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Office of Population Affairs
Office of the Assistant Secretary for Health
US Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Attn: "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services (RIN 0937-AA11)

The Guttmacher Institute is pleased to provide comments to the U.S. Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services," RIN 0937-AA11.

The Guttmacher Institute (Guttmacher) is a private, independent, nonprofit, nonpartisan corporation that advances sexual and reproductive health and rights through an interrelated program of research, policy analysis, and public education. The Institute's overarching goal is to ensure quality sexual and reproductive health for all people worldwide through a deeply integrated approach to science and policy, standing as a source of highly regarded, trustworthy and valuable information on sexual and reproductive health and rights, and communicating evidence on these topics clearly to media, policymakers and advocates. Guttmacher began as the Center for Family Planning Development in the late 1960s and contributed research to Congress in its creation of Title X. In the early 2010s, Guttmacher experts were among those selected to participate in the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs' (OPA) development of the national standards of care for family planning services.

Guttmacher strongly supports HHS's NPRM revoking the 2019 Title X regulations (the Trump rule) and reinstating the 2000 regulations with some revisions. Once finalized, the proposed rule would return Title X to its proper focus on "making comprehensive voluntary family planning services readily available to all persons desiring such services."[1] Furthermore, because of the devastating impact of the 2019 Title X regulations on the program's provider network and its patients,[2] Guttmacher supports finalization of the proposed rule as quickly as possible, and respectfully urges a 30-day implementation period.

The Trump rule has extensively damaged the Title X network, and Guttmacher supports swift restoration of the previous rules and network.

The Guttmacher Institute agrees with HHS's statement in the NPRM that "the 2019 rule was a solution in search of a problem, a solution whose severe public health consequences caused much greater

[1] Public Law 91-572 ("The Family Planning Services and Population Research Act of 1970"), section 2(1).
[2] Zolna M, Finn S and Frost J, Estimating the impact of changes in the Title X network on patient capacity, New York: Guttmacher Institute, 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; *see also Title X Family Planning Directory*.

problems."[3] The Title X rule presented an impossible choice for providers and was devastating both for those entities that stayed in the program and for those entities that left. Entities that stayed in the Title X program have borne a heavy burden of adhering to the new requirements while maintaining access to care for patients. Many other providers exited the program, hobbling the Title X network during a time of compounding national and state assaults on contraceptive access.[4]

When the 2019 rule was implemented in August 2019, grantees immediately began to withdraw from Title X rather than comply with the Trump rule's requirements. Overall, as the proposed rule notes, the Title X program lost more than 1,000 service sites.[5] Those sites represented approximately one quarter of all Title X-funded sites in 2019.[6]

The impact of the gag rule on the network's capacity was much greater than it might appear when looking at clinic numbers alone, because the gag rule intentionally targeted clinics specializing in reproductive health care services, sites that also serve the highest volume of contraceptive patients. In fact, Guttmacher data estimate that the Trump rule slashed the capacity of the Title X provider network to serve female contraceptive patients by at least 46%, causing 1.6 million patients to lose access to Title X-funded services[7] (See Appendix A).

Nearly two years later, six states continue to have no Title X-funded provider network (Hawaii, Maine, Oregon, Utah, Vermont, and Washington)[8] and an additional six states have a very limited Title X-funded network (Alaska, Connecticut, Massachusetts, Minnesota, New Hampshire, and New York).[9] Despite the Trump administration's assertion that their rule would prompt new entities to apply for Title X funding and result in more people being served,[10] OPA has been unable to find new grantees to fill the gaps the Trump rule created, including in the six states that lost all Title X-funded services, and has served far fewer clients than in previous years.[11]

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[3] NPRM p. 19817.

[4] Dawson R, Trump administration's domestic gag rule has slashed the Title X network's capacity by half, Guttmacher Institute, 2020, https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half

[5] NPRM p. 19815.

[6] Zolna M, Finn S and Frost J, Estimating the impact of changes in the Title X network on patient capacity, New York: Guttmacher Institute, 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; *see also Title X Family Planning Directory*.

[7] Id.

[8] NPRM p. 19815.

[9] NPRM p. 19815.

[10] 84 Fed. Reg. at 7,723, https://www.federalregister.gov/documents/2019/03/04/2019-03461/compliance-with-statutory-program-integrity-requirements.

