

**New York State Department of Health
Comprehensive Family Planning and Reproductive Health Program**

Comments in Response to Title X Notice of Proposed Rulemaking

The New York State Department of Health (NYSDOH) strongly opposes proposed rule changes as outlined in the U.S. Department of Health and Human Services' (HHS) Title X Notice of Proposed Rulemaking. The proposed rules will dramatically alter the landscape of federally funded family planning services, limiting access to high-quality reproductive health care and highly effective contraceptives, and imposing barriers for women and men seeking family planning and other vital preventive health care services. If enacted, these rules will reverse a decades-long decrease in teen and unplanned pregnancies across the United States.

As written, the proposed rules will negatively impact the current Title X program by:

- **Narrowing the definition and scope of family planning services available**
- **Lowering quality of care standards**
- **Creating barriers to accessing a full range of family planning and preventive health care services**
- **Dramatically reducing available options for and access to birth control methods**
- **Compromising physicians' ethics and ability to meet a basic duty of care**
- **Eliminating the ability of pregnant women to give informed consent on all legally available post-conception services**
- **Undermining confidentiality protections and trust between patients and their health care providers**
- **Limiting opportunities for localities and states to have input on changes to the Title X network**

The proposed rules create unnecessary, unethical, and potentially illegal barriers that will limit access to free or low-cost family planning services. If enacted, these proposed rules will most negatively impact the health and well-being of the primarily low-income, uninsured, underserved individuals of reproductive age who rely on the Title X safety net for access to contraceptive and other preventive health care services.

I. Comments and Recommendations on Each Proposed Revision to 42 CFR Part 59.

Following are the NYSDOH's comments and accompanying recommendations for proposed revisions to 42 CFR Part 59. The comments and recommendations detailed below relate to both proposed changes to the existing rules, and to the proposed addition of new rules.

Proposed Changes to Existing Rules

Section 59.2. Definitions.

The proposed rule adds a definition for "family planning" that excludes post-conception care.

- The newly proposed definition of family planning explicitly excludes provision of "post-conception care" which includes obstetric care, prenatal care, and abortion, as part of services defined as "family planning." Excluding post-conception care from the scope of services that may be provided in a family planning visit unnecessarily disrupts continuity of care for family planning

clients receiving a positive pregnancy test. This separation between family planning and early prenatal care is contrary to national standards promoting early access to prenatal care, especially for high-risk pregnant women who are more likely to delay entry into prenatal care.

- This definition fails to align with nationally recognized standards of care such as those found in “Providing Quality Family Planning Services: Recommendations of the CDC and the U.S. Office of Population Affairs” (QFP). The QFP, developed by the CDC and HHS’ Office of Population Affairs (OPA) itself, serves as the current Title X clinical guidance document and is based upon input from more than 35 federal and professional medical associations such as the U.S. Prevention Services Task Force and The American College of Obstetricians and Gynecologists, recommends that initial prenatal care be provided at a family planning visit when a woman receives a positive pregnancy test. The QFP specifically outlines:

“For clients who are considering or choose to continue the pregnancy, initial prenatal counseling should be provided in accordance with the recommendations of professional medical associations, such as American College of Obstetricians and Gynecologists (ACOG). The client should be informed that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife). In addition, the client should be encouraged to take a daily prenatal vitamin that includes folic acid; to avoid smoking, alcohol, and other drugs; and not to eat fish that might have high levels of mercury. If there might be delays in obtaining prenatal care, the client should be provided or referred for any needed sexually transmitted diseases (STD) screening (including HIV) and vaccinations.”¹

- The QFP recognizes that prenatal care is an essential public health intervention to improve pregnancy outcomes. Studies have demonstrated that prenatal care is associated with improved perinatal outcomes, and other benefits such as improved maternal health outcomes, subsequent use of pediatric care, and serves as an entry point into the health care system for women at social or economic risk.²
- Adequate prenatal care is a widely accepted determinant of maternal and child health. Prenatal care is considered adequate, based on the ACOG guidelines for prenatal visits in low-risk pregnancy, if it is initiated in the first trimester with regular visits of increasing frequency as term approaches.³ Early prenatal care is associated with postpartum behaviors of initiation and longer duration of breastfeeding and contraceptive use, both associated with increased birth spacing.⁴
- Current Title X providers have demonstrated their ability to successfully provide limited post-conception support - primarily assessment, education, and referral services - in a patient-centered manner and in accordance with QFP recommendations. The post-conception services provided in a family planning visit establish a foundation for ongoing prenatal care that can be especially

¹ Loretta Gavin, PhD, Susan Moskosky, MS, Marion Carter, PhD, et al, “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.” MMWR 2014; 63: No.4: 1. <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

² Rosenberg, Deborah, Arden Handler, Kristin M. Rankin, Meagan Zimbeck, and E. Kathleen Adams. "Prenatal Care Initiation among Very Low-income Women in the Aftermath of Welfare Reform: Does Pre-pregnancy Medicaid Coverage Make a Difference?" Maternal and Child Health Journal 11, no. 1 (2006): 11-17.

³ Partridge, Sarah, Jacques Balayla, Christina Holcroft, and Haim Abenheim. "Inadequate Prenatal Care Utilization and Risks of Infant Mortality and Poor Birth Outcome: A Retrospective Analysis of 28,729,765 U.S. Deliveries over 8 Years." American Journal of Perinatology 29, no. 10 (2012): 787-94.

⁴ Adejoke B. Ayoola, Mary D. Nettleman, Manfred Stommel, et al. “Time of Pregnancy Recognition and Prenatal Care Use: A Population-Based Study in the United States.” Birth 37, no. 1 (2010): 42.

critical for the estimated six in ten low-income and uninsured women who indicate that the family planning clinic is their primary source of medical care.⁵

- Women are at risk for late initiation into or receiving no prenatal care at all if they are young, poor, unemployed, members of minority groups, unmarried, have less than a high school education, lack health insurance, or have other children.⁶ Pregnant adolescents are less likely to receive adequate prenatal care with up to 55% of adolescents entering prenatal care late or not at all.⁷ Many Title X priority populations (including adolescents, low-income women, and women from racial/ethnic minorities) have historically lower rates of early entry into prenatal care than peers. Limiting a Title X provider's ability to provide initial prenatal care will create barriers that increase the likelihood that high-risk women will enter prenatal care late, or not at all, a factor that has been associated with poor health outcomes such as increased risk for prematurity, stillbirth, early neonatal death, late neonatal death and infant mortality.⁸

Recommendation:

We strongly recommend that no changes be made to the current language defining the scope of family planning services. Relying on the QFP recommendations to establish clinical standards, OPA has ensured that the Title X program may more easily update clinical services and protocols to better reflect nationally recognized standards of care as they evolve over time.

Section 59.2 Definitions.

The proposed rule adds a definition for “family planning” that includes adoption.

