

MEMORANDUM

TO: Interested Parties

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RE: Title X Family Planning Recommendations: Making It Right

Executive Summary

Family planning is one of the most important public health achievements of the 20th century,² and Title X is the only federal program dedicated to supporting this critical public health imperative. Nevertheless, in 2019, the Trump administration promulgated regulations³ that have had a devastating impact on Title X grantees and the people they serve. The “Trump Rule” caused family planning providers in 34 states to leave the program and at least 1.5 million people, many of whom are low-income and vulnerable,⁴ to lose access to Title X-funded care.⁵ Particularly now in the midst of a national pandemic, it is essential that the Biden administration act swiftly to restore the nation’s Title X network. This memo outlines steps the Biden administration should take on Day 1 and within the first 30 days of the President’s term.

¹ This memo was written by the National Family Planning & Reproductive Health Association (NFPRHA) in conjunction with Margaret Dotzel, Catherine Duval, and Casey Trombley-Shapiro Jonas at Zuckerman Spaeder LLP. In addition to the Zuckerman team’s vast legal expertise, they have first-hand experience in health law, including administrative actions, litigation, and legislative and policy matters. Dotzel is former Acting General Counsel and Deputy General Counsel at the US Department of Health and Human Services (HHS), where she worked alongside former HHS General Counsel and current Zuckerman partner William B. Schultz. Duval led teams of lawyers at the Internal Revenue Service and then the Department of State responsible for investigations and oversight-related matters during the Obama administration.

² Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Family Planning*, 48 *Morbidity & Mortality Weekly Reports* No. 47, 1073–80 (Dec. 3, 1999), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm>.

³ *Compliance With Statutory Program Integrity Requirements*, 84 *Fed. Reg.* 7,714 (Mar. 4, 2019).

⁴ Vulnerable populations—such as racial and ethnic minorities, the chronically ill, and LGBTQ+ individuals—are those whose health and health-care issues may be exacerbated by social factors. See Laura Joszt, *5 Vulnerable Populations in Healthcare*, *Am. J. of Managed Care* (July 20, 2018), <https://www.ajmc.com/view/5-vulnerable-populations-in-healthcare>.

⁵ These figures were calculated by NFPRHA using data collected by NFPRHA and by the Office of Population Affairs and reflect the best information available when this white paper was drafted. See *Title X Family Planning Directory*, OPA (Aug. 2020), <https://opa.hhs.gov/sites/default/files/2020-09/title-x-family-planning-directory-august2020.pdf>; *Title X Family Planning Directory*, OPA (June 2019), <https://opa.hhs.gov/sites/default/files/2020-07/Title-X-Family-Planning-Directory-June2019.pdf>.

Policy Changes Needed

There are immediate steps the Biden administration can and should take to reverse the damage the Trump Rule has inflicted, none of which requires legislation. Specifically, the administration should do the following.

1. **Day 1: Executive Action.** President Biden should issue a presidential memorandum⁶ directing the Department of Health and Human Services (HHS) to (a) immediately take all lawful steps to cease applying the Trump Rule; (b) undertake emergency rulemaking within 30 days to rescind the Trump Rule and reinstate the regulations that previously governed Title X; and (c) fully re-implement the US clinical standards for family planning developed in partnership by the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs (OPA) (known as the “QFP,” short for quality family planning) for providers to follow. This could be done as a standalone action or as part of a broader executive action that addresses multiple issues.
2. **First 30 Days: Interim Final Rule and Re-Implementation of the QFP.**⁷ Following the issuance of the Day 1 executive action, HHS should be prepared as soon as possible to (1) issue an interim final rule (IFR) rescinding the Trump Rule and reinstating the regulations that previously governed Title X and (2) fully re-implement the QFP, which Title X-funded providers were evaluated against prior to the Trump Rule.⁸ In an ideal world, HHS would issue the IFR very soon after the President’s executive action, but in any event within 30 days.⁹ The IFR should provide an opportunity for comments, which would satisfy the Administrative Procedure Act’s (APA)

⁶ Issuing an executive order, rather than a presidential memorandum, may send the strongest signal, but it would also require a cost estimate from the White House Office of Management and Budget (the estimated regulatory cost here is less than \$100 million; a presidential memorandum would therefore not have such a requirement).

⁷ The IFR need not incorporate the QFP in the codified regulations; OPA previously relied on the QFP in its Title X program guidelines, so the IFR preamble language need only state that OPA will once more instruct grantees to provide services in a manner consistent with the QFP.