[11] OPA released two competitive FOAs for "areas of high need" on May 29, 2020, intending to provide approximately $18 million through an estimated 10 grants to provide services in areas left without any Title X-funded services. *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. The FOAs yielded only five grantees, four of which were 2019 grantees with current projects and none of which would be providing services in the six states that lost their entire Title X-funded provider network. *See* Press Release, OPA, *OPA Awards $8.5 Million in Grants to Family Planning Services in Unserved & Underserved Areas* (Sept. 18, 2020),

As HHS rightly asserts in the proposed rule, federal data show the rapid and devastating impact of the Trump rule on access to critical family planning and sexual health services. Title X saw 844,083 fewer patients in 2019 compared to 2018 (3.1 million vs. 3.9 million).[12] That dramatic 21% drop in patients came after less than half a year of the Trump rule being in effect. This decrease meant that providers offered 280,000 fewer cancer screenings, 1.3 million fewer sexually transmitted infection screenings, and 278,000 fewer confidential HIV tests. Additionally, hundreds of thousands of people lost access to contraceptive care (225,688 fewer clients received oral contraceptives, 49,803 fewer clients received hormonal implants, and 86,008 fewer clients received IUDs) due to the rule. The preliminary numbers for 2020 as shared in the proposed rule are even worse – only an estimated 1.5 million people received Title X-supported services in 2020, a loss of 2.5 million people from the network in just two years, a drop of about 62%.[13]

In a 2016 Guttmacher study, six in ten women seeking contraceptive services at a Title X-funded health center reported that to be their only source of medical care in the past year.[14] Thus, this kind of precipitous decline in patients receiving services through the Title X program has concerning implications for broader access to care.

Guttmacher has monitored service provision and impact of the Title X program in terms of numbers of patients served, need for contraceptive services met, and unintended sexual and reproductive health outcomes prevented for decades (including as a research grantee for OPA continuously from 1993-2016). Throughout the history of Title X, since its inception in 1970, there has never been as sharp a decline in the number of patients served by the program as occurred between 2018 and 2019. For example, between 1995 and 2018, there were annual increases or decreases in patient volume that varied between 0% and 9%, but nothing like the 21% decline that occurred between 2018 to 2019 (See Appendix B).

The 2019 Title X rule severely undermined this bedrock public health program that has provided high quality, affordable family planning and sexual health care to millions for 50 years. Guttmacher strongly supports the revocation of the 2019 rule, and reinstatement of the 2000 regulations with revisions, so that the Title X program can return its focus to its patients and communities.

Guttmacher supports the rule's emphasis on health equity and inclusivity.

The administration's emphasis on health equity in the proposed rule is necessary to restore the integrity of the program. The statutory requirements that Title X-funded health centers prioritize people with low incomes and provide care regardless of ability to pay ensure that the Title X program is well-positioned to advance health equity for the patients it serves. However, the onerous requirements of the 2019 rule

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https://opa.hhs.gov/about/news/grant-award-announcements/opa-awards-85-million-grants-family-planning-services-unserved. OPA was able to fund only $8.6 million in grants under the FOA, with the remaining funding given as supplemental funding to the existing grantees. *Id*.

[12] NPRM p. 19815.

[13] NPRM p. 19815.

[14] Kavanaugh ML, Zolna MR and Burke KL, Use of health insurance among clients seeking contraceptive services at Title X-funded facilities in 2016, *Perspectives on Sexual and Reproductive Health*, 2018, 50(3):101–109, https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

diverted attention and resources from this important work and undermined Title X's mission to provide equitable, affordable, client-centered, quality family planning and sexual health services.

The COVID-19 pandemic has laid bare the many inequities in our nation's health care system and highlighted how systemic racism and other forms of oppression have resulted in pervasive health disparities and disproportionately poor health outcomes for people of color.[15] The Title X program has a significant role to play in combating these systemic barriers to care and ensuring that all people, regardless of their race, ethnicity, age, sexual orientation, gender identity, immigration status, employer, insurance status, or any other demographic, have timely access to comprehensive, high-quality family planning and sexual health services. The proposed rule's emphasis on health equity will further support these goals.

Definitions

Guttmacher strongly supports the additions the proposed rule makes to the definitions in the Title X regulations, including definitions for health equity and inclusivity. In particular, the transition from using the word "women" to the more inclusive "client" is more reflective of the diverse population of patients served by the Title X program. Gender identity should never be a barrier to receiving the care one needs and people who are capable of becoming pregnant, including queer, transgender, and nonbinary people, may have a need for family planning care, just as their sexual partners may.[16] The proposed rule's definitions help to illustrate key aspects of quality care including the importance of care that is client-centered, culturally and linguistically appropriate, and recognizes how trauma affects people. Defining how services should be provided is an important step towards a more equitable Title X program.

Addressing Systemic Racism

Particularly in the wake of CDC's recent declaration that racism is a serious threat to public health,[17] Guttmacher would like to see systemic racism explicitly included and addressed as part of the expectations related to health equity. Systemic racism and other forms of oppression have resulted in structural barriers to health care services. The Title X family planning program and today's provision of family planning services arose out of a history of reproductive coercion and a fundamental devaluing of the bodily autonomy of people of color and people with low incomes. This history has contributed to a justifiable mistrust of the health care system, particularly with respect to family planning. As the administration raises health equity as an important goal of Title X in the proposed rule, Guttmacher urges HHS to acknowledge and reckon with that history as a part of that work.