- The proposed definition of family planning is “the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved.” In this definition, “the means” of achieving family planning goals would: “include a broad range of acceptable and effective choices, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility (including adoption)”
- This definition is expanded to include adoption in the scope of services to be provided, going beyond existing guidelines that support referrals for adoption. The current section 59.5(a)(5) already mandates non-directive full options counseling for any pregnant client, which includes provision of information on adoption. Specifically, the QFP requires that, “Options counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP.”⁹ Both ACOG and the AAP provide guidance on options counseling in alignment with current Title X regulations which stipulate that providers should inform patients of

⁵ Frost, Jennifer J. “U.S. Women’s Use of Sexual and Reproductive Health Services: Trends, Sources of Care and Factors Associated with Use, 1995-2010.” Guttmacher Institute (2013).

⁶ Pagnini, Deanna L., and Nancy E. Reichman. “Psychosocial Factors and the Timing of Prenatal Care among Women in New Jersey’s HealthStart Program.” *Family Planning Perspectives* 32, no. 2 (2000): 56-57.”

⁷ Wiemann, Constance M., Abbey B. Berenson, Leticia Garcia-Del Pino, and Sharon L. McCombs. “Factors Associated with Adolescents Risk For Late Entry into Prenatal Care.” *Family Planning Perspectives* 29, no. 6 (1997): 273.

⁸ Partridge, Balayla, Holcroft, Abenheim. “Inadequate Prenatal Care Utilization and Risks of Infant Mortality and Poor Birth Outcome: A Retrospective Analysis of 28,729,765 U.S. Deliveries over 8 Years.” *American Journal of Perinatology* 29, no. 10 (2012): 787-94.

⁹ Gavin, Moskosky, Carter, et, al, “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.” *MMWR* 2014; 63: No.4. 1. pg. 14.

three medical options including: continuing pregnancy and parenting, continuing pregnancy and adoption/foster care, or terminating the pregnancy.¹⁰

- Including adoption in family planning services provided under Title X also pushes the bounds of a reasonable understanding of Congress' intent for the Title X program and thus the bounds of HHS's delegated authority, as discussed further *infra* pages 28-29.

Recommendation:

We strongly recommend that no changes be made to the current language defining the scope of family planning services. Relying on the QFP recommendations to establish clinical standards, OPA has ensured that the Title X program may more easily update clinical services and protocols to better reflect nationally recognized standards of care as they evolve over time

Section 59.2. Definitions.

The proposed rule amends the definition of “low-income family,” requiring documentation in unemancipated minors’ medical records of the efforts made to encourage family involvement in decision-making.

- The proposed amended language to Section 59.2 related to unemancipated minors requires Title X providers to indicate “the specific actions taken by the provider to encourage the minor to involve his/her family” in the decision to seek family planning services.
- A Title X legislative mandate, as outlined in the current Title X Program Guideline 9.12¹¹ requires Title X grantees to encourage but not require family participation in the decisions of minors, and grantees currently must certify such encouragement as a condition of Title X funding. The current practice has proven sufficient to ensure that Title X providers adequately discuss and encourage family participation in decision making with minor patients. However, the proposed rule imposes added emphasis and seeks to prevent minors from receiving confidential services for free if both conditions of encouragement of family participation and documentation of that discussion have not been met.
- The proposed rule represents an increased emphasis on family involvement that is likely to create additional barriers between providers and adolescent patients. Already sensitive to issues around confidentiality and provider bias, adolescent patients often require extra attention and assurance from providers to develop a rapport in which they are comfortable providing accurate medical and social histories and to adhere to provider advice. Requiring greater focus on discussions of family involvement and documentation of those discussions will not only shorten the amount of time providers can spend counseling adolescent patients but will also undermine patient trust and confidentiality.
- Adding such a barrier to minors’ access to the Title X program contravenes the goals of the program to be a confidential provider of services for adolescents regardless of family involvement. This intent has been recognized explicitly in the Title X statute itself since Congress amended it in 1978 and then again in 1981, and has been reaffirmed multiple times by the courts.¹²

¹⁰ “Diagnosis of Pregnancy & Providing Options Counseling for the Adolescent Patient” American Academy of Pediatrics, Clinical Report. 140, no. 3. September 2017

¹¹ “Program Requirements for Title X Funded Family Planning Projects: Version 1.0”. OPA. April 2014: <https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf>

¹² See, e.g., *Doe v. Pickett*, 480 F. Supp. 1218 (S.D.W.Va. 1979); *Planned Parenthood Association v. Matheson*, 582 F. Supp. 1001 (D.C. Utah 1983); *County of St. Charles v. Missouri Family Health Council*, 107 F.3d 682 (8th Cir. 1997), rehearing denied (8th Cir. 1997), cert. denied 522 U.S. 859 (1997); *Planned Parenthood Federation of America, Inc. v. Schweiker*, 559 F. Supp. 658 (D. D.C. 1983); *Planned Parenthood v. Heckler*, 712 F.2d 650, 663 (D.C. Cir. 1983).

- The additional documentation requirements outlined in the proposed rule will also create an increased burden on staff time and electronic medical record systems that are likely to increase programmatic costs with no subsequent increase in funding to offset these expenditures.

Recommendation:

We recommend that the definition of low-income family exclude the proposed amended language related to unemancipated minors. We support and work to ensure compliance of all subrecipient agencies with the existing Title X Program Requirement 9.12 and legislative mandate¹³ requiring that minor patients be counseled and encouraged to involve a family member in reproductive health care decisions. However, we believe that efforts and funds would be better used to support training for providers on the best methods to encourage family involvement.

Section 59.2. Definitions.

The proposed rule redefines “low-income” to include a woman who “has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage.”

- The current Title X regulations require that “no charge will be made for services provided to any person from a low-income family” except to the extent that payment can be made by a third-party payer (like commercial insurance or Medicaid). Individuals with incomes above 100% of the federal poverty level (FPL) are charged on a schedule of discounts based on their ability to pay or full fee, depending on their income level. These requirements are based in the Title X statute, which requires any person from a low-income family receive services from a Title X project at no charge and authorizes the Secretary of HHS to define low-income “so as to [e]nsure that economic status shall not be a deterrent to participation in the programs assisted under this title.”
- This change in definition would, when read in the context of the current regulations at §§ 59.5(a)(7) and (a)(8), explicitly enable and may require Title X-funded entities to provide free contraceptive services to women whose employers object to them having insurance coverage of contraception, regardless of their income.
- Although the proposed rule states that such women “can be considered” low income for the purposes of contraceptive services, and HHS states in the preamble that this change would allow such women to receive “free or low-cost” family planning services, the preamble also states that the proposed rule “would amend the definition . . . to include women who are unable to obtain certain family planning services” under their employer-sponsored coverage due to their employers’ religious beliefs or moral convictions. This language suggests that this definitional change would be a requirement and not merely permissive.
- Title X was designed and has functioned for decades as a safety net family planning program, with statutory allowances for the Secretary to define the scope of “low income” individuals who shall be provided care without charge only “so as to insure that economic status shall not be a deterrent to participation.” Twisting the definition beyond normal understanding to allow for the provision of free contraceptive services to women whose employers object to them having insurance coverage of contraception, *regardless of their income*, contravenes the intent of the program and thus stretches the bounds of the delegated regulatory authority of HHS, as discussed further *infra* pages 28-29.