⁸ See *Program Requirements for Title X Funded Family Planning Projects*, OPA, 5 (Apr. 2014), <https://www.nationalfamilyplanning.org/document.doc?id=1462>; see also CDC, *Providing Quality Family Planning Services: Recommendations of CDC and the US Office of Population Affairs*, 63 *Morbidity & Mortality Weekly Report* No. 4 (Apr. 25, 2014), <https://www.cdc.gov/mmwr/pdf/rr/rr6304.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 *Morbidity & Mortality Weekly Report* No. 9, 231–234 (Mar. 11, 2016), <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6509a3.pdf>; Loretta Gavin et al., *Update: Providing Quality Family Planning Services—Recommendations from CDC and the US Office of Population Affairs, 2017*, 66 *Morbidity & Mortality Weekly Report* No. 50, 1383–1385 (Dec. 22, 2017), <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6650a4-H.pdf>.

⁹ If the President does not issue an executive action, HHS should still proceed with issuing an IFR.

procedural requirements once the comments are received and taken into account in a published final rule.¹⁰

3. **Award New Grants.** The current service grant period ends in March 2022, meaning that no new competitions for funding are set to run until late 2021. It is important not only to get Title X funds to those jurisdictions and providers that lost all or most of their funding due to the Trump Rule as soon as possible, but also to restore the integrity of the Title X program through a nationwide competition for Title X funding under the re-implemented program requirements and clinical standards of care.

Rationale and Process

It is essential for millions of patients' health generally and reproductive health specifically that the Biden administration swiftly restore the nation's Title X network, which provides needed health services to vulnerable populations. The need is particularly urgent in light of the escalating pandemic.

Rescission of the Trump Rule is necessary, relatively simple, and powerfully symbolic. A presidential memorandum issued on Day 1 would send a strong and immediate signal to the Title X community and the public at large that the new administration is prioritizing the health of at-risk communities, including their access to family planning and sexual health services. Upon issuance of the presidential memorandum, current Title X-funded providers could resume following the rules that existed prior to the Trump Rule, including the QFP, and HHS could use enforcement discretion to allow this to proceed. This would allow providers to begin mending some of the damage the Trump Rule wrought.

An IFR and subsequent final rule rescinding the Trump Rule and reinstating the regulations that previously governed Title X and which expressly reference and recognize the QFP as the standards by which HHS will evaluate Title X projects is incredibly important. As the Biden administration seeks to re-establish the preeminence of evidence and science in public health, requiring that Title X-funded clinical services are provided in a manner consistent with the QFP is essential to re-establishing trust in Title X-funded care.

In issuing the IFR, HHS could be guided in part by the actions taken by the Clinton administration. In 1993, HHS issued an interim rule suspending regulations HHS had promulgated in 1988—which, among other things, had prohibited Title X-funded providers from offering any abortion-related information or

¹⁰ See *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2384 (2020) (noting that, “[f]ormal labels aside,” the IFRs at issue “contained all of the elements of a notice of proposed rulemaking as required by the APA”). In *Little Sisters*, the United States Supreme Court considered challenges to exemptions HHS and other agencies had promulgated to the Affordable Care Act’s requirement that most employers provide contraceptive coverage as part of their health insurance plans. See *id.* at 2372–73. The government had issued IFRs, rather than using the traditional rulemaking process, to implement these exemptions, *id.* at 2374, and one of the bases for challenging the government’s actions was that the agencies had never published a proposed rule, but instead combined the IFR with a request for comment in “a document entitled ‘Interim Final Rules with Request for Comments,’” *id.* at 2384. The Court rejected the argument that this process rendered the final rule procedurally invalid, ruling that the relevant IFR was an adequate substitute for a proposed rule because it “contain[ed] ‘reference to the legal authority under which the rule is proposed’ and ‘either the terms or substance of the proposed rule or a description of the subjects and issues involved.’” *Id.* (quoting 5 U.S.C. § 553(b)(2)–(3)). The Court further ruled that “[e]ven assuming that the APA requires an agency to publish a document entitled ‘notice of proposed rulemaking’ when the agency moves from an IFR to a final rule, there was no ‘prejudicial error’ here.” *Id.* at 2385 (quoting 5 U.S.C. § 706). The Court found that “the Departments issued an IFR that explained its position in fulsome detail and provided the public with an opportunity to comment on whether the regulations should be made permanent or subject to modification.” *Id.* (internal alterations, quotation marks, and citations omitted).

referrals, regardless of the patient's wishes¹¹—and announcing that, “on an interim basis, the agency’s nonregulatory compliance standards that existed prior to February 2, 1988 . . . will be used to administer the Family Planning Program.”¹² The agency simultaneously issued a separate notice of proposed rulemaking (NPRM), proposing to revoke the 1988 regulations and return the Title X program to the compliance standards that existed prior to their implementation.¹³