[15] Artiga S, Corallo B and Pham O, Racial disparities in COVID-19: Key findings from available data and analysis, Kaiser Family Foundation, 2020, https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-covid-19-key-findings-available-data-analysis/.
[16] Dawson R and Leong T, Not Up for Debate: LGBTQ People Need and Deserve Tailored Sexual and Reproductive Health Care, Guttmacher Inst., (Nov. 16, 2020), https://www.guttmacher.org/article/2020/11/not-debate-lgbtq-people-need-and-deserve-tailored-sexual-and-reproductive-health.
[17] Centers for Disease Control and Prevention, Media Statement from CDC Director Rochelle P. Walensky, MD, MPH, on Racism and Health, 2021, https://www.cdc.gov/media/releases/2021/s0408-racism-health.html.

Guttmacher supports protecting against state restrictions on provider networks.

The rule should ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients. There is mounting evidence that expelling well-qualified, trusted family planning providers from publicly funded health programs like Title X has adverse effects on patients' access to critical family planning and sexual health care. However, in recent years states have increasingly targeted some family planning providers for exclusion from key federal health programs, including Title X. As of May 2021, at least 15 states currently have laws on the books that, where funds flow through the state government, could negatively impact the Title X service delivery network.[18] Two additional states have similar bills that are likely to become law this year. Tiering and other prohibitions against family planning providers often exclude the very providers that are the most qualified and best-equipped to help Title X patients achieve their family planning goals.

The NPRM appropriately recognizes that "state policies restricting eligible subrecipients unnecessarily interfere with beneficiaries' access to the most accessible and qualified providers," and that "denying participation by family planning providers that can provide effective services has resulted in populations in certain geographic areas being left without Title X providers for an extended period of time."[19] Guttmacher strongly agrees with HHS that "state restrictions on subrecipient eligibility unrelated to the ability to deliver Title X services undermine the mission of the program to ensure widely available access to services by the most qualified providers."[20]

The intent of the Title X program is to help individuals—regardless of their economic status—achieve their family planning goals. Title X funding is therefore provided to public and nonprofit entities to "assist in the establishment and operation of voluntary family planning projects" that offer a broad range of effective family planning methods and services.[21] As noted in the NPRM, and supported by research conducted by the Guttmacher Institute, "[P]roviders with a reproductive health focus often provide a broader range of contraceptive methods on-site and therefore may reduce additional barriers to accessing services."[22] Specifically, Planned Parenthood clinics and other clinics with a reproductive health focus are more likely to offer long acting reversible contraceptive (LARC) methods, female barrier methods and nonprescription methods, including male condoms and natural family planning instruction, compared to clinics that focus on providing SRH care within a primary care setting.[23] In fact, clinics with a reproductive health focus were much more likely to meet the Healthy People 2020 objective of offering the full range of contraceptive methods compared to primary care focused sites (74% versus 48%).[24]

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[18] Guttmacher Institute, State Laws and Policies: State Family Planning Funding Restrictions, 2021, https://www.guttmacher.org/state-policy/explore/state-family-planning-funding-restrictions.
[19] NPRM p. 19817, citing Carter, M et al. (2016). Four aspects of the scope and quality of family planning services in U.S. publicly funded health centers: Results from a survey of health center administrators. Contraception. doi:10.1016/j.contraception.2016.04.009.
[20] NPRM p. 19817.
[21] 42 U.S.C. § 300.
[22] NPRM p. 19812.
[23] Zolna M and Frost J, Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.
[24] Id.

Further, to best achieve the program's goals, Title X has historically funded a diverse network of service delivery providers—including state, county, and local health departments, as well as hospitals, family planning councils, Planned Parenthood affiliates, federally qualified health centers (FQHCs), and other private non-profit organizations. These networks vary widely across communities because they are specifically established to provide the most effective care to their specific patient populations. Conservative policymakers have sought to take public funding for family planning away from Planned Parenthood and other providers focused on reproductive health, suggesting that FQHCs could take their place.[25] While FQHCs are an integral part of the publicly funded family planning effort in the United States, it is unrealistic to expect these sites to serve the millions of women who currently rely on Planned Parenthood health centers and other clinics with a reproductive health focus for high-quality contraceptive care.[26] It is imperative that HHS "ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients."[27]

Guttmacher supports the rule's strengthened confidentiality protections.