¹³ “Program Requirements for Title X Funded Family Planning Projects: Version 1.0”. OPA. April 2014: <https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf>

- Furthermore, Title X is designed to subsidize a program of care, not pay all of the cost of any service or activity—the Title X statute and regulations contemplate how Title X and third-party payers will work together to pay for care, directing Title X-funded agencies to seek payment from such third-party payers. Even more, Title X is already underfunded and overburdened.
- Nor can the Title X program absorb the unmet needs of insured individuals who have incomes above 250% of the FPL. Requiring Title X projects to prioritize and pay for these patients leaves fewer already-scarce dollars to serve the low-income patients at the heart of Title X’s purpose.

Recommendation:

We recommend that the definition of low-income family exclude the proposed amended language related to employer-sponsored health insurance coverage. We believe that, given limited funds, and in keeping with the statutory intent of the Title X program, Title X funding should be used to support services for those most vulnerable individuals – those who are low-income, uninsured, and/or medically underserved.

Section 59.5 Requirements of a Family Planning Project.

§ 59.5(a)(1):

The proposed rule removes the requirement that family planning methods offered by Title X providers must be “medically approved” and removes the requirement that Title X providers and programs offer more than one method of family planning.

- The term “medically approved” has been commonly interpreted as requiring that all Title X providers offer patients at least one form of each FDA-approved contraceptive method (including birth control pills, patch, shot, implant, IUD, condoms, and natural family planning/fertility-awareness based methods).
- This interpretation is in alignment with federal Affordable Care Act (ACA)¹⁴ and New York State Medicaid contraceptive coverage requirements¹⁵ which require coverage for most FDA-approved contraceptive drugs, devices, and products. The proposed rule is not consistent with these requirements, and represents a departure from nationally recognized standards of care, as outlined in the QFP¹⁶ guidelines for clinical care within the Title X program, as well as the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion on Access to Contraception¹⁷ which recommend that the full range of FDA-approved contraceptives methods and counseling be offered.
- The proposed removal of the requirements that family planning methods be “medically approved” and that providers offer more than one method of family planning are in contradiction to these national and state mandates, all nationally recognized standards of care, and the health needs of women who utilize the Title X program.
- Women take numerous factors into account when selecting birth control methods, including effectiveness, lack or presence of side effects, affordability, and how easy the contraceptive is to

¹⁴ U.S. Dept. of Health & Human Services, Affordable Care Act. “Birth Control Benefits – Healthcare.gov”:

<https://www.healthcare.gov/coverage/birth-control-benefits/>

¹⁵ NYS Dept. of Health, Office of Health Insurance Programs, “NYS Medicaid Family Planning Services Frequently Asked Questions” NYS Dept. of Health, Office of Health Insurance Programs. May 2015. Pg.4.

¹⁶ Gavin, Moskosky, Carter, et al, “Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs.” MMWR 2014; 63: No.4: 1. Retrieved: <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>

¹⁷ American College of Obstetricians (ACOG), Committee on Health Care for Underserved Women. “Committee Opinion: Access to Contraception.” Number 615, (2015).

obtain and use.¹⁸ Any limitation on the amount and type of contraceptive options made available will hamper the ability of each woman to select the contraceptive method that is most preferred and best suited for her health and lifestyle.

- If the family planning methods offered at Title X providers no longer represent the full range of medically accepted methods, women who rely on the Title X program may have nowhere else to go to seek the method that is best for them: 40% of women who receive services at Title X funded specialized family planning clinics indicate that it is their only source of care¹⁹ and in some rural areas, a Title X family planning clinic may be the only provider of contraceptive care within a large geographic area.²⁰ Limiting the options available to women who seek care at these clinics will force them to use methods that are not their first choice, that do not have the desired level of effectiveness, or that have undesirable side effects.
- Dissatisfaction with available contraceptive method has been linked to inconsistent method use and increased rates of unplanned pregnancies.²¹ By no longer requiring that Title X projects offer a broad range of medically approved contraceptive methods, women will have fewer birth control options and will be less likely to access highly effective birth control methods, which could lead to increased inconsistent birth control method use, a subsequent increased risk of unplanned pregnancies and, in turn, more abortions.
- These proposed changes could dramatically alter the ability of Title X clients to select the appropriate birth control method that best suits their needs. Currently, that means women who access contraception via a NYS Title X program have dozens of contraceptive method options made available to them, including different types of pills, patches, and rings which deliver hormones, barrier methods including condoms, diaphragms and caps, as well as behavioral interventions including abstinence and natural family planning. In the NYS FPP alone, this rule change could mean that the 203,261 women who left their Title X visit with a method of birth control in 2017 could find their available options severely limited. While oral birth control pills, condoms and hormonal injections remain popular, more and more women are expanding their birth control selection to include new options. Of those 203,261 clients roughly 21%, or over 43,000 women, selected a highly effective (LARC – long acting reversible method including IUD, IUD, or implant) birth control method, options which are associated with significantly lower failure rates than other contraceptive options. Based on 2017 NYS FPP data, NYS clients demonstrate a clear preference for selecting contraceptive methods which are often most or moderately effective, with very few women opting for natural family planning/fertility awareness methods (.012%), abstinence (3.12%), or lactation amenorrhea method (.016%). Limiting birth control methods would not only severely undermine the integrity of the program, but it would all but ensure women aren't able to identify and use a method that suits the unique medical and social needs of each and every patient.

Recommendation:

We strongly recommend that regulatory language in 59.5(a)(1) retain the current language requiring family planning methods be “medically approved” and the requirement that a broad range of family planning methods be offered by Title X providers. As a critical part of the health care safety net, Title X

¹⁸ Lauren N. Lessard, Deborah Karasek, Sandi Ma, et al, “Contraceptive Features Preferred by Women At High Risk for Unintended Pregnancy,” *Perspectives on Sexual and Reproductive Health* 44, no. 3 (2012): 194.

¹⁹ Frost, Jennifer J., Rachel Benson Gold, and Amelia Bucek. "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Womens Health Care Needs." *Womens Health Issues* 22, no. 6 (2012).

²⁰ American College of Obstetricians and Gynecologists (ACOG) Committee on Health Care for Underserved Women. “Committee Opinion: Health Disparities in Rural Women”, number 586 (2014).

²¹ Lessard, Karasek, Ma, et al. 199.

clinics provide services to individuals who may not otherwise have access to health care, including contraceptive services. Title X providers should continue to offer as broad a range of medically approved contraceptive methods as possible to ensure that all women can access and select the method best suited to their unique needs, medical history, and lifestyle. Women should not be limited in contraceptive choices based on income, geography, or cost.

§ 59.5(a)(5):

The proposed rule removes all current language requiring that Title X programs provide women with a positive pregnancy test with information and counseling regarding pregnancy options, as defined in current Title X program regulation. Per § 59.5, all Title X programs are currently required to provide pregnant women the opportunity to be given information and counseling on each of three options: prenatal care and delivery; infant care, foster care, adoption; and pregnancy termination. Current regulation goes on to stipulate that when information is requested programs must “provide neutral, factual information and nondirective counseling on each of the options, referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.”²²In addition, the proposed rule prohibits promotion, referral for, support for, or presentation of abortion.