The Biden administration should combine these steps into one, issuing one IFR that rescinds the Trump Rule and returns the Title X program to the compliance standards and program requirements operative prior to the Trump Rule. Thus, upon issuance of the IFR, the regulations finalized on July 3, 2000 would once again govern Title X.¹⁴

The IFR and full re-implementation of the QFP would in effect be a stop-gap measure, aimed only at returning to the conditions that existed before the Trump Rule came into effect. A regulation aimed toward making positive, forward-thinking changes to Title X could then be routed through the standard rulemaking process.¹⁵

Once the Trump Rule is rescinded and replaced with the previously governing Title X regulations and Title X-funded providers are once more permitted and expected to provide care in a manner consistent with the QFP, it is critical to get funding as quickly as possible to those jurisdictions the Trump Rule caused to lose all or a significant portion of their Title X funding and to ensure funding no longer flows to those providers that do not follow the CDC’s standards.

Moving up the grant competition currently scheduled for late 2021 would be the best way to get Title X funds to those areas in desperate need, but at a minimum, HHS should seek to issue a FOA aimed at getting short-term funding to those jurisdictions most in need.¹⁶ Creating a path for experienced grantees to regain funding as quickly as possible must be a top priority.¹⁷ Although entities that withdrew from

¹¹ See 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. 2,922, 2,927 (Feb. 2, 1988).

¹² Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7,462, 7,462 (Feb. 5, 1993).

¹³ Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7,464 (Feb. 5, 1993).

¹⁴ See Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270 (July 3, 2000). Where applicable, amendments to the regulations made after July 3, 2000 but prior to the Trump Rule should govern. All such amendments were non-substantive. See Federal Awarding Agency Regulatory Implementation of Office of Management and Budget’s Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Technical Amendments, 81 Fed. Reg. 3,004, 3,008 (Jan. 20, 2016); Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 49,057 (Aug. 10, 2000) (Corrections).

¹⁵ In addition to administrative actions to repair the damage done by the Trump Rule and to reinstate the pre-Trump era regulations and program requirements, an update to the Title X regulations is essential for the longer-term health and success of the program. An NPRM and final rule is not necessary in the first 30 days of a new administration but should be issued early enough to ensure that it can be finalized within four years.

¹⁶ If there is no current funding available to the Title X program, HHS could seek funding as part of COVID-19 or other emergency appropriations.

¹⁷ Nineteen Title X grantees, with service areas in 16 states, withdrew from the Title X program rather than comply with the Trump Rule. In the six states that lost all Title X services (Hawaii, Maine, Oregon, Utah, Vermont, and Washington State), six former grantees—which include four state agencies and two private nonprofits—stand ready to return to the program once the Trump Rule is revoked. In the six states that have been without one or more primary grantees since the summer of 2019 (Alaska, Connecticut, Illinois, Massachusetts, Minnesota, and New York), nine former grantees—three state agencies and six private nonprofits—would seek to return to the program. And in the three states that lost a grantee, leaving part of the state without

Title X due to the Trump Rule will be able to compete for grants for the project period scheduled to start in April 2022, a short-term FOA would help cover the interim period.

It is also possible HHS could run expedited grantmaking under an emergency designation, essentially making grants directly to former grantees.¹⁸ This path to grantmaking would have an abbreviated application process and a limited project term. Emergency grantmaking may be a viable path to providing initial funds to grantees in areas where there has been no Title X funding since the summer of 2019.

Conclusion

As the Biden administration seeks to bring the COVID-19 pandemic under control, restoring the Title X network and once more allowing Title X-funded providers to offer the best possible care to their patients will be essential. Title X-funded providers are disproportionately shouldering the burdens of the pandemic—medically as well as financially—while simultaneously shouldering the burdens of the havoc wrought by the Trump Rule, which will continue without immediate executive action. Fortunately, there are immediate and simple steps the Biden administration can—and should—take to begin to restore the Title X program and community.

any Title X services (Idaho, New Hampshire, and Ohio), three former grantees (private nonprofits) would seek to re-enter the program. See *HHS Issues Supplemental Grant Awards to Title X Recipients*, HHS (Sept. 30, 2019), <https://www.hhs.gov/about/news/2019/09/30/hhs-issues-supplemental-grant-awards-to-title-x-recipients.html>; see generally *Title X Family Planning Directory*, OPA (Sept. 2020), <https://opa.hhs.gov/sites/default/files/2020-10/title-x-family-planning-directory-september2020.pdf> (no service sites listed for Hawaii). OPA's most recent service grant FOAs, released on May 29, 2020, were for "areas of high need," which could serve as an example for targeted FOAs in 2021.

¹⁸ HHS has granted Title X funds under such an emergency designation at least once in the last decade, in 2011. See *N.H. Right to Life v. HHS*, 778 F.3d 43, 46–47 (1st Cir. 2015).