Two interrelated hallmarks of Title X have been the program's historically strong protections for patient confidentiality and its commitment to serving adolescents. Since the 1970s, federal law has required that both adolescents and adults be able to receive confidential family planning services in Title X projects. Research shows these confidentiality protections are one of the reasons individuals choose to seek care at Title X sites.[28]

Confidentiality is a core principle of any medical care, and it is particularly important for services as sensitive as family planning. Patients seeking family planning services encompass a broad spectrum of patient populations.[29] All people are entitled to confidentiality in medical care, and it is especially crucial for adolescents. young adults, and people at risk of or experiencing domestic or intimate

[25] Hasstedt K, Federally Qualified Health Centers: Vital Sources of Care, No Substitute for the Family Planning Safety Net, *Guttmacher Policy Review*, 2017, 20:67–72, https://www.guttmacher.org/gpr/2017/05/federally-qualified-health-centers-vital-sources-care-no-substitute-family-planning.
[26] Id.
[27] NPRM pp. 19812, 19817.
[28] Frost J, Benson R, and Bucek A, Specialized Family Planning Clinics in the United States: why women choose them and their role in meeting women's health care needs. *Women's Health Issues*. 2012 Nov-Dec;22(6):e519-25, https://pubmed.ncbi.nlm.nih.gov/23122212/.
[29] Gold R, A New Frontier in the Era of Health Reform: Protecting Confidentiality for Individuals Insured as Dependents, *Guttmacher Policy Review,* 2013, 16:2-7, https://www.guttmacher.org/pubs/gpr/16/4/gpr160402.pdf.

partner violence.[30] Leading medical provider groups recognize the importance of confidentiality for adolescents and people seeking sexual and reproductive health care.[31]

Privacy is paramount to adolescents' ability to access sexual and reproductive health care. Confidentiality affects people's likelihood of obtaining care: adolescents who are concerned that their parents may find out about their care or who do not have one-on-one appointment time with their provider are less likely to receive sexual or reproductive health care.[32]

The 2019 Title X rule weakened the program's confidentiality protections by requiring providers to encourage family involvement even when it could be harmful, by giving the HHS Secretary oversight authority in the enforcement of complex and nuanced state reporting laws, and by adding new, inappropriate reporting and documentation obligations on providers. In doing so, the 2019 rule undermined the provider-patient relationship to the detriment of public health.

The providers most trusted for their confidential care were also the ones most likely to leave the program as a result of the 2019 rule. Compared with clients at other types of facilities, those accessing care at a Planned Parenthood more commonly identified confidentiality of services as one of the primary reasons for seeking care there.[33] Another study documented that Planned Parenthood health centers, reproductive health focused clinics, and Title X sites have more confidentiality practices in place for younger patients as compared to counterparts.[34]

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[30] Burke P et al., *Sexual and Reproductive Health Care: A Position Paper of the Society for Adolescent Health and Medicine*, 54 Journal of Adolescent Health 491, 491-496, (2014), https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf; Reddy D et al., *Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services*, 288 Journal of American Medical Association 710, 710–714 (2002); Jones R et al., *Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception*, 293 Journal of American Medical Association 340, 340–348; Fuentes L et al., *Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services*, 62 Journal of Adolescent Health 36, 36-43; *National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings,* Family Violence Prevention Fund (2004), http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf.

[31] See American Academy of Family Physicians, Adolescent health care, confidentiality, 2020, https://www.aafp.org/about/policies/all/adolescent-confidentiality.html; Alderman EM, Breuner CC and Committee on Adolescence, Unique needs of the adolescent, Pediatrics, 2019, 144(6):E20193150, https://pediatrics.aappublications.org/content/pediatrics/144/6/e20193150.full.pdf?download=true; ACOG, Counseling adolescents about contraception, ACOG Committee Opinion No. 710, Obstetrics & Gynecology, 2017, 130:e74-80, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/counseling-adolescents-about-contraception; American Medical Association, Confidential Health Services for Adolescents H-60.965, 2014, Confidentiality in adolescent health care, https://policysearch.ama-assn.org/policyfinder/detail/consent%20children%20and%20youth?uri=%2FAMADoc%2FHOD.xml-0-5059.xml

[32] Copen C, Dittus P and Leichliter J, Confidentiality concerns and sexual and reproductive health care among adolescents and young adults aged 15–25, National Center for Health Statistics Data Brief, 2016, No. 266, https://www.cdc.gov/nchs/products/databriefs/db266.htm.

[33] Kavanaugh M, Zolna M, and Burke K, Use of health insurance among clients seeking contraceptive services at Title X-funded facilities in 2016, *Perspectives on Sexual and Reproductive Health,* 2018, 50(3):101–109, https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

[34] Kavanaugh K et al., Meeting the contraceptive needs of teens and young adults: youth-friendly and long-acting reversible contraceptive services in U.S. family planning facilities, *Journal of Adolescent Health*, 2012, 52(3): 284-292, https://www.jahonline.org/action/showPdf?pii=S1054-139X%2812%2900713-6.

The NPRM would reinstate the pre-2019 Title X confidentiality regulations[35] while making important improvements. First, the NPRM eliminates the 2019 rule's unnecessary and harmful requirements to take and document specific actions to encourage family involvement in the family planning decisionmaking of adolescents, without including the statutory limitation "[t]o the extent practicable"[36] and with complete disregard for the expertise, training, and experience Title X providers already use in assisting adolescents to involve their families in decisions about family planning services and other key health care matters when realistic and appropriate.