- Removing the requirement that programs provide patients with all medically accurate health options, especially upon patient request, is in direct opposition to nearly all medically accepted standards of care, most importantly the doctrine of informed consent. Informed consent bases itself in the fundamental idea that all patients have the right to self-determination in care, determination based on a thorough understanding of their medical status and available treatment options. Removing a patient’s ability to obtain information on all legally and medically appropriate options regarding pregnancy, and to discuss this information with a trusted medical provider, is to remove any ability for Title X patients to make informed consent on a range of health care issues that directly impact their life and fertility.²³
- Implementation of this rule would serve to undermine medical ethics as defined and accepted by almost every professional physicians’ association. Beginning with the American Medical Association, their Code of Medical Ethics states that “withholding information without the patient’s knowledge or consent is ethically unacceptable.”²⁴ This commitment to providing patients with information on their full range of reproductive options has been clearly supported by numerous other professional medical associations including; American Congress of Obstetricians and Gynecologists (ACOG), American Academy of Pediatrics (AAP), American Academy of Physician Assistants (APPA), Association of Women’s Health, Obstetrics and Neonatal Nurses.²⁵ In undermining medical ethics, this rule would put providers in a precarious position of potentially violating their duty to adhere to a standard of care set forth by State law by advising and counseling a patient on all of their pregnancy options, discussed further *infra* page 33.
- Restricting physicians’ speech and ability to provide full options counselling would threaten the patient/provider relationship, creating friction and barriers to care. This threat would likely be exacerbated for the Title X priority population, which includes low-income women and women of

²² 42 U.S.C. § 300a-4. §59.5 “What requirements must be met by a family planning project”: 65 FR 41278, July 3, 2000.

<https://www.ecfr.gov/cgi-bin/text-idx?SID=beacfd044d5a71d9fdb2a76300994972&mc=true&node=sp42.1.59.a&rgn=div6>

²³ Kinsey Hasstedt. “Unbiased Information on and Referral for All Pregnancy Options Are Essential to Informed Consent in Reproductive Health Care” *Guttmacher Institute* (2018).

²⁴ AMA, Opinion 1.1.3: “Withholding information from patients, Code of Medical Ethics, 2016.”

²⁵ Hasstedt, “Unbiased Information on and Referral for All Pregnancy Options”

color whose communities have historical experiences of coercion in health care settings and thus who often have an increased mistrust of medical providers.²⁶

- Further, research has demonstrated that restricting information on, and access to, abortion care does not improve health or well-being for women or children in states/municipalities with restrictive abortion laws. According to assessments of child well-being indicators, states that restrict abortion access “have (a) more low birthweight babies; (b) a greater infant mortality rate; (c) a lower rate of domestic infant adoptions; (d) a lower rate of child placement in foster care; (e) less financial assistance to unmarried mothers; (f) a higher child death rate; (g) a greater percentage of children in poverty; and (h) a larger percentage of children who have repeated a school grade.”²⁷
- Given the high rates of unplanned pregnancy in New York state, coupled with the limited access points for low-income women seeking reproductive health care, it has been and continues to be essential to expedite entry into care for any patient seen with a confirmed pregnancy. Although unplanned pregnancy remains a public health concern for NYS, a proven template exists to address this issue as demonstrated by the overwhelming success of NYS’s Teen Pregnancy Prevention activities. Serving as a model for other publicly funded family planning services, the success NYS has demonstrated in reducing both teen pregnancy and birth underscores the ability of public health programs to meet public need. Over the past 20 years, NYS has seen dramatic reductions in both teen birth, down 71% from 1991 to 2016 and teen pregnancy, down 61% from 1988 to 2013²⁸. Currently, Title X guidelines emphasize using the pregnancy test visit as an opportunity to screen women for any high-risk behavior (substance use, intimate partner violence, human trafficking), provide essential information and counseling on their preferred pregnancy option, and, whenever possible and desired, facilitate their early entry into prenatal care. This seamless integration of services not only eliminates redundant visits and expenses but helps to ensure that patients with a confirmed pregnancy receive timely access to medically necessary information and services regardless of their pregnancy decisions.

Recommendation:

We recommend that regulatory language in § 59.5(a)(5) remain unchanged from the current regulations. Current language that includes a requirement for full pregnancy options counseling is consistent with the American Medical Association Code of Ethics and recommendations from numerous professional associations. This requirement will ensure that all women across the Title X program receive the same, complete information and level of care regardless of where or from whom they receive services, ensuring a level of equity in patient education necessary to ensure the health and well-being of women in New York.

§ 59.5(a)(10):

The proposed rule removes language requiring the involvement of local stakeholders in a Title X application that seeks to consolidate or otherwise impact the current operations of local and regional entities.

- Allowing local input on the Title X program is an essential component to ensuring that services offered meet the unique needs and values of the community that they are tasked with serving. One of the more complex reproductive health problems currently facing the NYS Title X is the persistent racial and ethnic disparities seen in unintended and teen pregnancy rates, as well as

²⁶ Hasstedt (2018).

²⁷ Marshall Medoff, “Pro-Choice Versus Pro-Life: The Relationship Between State Abortion Policy and Child Well-Being in the United States,” *Health Care for Women International*, 37 (2016): 168.

²⁸ <https://powertodecide.org/what-we-do/information/national-state-data/new-york>

maternal mortality and morbidity. These steep disparities by race serve to underscore the reality that trying a one size fits all approach, even if that approach comes with a proven track record, across diverse communities within NYS, cannot address the complex structural and systemic issues contributing to racism and disproportionately poor health outcomes in the African American community in NYS. By proactively engaging communities to become part of building solutions, our Title X programs are leading the way in developing new and innovative strategies to address racism, poverty, and other social determinate factors that contribute to health inequities. By engaging community members to provide feedback, direction, and even decision-making authority, Title X programs have evolved over time to become more responsive to the unique needs of individual communities. This feedback has been used to determine hours of operations, locations of health centers, and the introduction of new programs to target emerging communities. Implementing this proposed rule and removing the basic mandates for community involvement would halt this forward progress and contribute to continued health inequities across NYS.

- The proposed amendment to the rule, changing the eligibility of current Title X providers, will result in the potential loss of current providers from Title X will reduce the availability and quality of family planning services without any input by local stakeholders, community members, and/or family planning experts. This could mean that long standing community service organizations, well known for providing free or low cost reproductive health services would no longer be able to meet the needs of their community. In NYS this could represent a loss in services to the over 300,000 clients who receive family planning services through the NYS Family Planning Program annually.
- The proposed rule will effectively shut out current Title X providers with local area expertise and a history of providing Title X services from participation in decision-making processes that could impact the availability and quality of family planning services in communities across the state.

Recommendation:

We recommend that regulatory language in § 59.5(a)(10) remain unchanged to preserve opportunities for local stakeholder input. By allowing community members to have a voice in shaping program goals, policies, and activities, Title X programs can actively promote health equity and improve health outcomes in some of the most disadvantaged communities in New York State, better fulfilling the intent and goals of the Title X program.

