed rulemaking (NPRM) to revoke the Gag Rule and return to the pre-1988 regulations and compliance standards.¹⁸ When HHS finalized those

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.

¹³ 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).

¹⁴ *Id*.

¹⁵ Rust v. Sullivan, 500 U.S. 173, 203 (1991).

¹⁶ See Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270, 41,271 (July 3, 2000).

¹⁷ Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7462, 7462 (Feb. 5, 1993).

¹⁸ 58 Fed. Reg. at 7464.

regulations in 2000, it also formalized its previous interpretation that 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. 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*." 20

C. 2019 Regulatory Changes Devastated the Title X Network

Although the 2000 rule's "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 18 years, ²¹ in 2019, HHS reinstated the majority of the 1988 Gag Rule along with additional burdensome and unnecessary requirements and restrictions (the 2019 rule). ²² HHS enacted the 2019 rule over the vigorous objections of leading medical, family planning, reproductive health, evidence-based research, reproductive justice,

¹⁹ 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).

²⁰ 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).

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

²² See Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7714, 7722–77 (Mar. 4, 2019).

and civil rights organizations, among others. 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,²³ prohibiting providers from referring patients for abortion services,²⁴ and requiring providers to refer all pregnant patients for prenatal care, regardless of patients' expressed wishes;²⁵ and (2) mandated that Title X-funded providers "maintain physical and financial separation from locations which provide abortion as a method of family planning."²⁶

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.²⁷

Largely because of the changes outlined above, the 2019 rule devastated the previously robust Title X network, which lost 19 grantees when the rule went into

²³ See id. at 7724 (provider "may provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options") (emphasis added).

²⁴ *Id.* at 7762.

²⁵ *Id.* at 7747–78, 7788–89.

²⁶ *Id.* at 7715.

²⁷ *Id.* at 7774.

effect and nearly 1,000 health centers overall—about one quarter of all Title X service sites.²⁸ Six states were left entirely without a Title X-funded provider network.²⁹ Ultimately, the 2019 rule caused approximately 1.5 million patients to lose access to Title X-funded services.³⁰

Despite the claim that the 2019 rule would lead new entities to apply for Title X funding and result in "more clients being served,"³¹ the reality was far different, and HHS struggled to recruit additional grantees.³² 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.³³ At that time, HHS asserted that "the supplemental awards will enable grantees to come close to—if not exceed—prior Title X patient coverage,"³⁴ presumably during the six-month duration of the

²⁸ See Fowler et al., supra note 4, 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/estima ting_the_impact_of_changes_in_the_title_x_network_on_patient_capacity_2.pdf.

²⁹ Fowler et al., *supra* note 4, at ES-5 (Hawaii, Maine, Oregon, Utah, Vermont, and Washington).

³⁰ *Id.* at ES-4.

³¹ 84 Fed. Reg. at 7723.

 $^{^{32}}$ Order, RE 50, Page ID # 653.

³³ 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.

 $^{^{34}}$ *Id*.

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 2020.³⁵

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. 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. The states that lost their entire Title X-funded network due to the 2019 rule.

³⁵ 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 4, at ES-4. 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 4, at 54.

³⁶ 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.

³⁷ 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-

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

To reverse the 2019 rule's damage and reestablish patient access to high-quality family planning services nationwide, HHS finalized new regulations on October 7, 2021 (the 2021 rule),³⁸ which were largely modeled on the 2000 rule.³⁹ 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 similar provisions in the 2000 rule,⁴⁰ they filed suit and moved to preliminarily enjoin the 2021 rule on October 25.⁴¹ The district court denied the motion,⁴² and Appellants now move to enjoin the rule pending their appeal of that order.⁴³

million-grants-family-planning-services-unserved.

³⁸ 86 Fed. Reg. 56,144.

³⁹ *Id*.

⁴⁰ See Order, RE 50, Page ID # 651.

⁴¹ See Compl., RE 1; Mot. Prelim. Inj., RE 2.

⁴² See Order, RE 50. The district court also denied Appellants' motion for an injunction pending appeal in a notation order.

⁴³ Appellants' Mot. for Inj. Pending Appeal (App. Mot.).

DISCUSSION

HHS drew on decades of experience, evidence, and expertise administering Title X to issue the 2021 rule. 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 needs; and prohibits providers from directing patients toward information and services that are not welcome, all in compliance with the Title X statute.

Continued implementation of the 2021 rule is critical to restore patient access to high-quality family planning services nationwide.⁴⁴ Enjoining the rule would again wreak havoc on the Title X program, and Appellants' assertions to the contrary are premised on a fundamental misunderstanding of the statute and rule.

A. Reinstating the 2019 Rule's Strict Separation Requirements Even Temporarily Would Undermine Restoration of 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.⁴⁵

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⁴⁴ 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).

⁴⁵ See id. at 56,145.

"[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 grantees" and no improper co-mingling of funds with prohibited activities. 46

Appellants assert that "noncompliance would not have been detected under a lax detection regime," without acknowledging OPA's rigorous approach to monitoring compliance—including independent financial audits; yearly comprehensive financial and budget reviews; and periodic and comprehensive program reviews and site visits. Appellants instead presume the merits of their argument that Title X *must* be interpreted to require the 2019 rule's strict separation requirements and restrictions. However, as the district court correctly held, the

⁴⁶ *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.* 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. App. Mot. 3 (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.

⁴⁷ App. Mot. 17.

⁴⁸ See Napili, supra note 8, at 22.

⁴⁹ App. Mot. 17 (arguing that "the overlap of Title X funding and abortion saved abortion providers money" and "[t]hat is the compliance problem"); see also id. at

Title X statute is ambiguous, and HHS is entitled to deference on its statutory interpretation.⁵⁰

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.⁵¹ Further, because the 2019 rule granted HHS broad discretion in evaluating the adequacy of projects' separation from abortion services,⁵² it created significant uncertainty regarding what would satisfy the requirements.⁵³ These requirements therefore resulted not in increased compliance with Title X but instead in an exodus of providers from the Title X program. While the 2021 rule imposes reasonable

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⁵⁰ Order, RE 50, Page ID # 657–58; see also Rust, 500 U.S. at 184–85.

⁵¹ 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 Sec'y, OPA, 37 (July 31, 2018), https://www.nationalfamilyplan ning.org/file/NFPRHA-Comments 07312018 FINAL.pdf.

⁵² 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").

⁵³ 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").

financial separation requirements that comply with Title X and provides specific guidelines for Title X-funded projects that share facilities with abortion service providers—such as pro-rated designation of costs for common waiting rooms and proper allotment of salaries for common staff⁵⁴—enjoining the 2021 rule would reimpose the 2019 rule's unnecessary and burdensome requirements and further delay restoration of a robust Title X network.

B. Enjoining the 2021 Rule Would Prevent Providers from Centering Patients' Wishes and Needs

The 2021 rule recenters the patient in Title X by again requiring 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. 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*."55

⁵⁴ 65 Fed. Reg. at 41,282.

⁵⁵ Letter from Clare Coleman, President & CEO, NFPRHA, to OPA, *supra* note 53, at 13 (emphasis added).

Enjoining the 2021 rule and reimposing the 2019 rule would directly violate Congress's requirements that Title X-funded services "shall be voluntary" and that pregnancy counseling "shall be nondirective," in addition to being inconsistent with HHS's own guidelines for quality family planning services.

CONCLUSION

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

Dated: January 21, 2022 Respectfully submitted,

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⁵⁶ 42 U.S.C. § 300a-5.

⁵⁷ See, e.g., 134 Stat. at 1570.

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