Second, the NPRM eliminates the 2019 rule's attempt to give HHS substantial oversight of compliance with complex state reporting requirements concerning child abuse, child molestation, sexual abuse, rape, incest, or human trafficking. Combined with the 2019 rule's requirements to collect and document specific information in Title X records, as well as that rule's attempt to give HHS the authority to impose harsh penalties if HHS (not the state) believes a Title X project is out of compliance, the 2019 rule pushed providers toward inappropriate screening and over-reporting. These things would harm patients and undermine the provider-patient relationship, ultimately resulting in fewer patients seeking critical health services.

Determinations regarding compliance with state reporting laws properly rest with state authorities. State reporting laws are complex and vary widely from state to state.[37] They seek a nuanced balance between the need to protect those who experience abuse and ensure that law enforcement can bring victimizers to justice with the need to ensure that patients are able to seek critical health care services they might avoid if they do not trust their health care provider. Thus, many state laws include both specific requirements that clearly trigger an obligation to make a report and others that allow for the exercise of discretion by health care professionals.

Third, the NPRM adds important clarification to how Title X-funded entities are to balance client confidentiality with the program's statutory requirement that "no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge."[38]

Guttmacher welcomes the NPRM's addition of language codifying a longstanding practice that had been included in the 2014 Title X Program Requirements that reasonable efforts must be made to "collect charges without jeopardizing client confidentiality," along with a new requirement that clients be informed of "any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client."[39] HHS is right to recognize the potential for harm from varied state and local laws regarding the accessibility of client information to insurance policyholders that are not the client. The number of patients with private insurance has increased

[35] Title X's confidentiality requirements are currently largely codified at 42 C.F.R. § 59.11; the NPRM proposes reorganizing the Title X regulations so that the confidentiality section would now be § 59.10.
[36] 42 U.S.C. § 300.
[37] *See, e.g.*, Gudeman R and Monasterio E, Mandated Child Abuse Reporting Law: Developing and Implementing Policies and Training, *National Center for Youth Law and Family Planning National Training Center for Service Delivery* (2014), http://www.cardeaservices.org/documents/resources/Mandated-Child-Abuse-Reporting-Law-GUIDE-20140619.pdf.
[38] 42 U.S.C. § 300a-4.
[39] NPRM p. 19832.

since Title X began, and so has the potential risks of disclosure of sensitive information. These proposed additions to the Title X regulations will help to ensure that confidentiality remains paramount in Title X.

The NPRM proactively addresses the potential within the Title X regulations themselves for harm related to disclosure of a client's sensitive information to third parties such as policyholders who are not the client. In addition, HHS should evaluate Title X's interaction with other laws and regulations for possible conflicts that could undermine Title X clients' confidentiality and potentially subject them to harm.

Guttmacher supports the proposed rule's return to the purpose of the Title X program and standard of care.

Title X was expressly created in 1970 to make "'comprehensive family planning services readily available to all persons desiring such services."[40] Specifically, many low-income women had more children than they desired, because both the pill and the other most effective contraceptive method at the time, the copper intrauterine device (IUD), were both expensive. Congress enacted Title X to help low-income individuals who desired but could not access the contraceptive methods that more affluent members of society could, and who were:

> forced to do without, or to rely heavily on the least effective nonmedical techniques for fertility control unless they happen to reside in an area where family planning services are made readily available by public health services or voluntary agencies.[41]

For this reason, the statute requires Title X projects to "offer a broad range of acceptable and effective family planning methods and services," and prioritizes a project's capacity to make rapid and effective use of federal funds for family planning.

The 2019 rule undermined this longstanding standard of care in a variety of ways. It eliminated the term "medically approved" from the longstanding regulatory requirement that projects provide "a broad range of acceptable and effective medically approved family planning methods."[42] It also included overly permissive language that enabled providers who object to fundamental tenets of the Title X program, providing high-quality, confidential services and information that center individual decision making, to participate in it. The rule also diverged from the Office of Population Affairs and the CDC's clinical standards, the Quality Family Planning guidelines.

Furthermore, the 2019 rule made drastic changes to pregnancy counseling by Title X providers that violated Congress' explicit, repeated mandates; contradicted central principles of medical ethics; and attempted to enlist clinicians in deceiving and delaying patients who seek information about or access to abortion providers. Specifically, the rule eliminated the long-standing program requirement to provide pregnant patients with nondirective counseling about all of their pregnancy options. It permitted entities

[40] *Planned Parenthood Federation of America, Inc. v. Heckler*, 712 F.2d 650, 651 (D.C. Cir. 1983) (quoting S. REP. NO. 91-1004, at 2 (1970)).
[41] S. REP. NO. 91-1004, at 9 (1970).
[42] 83 Fed. Reg. at 25530.

to only provide counseling on carrying a pregnancy to term and adoption, requires providers to refer all pregnant patients to prenatal care, and prohibited providers from making referrals for abortion, all regardless of a patient's communicated desires.