§ 59.5(a)(12):

The proposed rule adds a new requirement that Title X providers, “in order to promote holistic health and provide seamless care” offer comprehensive onsite primary care or have “robust” referral linkages with primary care providers within close geographical proximity to the Title X provider.

- The QFP, developed by the CDC and OPA, through the combined efforts of numerous health care professionals and with approval from all major family planning medical associations, currently provides clear, consistent, and factually accurate guidance on all aspects of family planning care as well as detailed instructions on expanding the scope of that care to promote preconception health among all women of reproductive age. In its current form, this document contains enough information for Title X providers to be able to meaningfully implement holistic health care for women throughout the life course.
- For women whose only source of health care is the specialized family planning clinic, the clinic serves as an entry point to the health care system, a role that presents family planning clinics with

a vital obligation.²⁹ The results of a recent study illustrate this vital role of specialized family planning clinics:

- One in eight (12%) of respondents made no prior visit for medical care in the past year, and 29% had only received care at the specialized family planning clinic. For these 41% of respondents, the specialized family planning clinic was their only source for medical care during the year. The majority of respondents (59%) had made at least one other visit for medical care in the prior year to a different provider, but when it came to making a visit for contraceptive or reproductive health care, they chose to visit a specialized family planning provider. 10% of visits were for pregnancy tests only.
- Uninsured women were more likely than privately insured women to have received no prior medical care or to have received all their care at the clinic--resulting in half of all uninsured women relying on the specialized family planning clinic as their only source of medical care. In contrast, only one in four (27%) women with private health insurance was relying solely on the specialized clinic for medical care.
- The proposed amended rule does recognize that family planning is an entry point for care for many women and seeks to leverage that by offering additional services and encouraging linkages to primary care. However, as written, this provision contradicts other sections of the proposed rule that place limits on the scope of services that can be delivered in a family planning clinic.
- Additionally, the amended rule does not clearly define what services would be included in “holistic” health care and fails to demonstrate how limiting the scope of expanded services through explicitly prohibiting post-conception care would improve health outcomes for Title X patients.
- Removing requirements that mandate use of the QFP and replacing them with the vague language included in this rule will only serve to undermine the intention of the Title X Program and result in women accessing fewer and lower quality health care services than what they can currently obtain in the Title X program.

Recommendation:

We recommend that the new § 59.5(a)(12) not be implemented in the Title X program. We support the continued use of the QFP as the primary guidance document to define the full scope of clinical services that should ideally be made available in a Title X program to promote holistic health and seamless care.

§ 59.5(a)(13):

The proposed rule establishes new requirements for increased reporting by including subrecipient and referral agencies and individuals by name, location, expertise and services to be provided.

- The new reporting requirements would require details about subrecipients and their referral organizations, and the extent of their collaborations to be submitted at the time of grant application, and in subsequent required reports, creating a significant undue administrative burden for Title X grantees and monitoring organizations.
- NYSDOH, as a Title X grantee, contracts with a range of subrecipient agencies who provide direct clinical services as part of the NYS Family Planning Program (FPP). Some subrecipient organizations may choose to subcontract a portion of their clinical services to other health care providers within their community, and as such NYSDOH has oversight of that subcontracting relationship.

²⁹ Frost, Jennifer J., Rachel Benson Gold, and Amelia Bucek. "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Womens Health Care Needs." *Womens Health Issues* 22, no. 6 (2012).

- NYSDOH does not contract directly with, or provide Title X funds to, any referral partners of sub-recipient agencies.
- Referral partners of subrecipient agencies typically consist of a wide range of community partners meant to create a network of support to meet the medical and social needs of patients that are outside of the scope of services of the Title X clinic. Depending on the geographic region in which the Title X subrecipient agency operates and the defined community need, each subrecipient agency could potentially have hundreds of referral partners. Referral partner relationships take many forms and can exist both with and without formal written agreements. The vast majority of referral networks consist of informal or formal partnerships without a financial relationship. Those referral networks are based on assuring that patients have access to services one party does not provide, such as assistance with food or housing, and encompass a wide range of interactions from shared case management to a simple referral for services. As written, the proposed rule aims to push the boundaries of program monitoring by dramatically expanding the scope of Title X grantee oversight of subrecipient agencies' referral partners with whom NYSDOH will have no contractual or fiduciary relationship.
- For these reasons, NYSDOH is not comfortable expanding beyond its current role in monitoring the extent to which subrecipient agencies establish and maintain the appropriate referral networks to meet client need as part of the contractual relationship between NYSDOH and subrecipient agencies.

Recommendation:

We recommend that §59.5(a)(13) is not implemented in the Title X program. We recommend that subrecipient agencies continue to be responsible for identifying, evaluating, and collaborating with referral partners and that information be shared routinely with NYSDOH as the Title X grantee. We do not support requirements for Title X grantees to perform additional referral partner oversight and monitoring.

§ 59.5(a)(14):

The proposed rule requires encouragement of family participation and documentation of specific actions taken to encourage family participation in the decision of minors to seek family planning services (or reasons why such family participation was not encouraged.)

- Although a Title X legislative mandate already requires Title X grantees to encourage family participation in the decisions of minors, and grantees currently must certify such encouragement as a condition of Title X funding, the proposed rule imposes an added emphasis on this matter.
- In addition to the harm discussed *supra* page 4, the additional documentation requirements outlined in the proposed rule will create an increased burden on staff time and electronic medical record systems that are likely to increase programmatic costs with no subsequent increase in funding to offset these expenditures. These requirements will force providers to spend less time providing direct patient services and more time completing unnecessary documentation.
- No other type of family planning counseling requires that providers document the substance of their conversation. Providers are trusted to use their professional judgment and expertise when counseling patients on pregnancy options, birth control choices, sexual risk avoidance behavior, and other complex sensitive topics. To single out this one aspect of family planning practice for special attention and extra documentation is unnecessary.

Recommendation:

We recommend that §59.5(a)(14) is not implemented in the Title X program. We support and work to ensure compliance of all sub-recipient agencies within the existing Title X legislative mandates³⁰ requiring that minor patients be counseled and encouraged to involve a family member in reproductive health care decisions. However, we do not support the unnecessary burden of excessive documentation and believe that efforts and funds would be better used to support training for providers on the best methods to encourage family involvement consistent with minor patients' confidentiality rights, health needs, and best interests.

Section 59.7 Criteria used to determine funding for family planning projects.

The proposed rule removes previous criteria used to determine which projects will receive Title X funding and replaces it with new criteria that emphasize compliance with Title X statutory provisions restricting the provision of abortion services using Title X funds and with newly developed Title X program priorities, which were first introduced in the February 2018 FOA.