Guttmacher applauds HHS for the proposed rule's return to the core mission of the Title X program. If finalized, the revised program will once again match patients' expectations that they will receive high-quality, client-centered care that includes comprehensive, medically accurate counseling and information, and referrals for any other services sought. Specifically, Guttmacher strongly supports the following changes and urges the administration to finalize them:

- The inclusion of "FDA-approved contraceptive services" and reinstatement of the term "medically approved" to the proposed definition of family planning services;
- The requirement that Title X service sites refer patients out if the site does not offer the contraceptive method of the patient's choice;
- Provide services "in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with national recognized standards of care;"[43]
- The reinstatement of the requirement to offer nondirective options counseling to pregnant patients on each of the three options – 1) prenatal care and delivery, 2) infant care, foster care, or adoption, 3) pregnancy termination – if requested by the patient, including referral upon request.
- The elimination of unnecessary, unworkable physical, systems, and administration separation, contrary to the requirements and realities of modern quality health care.

Guttmacher supports modernizing the Title X regulations for the program's future success.

To continue a 50-year track record of success, the Title X program must adapt to changes in the health care delivery landscape. The NPRM makes necessary changes to the 2000 regulation it is based upon regarding non-physician providers, telehealth, and faith-based organizations, though in some areas it could be improved.

The NPRM makes an important update in § 59.5(b)(1) in recognition that medical services in many Title X-funded health centers can be and are provided by health care providers who are not physicians. In fact, the NPRM preamble specifically mentions physician assistants and nurse practitioners as the types of health care providers that provide consultation in Title X settings. Indeed, nurse practitioners, certified nurse midwives, and physician assistants accounted for 67% of the Title X program's full-time equivalent (FTE) Clinical Services Provider (CSPs) in 2019; physicians and registered nurses with an expanded scope of practice accounted for 24% and 9% of all CSP FTEs, respectively.

However, it is important to note that "consultation by a [health care] provider" is not and should not be limited only to the examples cited by HHS, as these CSPs represent only one facet of health care providers in Title X settings.[44] In 2019, 23% – or more than 1.07 million – of family planning

[43] NPRM p. 19830.
[44] Fowler C et al., Family Planning Annual Report: 2019 National Summary, Washington, DC: OPA, HHS, 2020, https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.

encounters fell under the primary responsibility of other service providers, including registered nurses practicing within a standard scope of practice, licensed practical nurses, health educators, and social workers. These professionals not only account for a substantial number of Title X encounters on their own, but also provide critical support to CSPs in team-based care models typical to modern health care delivery. They are more likely to be Black, Indigenous, and People of Color—racial/ethnic groups that are both persistently underrepresented in health care professions and more reflective of clients served through the Title X program.[45,46] Guttmacher encourages HHS to elevate the critical role these health care professionals play in the Title X program.

Among enhancements it proposes to the 2000 regulations through the NPRM, HHS specifically highlights "telemedicine." The importance of telehealth, more broadly, has been growing in recent years and has become particularly clear in the context of the COVID-19 public health emergency. Since spring 2020, use of telehealth modalities has allowed tens – if not hundreds – of thousands of Title X users to remotely access many Title X services without placing themselves at increased risk for potential COVID-19 exposure.

That said, the Department's use of the narrower term "telemedicine" in the NPRM instead of "telehealth" is of concern, with "telehealth" referring to a broader scope of remote health care services than telemedicine and includes non-clinical services like counseling and education.[47] Accordingly, in addition to its change from "physician" to "[health care] provider" in § 59.5(b)(1), HHS can further improve the Title X regulations by explicitly naming and defining "telehealth" to clarify that section as follows:

> 59.5(b)(1): Provide for clinical and other qualifying services related to family planning (including consultation by a healthcare provider, family planning counseling and education, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies), in person or via telehealth, including audio-only modalities, regardless of the patient's or provider's setting, and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

The NPRM also proposes making a "technical correction" to § 59.12 to include 45 CFR part 87, the "Equal Treatment for Faith-based Organizations" rule (faith-based organizations rule) in the list of regulations that apply to Title X. The previous administration, which finalized the faith-based organizations rule on December 17, 2020, explicitly declined to apply this rule to Title X. Furthermore, the faith-based organizations rule, finalized on December 17, 2020, insofar as it applies to HHS grant programs, only "applies to grants awarded in HHS social service programs." As Title X is a health service program, with grants made to entities "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods

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[45] Salsberg E et al., Estimation and comparison of current and future racial/ethnic representation in the US health care workforce, *JAMA Netw Open.* 2021;4(3):e213789. doi:10.1001/jamanetworkopen.2021.3789.
[46] Fowler C et al., Family Planning Annual Report: 2019 National Summary, Washington, DC: OPA, HHS, 2020, https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.
[47] Board on Health Care Services; Institute of Medicine, *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary*, Washington (DC): National Academies Press (US); 2012 Nov 20. 1, Introduction. https://www.ncbi.nlm.nih.gov/books/NBK207150/.