- The proposed rule amends the long-standing criteria by which Title X applicants are reviewed. Since 1971, the Title X regulations have specified that seven criteria be used for selecting Title X grantees, which has resulted in a relatively stable network of grantees and subrecipients that have developed a high level of expertise in the provision of family planning services.
- In the proposed rule these seven criteria have been eliminated and replaced with four broad criteria that emphasize statutory and regulatory compliance, and that are vague and internally inconsistent. Criteria concerning the adequacy of the applicant's facilities and staff, and the availability of non-federal resources for the project have been removed. Other criteria have been modified and made more nebulous, combining two or more previously distinct criteria into one. For example, the number of patients to be served has been modified to indicate that the applicant should also target sparsely populated areas and places in which family planning services are not available. Also, the capacity to make rapid and effective use of grant funds is now linked to applicants that make use of funds "among a broad range of partners and diverse subrecipients...and among non-traditional Title X partnering organizations." These proposed changes to the scoring criteria make any meaningful merits review scoring difficult.
- Furthermore, the proposed changes create a new avenue to quickly remove applications from consideration if they "do not clearly address how the proposal will satisfy the requirements of this regulation" and gives HHS broad discretion to disqualify applicants before any objective merits panel review has taken place. The proposed rule includes very little detail on how HHS will determine whether an application has addressed how it will satisfy regulatory requirements, and will allow HHS to advance only favored applications to the review panels.
- Based on the new changes, it will be easier for HHS to deny funding to existing providers and give preference to non-traditional organizations and provider types over proven and experienced providers of family planning services.
- Additionally, if applied retroactively, the proposed rules would alter the scoring criteria for the Title X FOA that was released in February 2018. To change the rules and scoring criteria of an FOA after applications have been submitting would be unfair to applicants that applied and to entities that decided not to apply. Applicants deserve the opportunity to fairly understand the rules and criteria on which they will be judged prior to submitting applications. The proposed changes to scoring criteria would dramatically alter what was previously known to impact scoring and, had

³⁰ <https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/legislative-mandates/index.html>

this information been public prior to the application due date, would certainly have resulted in applicants prioritizing different themes, activities, and answers in their response.

Recommendation:

We recommend that proposed changes to §59.7 are not implemented in the Title X program. All Title X applicants that meet grant eligibility requirements should continue to be reviewed by objective merit review panels, consistent with best practices for ensuring public health. Existing review criteria have been in place for decades and have provided clear guidelines for the selection of Title X grantees.

Section 59.11 Confidentiality.

The proposed rule adds language potentially limiting confidentiality protections for patients.

- Title X has had strong confidentiality protections for patients in place since the inception of the program. These confidentiality protections are one of the primary reasons that individuals choose to seek care at Title X sites.³¹
- While proposed changes align with previously applied Title X program requirements, the new rule expands language requiring intimate partner violence and human trafficking reporting, emphasizing compliance with notification and reporting laws ahead of patients' needs and confidentiality concerns, which could lead to patients withholding important information from providers or not seeking care at all from Title X providers.
- The proposed language is also vague, in that it states all Title X programs will be required to comply with "similar reporting laws" and that the project must provide "appropriate documentation or other assurance satisfactory to the Secretary of HHS," which is unclear enough that it could be translated into requirements by HHS that could force Title X programs to take action violating established medical ethics. The language also requires that Title X grantee organizations demonstrate compliance in way that could see HHS seeking individual patient medical records as a means of proving compliance, an action which would dramatically undermine Title X's longstanding commitment to confidentiality.

Recommendation:

We recommend that proposed changes to §59.11 are not implemented. We support the continued inclusion of the existing language in Title X Program Guidelines and efforts to expand opportunities to identify and support individuals at risk for or experiencing both IPV and/or human trafficking. We recommend additional funding to support enhanced training and technical assistance opportunities for Title X providers in these areas.

Proposed Addition of New Rules

The notice of proposed rulemaking includes the addition of several new sections emphasizing the existing Title X statutory prohibition on using Title X funds to provide abortion as a method of family planning. These new standards are designed to target abortion-related activities and entities that provide abortion care outside of their Title X funded services. However, there would be severe implications for *all* Title X funded entities, the services they provide, and the ability of patients to access comprehensive family planning services and reproductive health care. In New York state, the added cost and prohibitive

³¹ Frost, Jennifer J., Rachel Benson Gold, and Amelia Bucek. "Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Womens Health Care Needs." *Womens Health Issues* 22, no. 6 (2012).

burdens to vital and long-standing participants in the Title X program would threaten access to family planning services for thousands of women.

Section 59.13 Standards of compliance with prohibition of abortion.

The proposed rule creates a new unnecessary requirement to demonstrate compliance with the existing statutory prohibition of abortion.

- The statutory requirement in Title X, 42 U.S.C. § 300a-6, that prohibits the use of Title X funds from being “used in programs where abortion is a method of family planning” has long been in place. Current Title X grantees and subrecipients demonstrate compliance with 42 U.S.C. § 300a-6 through annual signed assurances stating that the organization complies with this rule and regular NYSDOH monitoring and audits.
- The proposed rule imposes a new burden on Title X grantees to “provide assurance” of compliance with the provisions of 42 U.S.C. § 300a-6, which are expanded under proposed § 59.14 through § 59.16.
- As written, the proposed rule does not clearly articulate how compliance should be demonstrated, and what documentary evidence would be necessary to provide this assurance.
- Proposed § 59.14 through § 59.16, as is discussed further below, are much farther reaching than existing statutory language in that promotion and referral to abortion are prohibited, and physical and financial separation from abortion providers is required. As such, it is expected that documentary evidence needed to demonstrate compliance with these new requirements would also be much more extensive than current requirement.

Recommendation:

We recommend that §59.13 is not implemented in the Title X program. We support the continuation of existing practices to monitor Title X grantee and subrecipient compliance with the statutory prohibition on abortion.

Section 59.14 Prohibition on referral for abortion.

The proposed rule creates specific prohibitions on referrals for abortion, and requires referral for prenatal services. The sections of the proposed rule, either implemented individually or together, would compromise physicians’ ethics and ability to meet a basic duty of care, and eliminate the ability of pregnant women to give informed consent on all legally available post-conception services. NYSDOH first discusses the individual sections of the rule below, and the NYSDOH recommendation for §59.14 as a whole follows.

§59.14(a):

The proposed rule creates a specific prohibition on referrals for abortion which includes detailed limitations on a physician’s ability to refer patients for an abortion, even upon request.

- The proposed rule prohibits all Title X patients from receiving any information on the availability of abortion services, even if this information is specifically requested by the patient.
- The proposed rule limits the free speech and clinical oversight of Title X physicians by dictating the circumstances and manner in which they may be able to provide very limited information on abortion services, even to women with a positive pregnancy test who specifically request this information. The new rule goes so far as to give stipulations on how to compose a list of referral partners who may or may not provide abortion services, disallowing the identification of partners

who do provide abortion services even upon request, potentially confusing and misleading patients.

- As discussed further *supra* pages 8-9, such restrictions on a provider's ability to provide full options counseling and information on medical services to a patient compromises the provider's medical ethics and brings the provider into conflict with state law on duty of care.

§59.14(b):

The proposed rule prohibits the provision of any services to individuals who are “medically verified as pregnant” eliminating the ability of any Title X recipient to provide basic prenatal care and screening for women who receive a positive pregnancy test at a Title X funded site.

- As written, this requirement to refer all women with a positive pregnancy test to prenatal care regardless of their wishes is essentially directive counseling. If implemented, this proposed rule would remove any possibility of Title X patients exercising informed consent when making medical decisions related to a pregnancy diagnosis. Requiring physicians to provide directive counseling on only one option for pregnancy management will effectively force health care providers to deliberately deceive patients regarding their health care options, thus rendering them unable to make a fully informed decision. In order for patients to make decisions based on informed consent it is imperative that providers assist patients in fully understanding their health condition, in this case pregnancy, and are informed of the benefits and risks of all viable medical options to manage their condition. With the implementation of this rule, any patient receiving a pregnancy diagnosis through a Title X provider will be denied basic health care information necessary for them to exercise informed consent.
- The proposed rule limits the ability to provide early prenatal care for those women who do chose to continue their pregnancy. As discussed *supra* pages 2-3, early access to prenatal care is known to improve birth outcomes. Access to this care via a Title X provider can be especially necessary for the vulnerable populations served by the Title X program who often enter prenatal care late. Initiation of prenatal care during the first trimester is described by the Institute of Medicine as a measure of timely care.³² The period of greatest sensitivity of the developing fetus to maternal health conditions and environmental exposures is between 4 and 10 weeks of pregnancy, that is, between the woman's first and third missed period.³³
- A number of factors can impact the timing and adequacy of prenatal care that women access. Barriers to access may range from geography/location, lack of transportation, uninsured/underinsured, inability to find a provider that accepts her insurance, appointment wait times, lack of benefits to attend prenatal care appointments, to interpersonal violence/domestic violence issues and personal beliefs. Ensuring that all women have timely access to early prenatal care services is important in decreasing health disparities and improving maternal and infant outcomes within the United States.³⁴
- Increasing the availability and access to prenatal care services may be important in preventing adverse birth outcomes especially among women suffering from partner violence.³⁵

³² Ayoola, Nettleman, Stommel, et al. “Time of Pregnancy Recognition and Prenatal Care Use: A Population-Based Study in the United States.” *Birth* 37, no. 1 (2010): 39.

³³ Preconception Care: A Systematic Review Carol C. Korenbrot, PhD, Alycia Steinberg, MPH, Catherine Bender, BA, and Sydne Newberry, DrPH *Maternal and Child Health Journal*, Vol. 6, No. 2, June 2002

³⁴ Women's Perceptions of Access to Prenatal Care in the United States: A Literature Review, Julia C. Phillippi, CNM, MSN, J Midwifery *Womens Health* 2009;54:219–225.

³⁵ Intimate Partner Violence and Utilization of Prenatal Care in the US Susan Cha, BA, MPH and Saba W. Masho, MD, MPH, DrPH, *Journal of Interpersonal Violence* 2014, Vol. 29(5) 911–927.

§59.14(c):

The proposed rule restricts the use of referrals as an indirect means of encouraging or promoting abortion.

- The proposed rule restricts the physician's ability to meet the patient's needs by requiring that referrals for abortion services be disguised within a list of providers that provide comprehensive prenatal care. This continues to limit a patient's ability to get information on abortion, even upon request
- As discussed further *supra* pages 8 and 16, by limiting a patient's ability to get information on abortion or a provider's ability to refer, this rule compromises a patient's informed consent and a provider's medical ethics.

§59.14(d):

The proposed rule clarifies that the rule should not be interpreted as prohibiting information on contraception, and that the prohibition is specifically for information related to abortion.

- Although seeming to encourage increased information and access to contraceptive information, this rule if implemented will actually do nothing substantive to ensure that Title X patients have access to or information about contraceptive options. While clarifying that Title X programs are not expressly prohibited from providing information on contraception, this rule does not require or even encourage funded projects to provide comprehensive information on all contraceptive options. Merely clarifying that an action is not prohibited cannot be interpreted as an endorsement or mandate to implement said action.
- Further, while this rule does clarify the ability of programs to provide information on contraceptive methods, it does not require that the program actually offer any of those methods to patients. Again, this rule seeks to provide the appearance of increasing contraceptive access while literally doing nothing to actually ensure that women and men being served by the Title X program have the ability to obtain any FDA approved contraceptive method of their choice.

Recommendation:

We strongly recommend that §59.14 is not implemented in the Title X program. By removing requirements for comprehensive, non-directive patient counseling on all post-conception options (including abortion care) the proposed rule infringes on the free speech rights of health care providers, requires that health care providers work contrary to almost all accepted standards of medical ethics, and removes the ability of Title X patients to give informed consent for medical care based on their knowledge of all available medical options.

Section 59.15 Maintenance of physical and financial separation

The proposed rule purports to interpret 42 U.S.C. § 300a-6's existing restriction on the use of Title X funds for "programs where abortion is a method of family planning", but dramatically expands the expectation of how non-Title X funds used for abortion services should be segregated.

- New requirements dictate that a facility that provides both Title X services and abortion care must ensure physical and financial separation between family planning and abortion services.
- This requirement fails to understand the structure of most family planning programs, which often function within the context of larger women's and other health organizations. Family planning services are viewed as one component of a broad spectrum of gynecological services available to women. This spectrum includes family planning services, health care procedures meant to enhance fertility, labor, and delivery, as well as abortion services. Arbitrarily selecting one of these commonplace services (abortion) to penalize an organization for performing, independent of their

Title X program is not only unfair but creates an undue burden to many of the most comprehensive programs.

§59.15(a):

The proposed rule specifies that separate accounting records must be maintained by all Title X subrecipient agencies that provide abortion services.

- Currently any Title X funded organization that also provides abortion care is required to apply a cost allocation methodology for program administration of Title X allowable expenses such as financial records management, accounting software, payroll software, insurance, and the agency's administrative staff between Title X allowable services and the provision of abortion.
- This proposed rule would require non-profit organizations to duplicate expenses in order to separate abortion services, creating an excessive financial burden on organizations that often run on very tight margins.
- These new requirements that would create duplicated administrative functions also run counter to the last several years of work done within the NYSFPP to reduce administrative overhead on grant funded programs by identifying beneficial financial partnerships and collaboration between Title X providers and other health care professionals. Through extensive investment in health systems improvement strategies such as Delivery System Reform Incentive Payments (DSRIP) and other Health Information Technology (HIT) activities, NYS has lead the nation in working to eliminate redundancies in the health care delivery system to lower costs for both government payors and consumers. This work has supported the consolidation of administrative functions within numerous large hospital and primary care provider systems, has funded the introduction of HIT projects and applications reducing provider workload and increasing efficiency at which providers can see and treat patients, and emphasized shared decision making to reduce the cost and burden of administrative functions within many smaller health care organizations. To add new regulations to the Title X program that knowingly expand the required cost and burden of administrative services is to run contrary to current best practices in health systems management and, specifically in NYS, negate millions of dollars of effort in health care systems reform which many current Title X programs have participated.
- Implementation of this rule would add significant additional expenses to the majority of Title X programs within NYS, none of which would go to support direct patient care. This would require potentially double the funds to support: administrative staff, fiscal staff, and fiscal operating systems (which can cost thousands of dollars annually). These additional expenses required by this rule would then mean that less funds would be spent on: clinical staff time, clinical supplies, contraceptive supplies, educational materials, education, and counseling activities, as well as essential community health prevention activities aimed at reducing the incidence of unplanned pregnancies in communities across NYS.