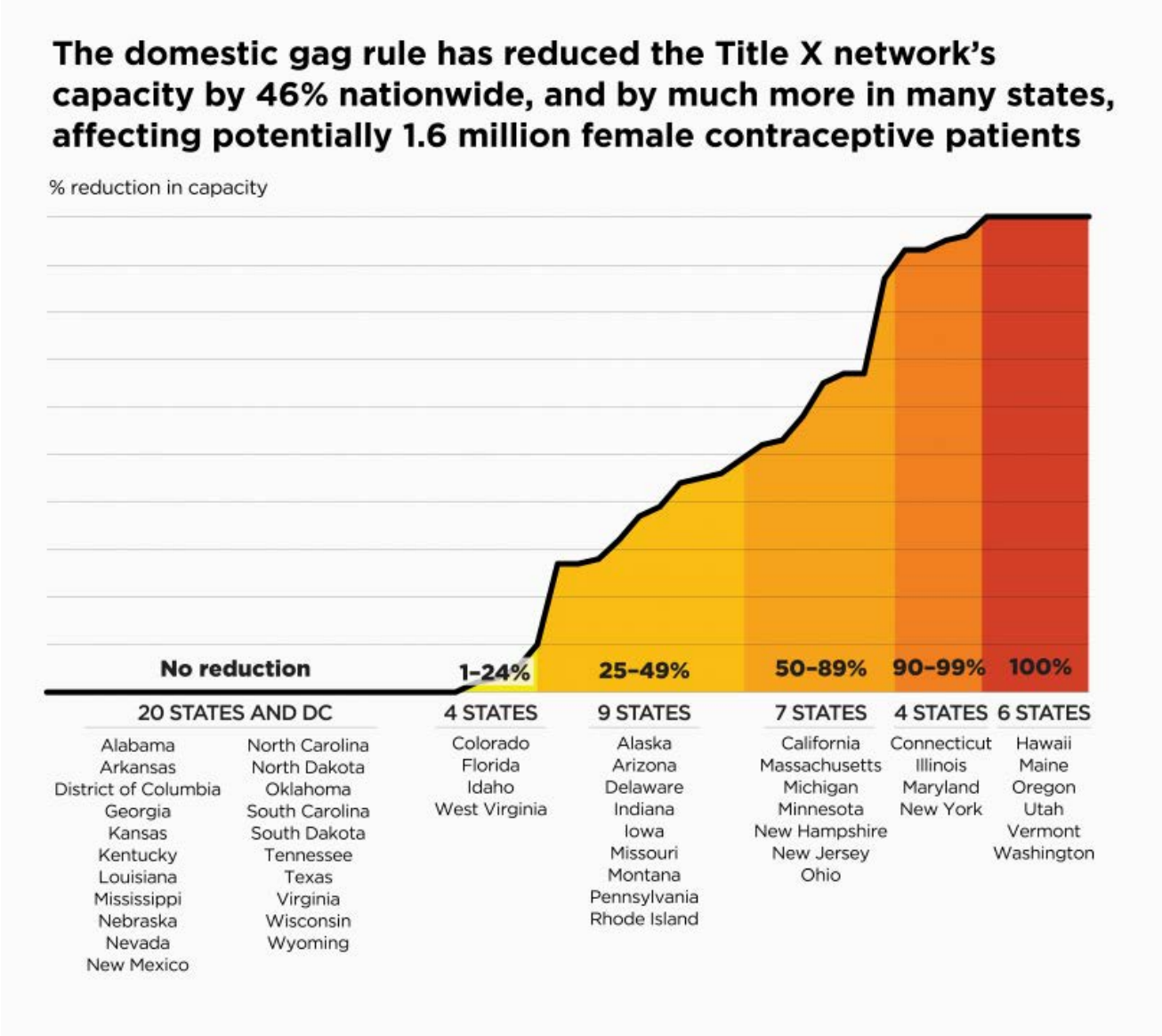
and services," 45 CFR part 87 does not rightfully apply, and should therefore not be included in the final Title X rule.

For 50 years, the Title X family planning program has been a critical underpinning of the public health safety-net infrastructure that serves millions of low-income people each year. Guttmacher appreciates the opportunity to comment on the NPRM, "Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services." If you require additional information about the issues raised in these comments, please contact Ruth Dawson at rdawson@guttmacher.org or (202) 802-0194.

Sincerely,

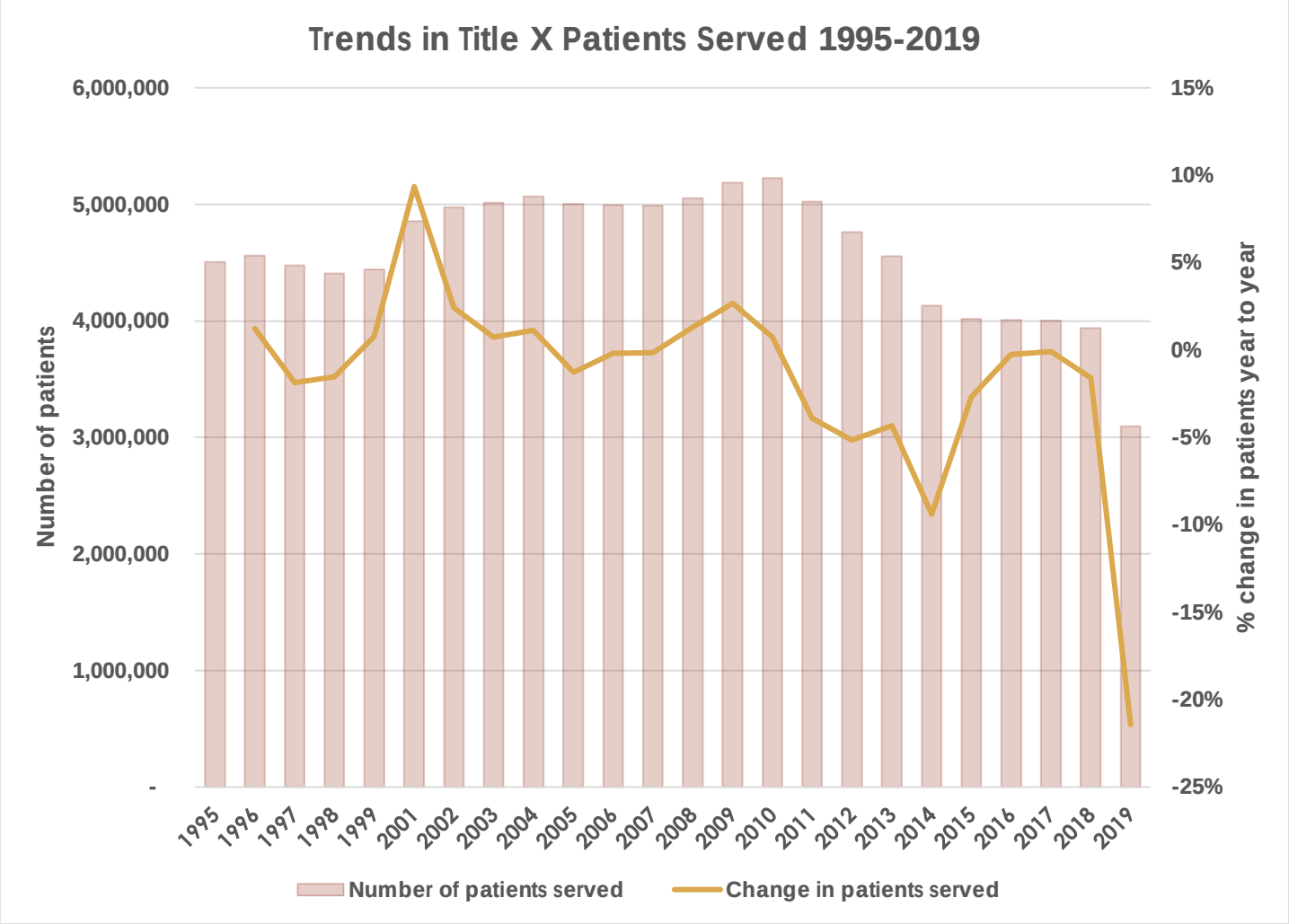
Heather Boonstra
Vice President for Public Policy
Guttmacher Institute

Appendix A:



The research underlying this graph was conducted by Mia R. Zolna, Sean Finn and Jennifer J. Frost of the Guttmacher Institute, using data from the Guttmacher Institute and the federal Office of Population Affairs. Full information about the methodology and limitations and a table with state-level findings on clinics that left the network and resulting losses in patient capacity can be found here:
https://www.guttmacher.org/article/2020/02/estimating-impact-changes-title-x-network-patient-capacity

Appendix B:



Sources:

2009-2019: Fowler, C. I., Gable, J., Lasater, B., & Asman, K. (September 2020). Family Planning Annual Report: 2019 National Summary. Washington, DC: Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services. https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf

1999-2008: Fowler, CI, Gable, J, Wang, J, and Lyda-McDonald, B. (November 2009). Family Planning Annual Report: 2008 National Summary. Research Triangle Park, NC: RTI International. https://opa.hhs.gov/sites/default/files/2020-07/fpar-2008-national-summary.pdf

1995-1997: Manzella, K and Frost, JJ. (November 2001). Family Planning Annual Report: 2000 National Summary. New York, NY: Guttmacher Institute