§59.15(b):

The proposed rule specifies that physical separation must be maintained. This proposed rule would mandate the physical separation (distinct consultation, exam, and waiting rooms) between office/exam space where abortion services are performed and the area where any Title X services are provided. In addition, the rule specifies that abortion service/provision must also have their own phone number, email address, educational services, and websites.

- These requirements fully fail to understand the way in which abortion care is integrated into the larger infrastructure of women's health organizations while still, through pro-rating shared services (i.e. time and effort reporting for staff, square footage allocation, etc.) ensure that no Title X funds ever support the provision of abortion.

- By creating a physical separation just for abortion care, this rule demonstrates a clear lack of understanding of the manner in which women choose to access obstetrical/gynecological services. Abortion care is a standard component of obstetrical/gynecological care and there is no medical or scientific reason why abortion care specifically should be segregated from other outpatient obstetrical/gynecological care. Abortion services are a common outpatient medical procedure performed in the United States. This procedure is safely completed in outpatient clinical settings across the United States and poses no additional risk that would necessitate separate facilities from those performing other semi-complex outpatient obstetrical/gynecological procedures like colposcopy, cryosurgery, and/or LEEPs (all of which are currently included in the NYS FPP).
- This new requirement is not necessary, as programs have successfully segregated abortion care without confusion by patients, subrecipient agencies, or the public, as discussed *infra* pages 23 and 26.
- If implemented this rule would serve to double expenses within many Title X programs, further limiting the amount of funds that can be allocated toward expenses that actually benefit patients (i.e. clinical staff time, contraceptive supplies, education and counseling services, etc.).
- In addition to increasing the cost burden for organizations which provide abortion services, which are already financially segregated from Title X services, requiring a physical separation would serve to highlight locations where abortion services solely are provided, an action that could likely increase the potential risk of those locations being a target of violent crime or protest. Taking action that could increase this risk runs counter to the recognition by both the federal and state governments, memorialized in 18 U.S.C. § 248 and N.Y. Penal Law §§ 240.70-240.71.

§59.15(c):

The proposed rule specifies that distinct personnel, electronic, or paper-based health care records, and work stations must be maintained.

- Electronic health records (EHR) represent one of the most significant expenses for any family planning provider. The bulk of costs, which can often reach tens if not hundreds of thousands of dollars, are typically incurred in the set up and initial roll out of any new EHR system. If implemented, this rule would require an immediate influx of hundreds of thousands of dollars for most of the currently funded NYSDOH Title X subrecipient agencies within the first year for a new system. Adding this requirement without any increase in available funding would make implementing this change financially impossible for many of the programs, especially the smaller, rural serving organizations. Any loss of part or all of the current Title X program network would be a serious blow to patient access. Many Title X programs serve communities with few or no other health care providers and the loss of their Title X program could exacerbate already struggling provider shortage areas. Additionally, expenses related to establishing a new EHR system extend beyond the software licensing costs and typically include significant hardware and infrastructure expenses as well. Per language in the NYSDOH master contract, providers may not purchase any equipment in the final year of a grant cycle (which ends in 2019), therefore beginning 1/1/19 all NYSFPP organizations will be prohibited from purchasing equipment and therefore unable to comply with new requirements in the expected timeframe.
- NYSDOH maintains this new requirement is not necessary as programs have successfully segregated abortion care through the established practice of pro-rating expenses between the Title X program and the provision of abortion services. Budgets submitted to NYSDOH annually are reviewed by program staff with a particular emphasis on ensuring segregation of any abortion related expenses on all budgets, fee scales, formularies, and other program documents.

§59.15(d):

The proposed rule requires that signs and other ways in which the agency identifies itself remove any reference to abortion services.

- This proposed rule goes well beyond the scope of any current or former Title X program guideline or mandate. The Title X program has current regulations which emphasize community oversight and control of all Title X education, outreach, and marketing materials through a committee review process known as the “Information & Education Committee” requirements. Clearly stipulating this committee be comprised of individuals who broadly represent the communities in which the Title X program operates, this requirement stipulates that Title X programs obtain input from, and listen to the guidance of community members when developing all publicly distributed materials. This new requirement would essentially circumvent that process for signage and other agency marketing materials, removing control and oversight from communities and placing it with HHS.
- In addition to circumventing current regulations mandating community involvement in the development of marketing materials, this new rule imposes requirements on the content of materials developed well beyond the current scope of Title X contract oversight. As a grantee organization, NYSDOH does and will continue to, review and approve how programs spend the grant funds provided to them. However, NYSDOH, and HHS as its funding organization, lack the oversight to impose further requirements on how programs elect to spend other non-grant funds – including on the content of program’s materials developed with other, often private funds. None of the currently funded NYS FPP agencies operate solely utilizing grant funds and supplement their grant awards with organizational funds, donor funds, and/or revenue generated from the provision of services. Therefore, it is very likely that a Title X program could opt to pay for the creation and installation of signage using funds other than those they received as part of their Title X, in which case NYSDOH contends it would lack the legal authority to dictate the content of signage paid for by private funds.

Recommendation:

We strongly recommend this proposed rule not be enacted as part of the Title X program.

Section 59.16. Prohibition on activities that encourage, promote, or advocate for abortion.

§59.16(a):

The proposed rule prohibits such activities as lobbying, paying dues to a group that advocates for abortion, and developing or disseminating materials advocating abortion.

§59.16(b):

The proposed rule provides a series of examples to illustrate what activities demonstrate compliance or non-compliance with paragraph a.

- NYSDOH continues to maintain that this rule, and its subsequent examples, are both unnecessary additions to the Title X program, and like so many of the other proposed rules in the Notice of Proposed Rulemaking are solutions in search of a problem. Current, and future NYS FPP organizations must be 501c3 eligible organizations to be eligible to apply for funding through this grant programs and as such, those organizations are clearly prohibited from funding or engaging in any kind of lobbying activities per IRS law.
- NYSDOH also contends this rule extends beyond the scope of allowable oversight by HHS and NYSDOH of the Title X program and subrecipient agencies by stipulating that Title X funds cannot be used to support organizations which engage in lobbying, even if the Title X funds used

do not support lobbying activities. Many advocacy organizations or other associations which engage in lobbying activities also provide vital educational and institutional support to Title X providers, independent of their, often separately funded, lobbying activities. Prohibiting Title X providers from using their funds to pay dues into these organizations, even if those dues are not used specifically to fund advocacy for abortion represents an overreach and fails to take into account the essential educational functions of many of these organizations. Strictly interpreted this rule could prohibit Title X agencies from paying dues to, and being able to collaborate with organizations like: American College of Obstetricians & Gynecologists, National Family Planning & Reproductive Health Association, Planned Parenthood Federation of America, and other nationally recognized organizations known for being leaders in the provision of clinical education and technical assistance to reproductive health care organizations.

Recommendation:

We strongly recommend this proposed rule not be enacted as part of the Title X program.

Section 59.17. Compliance with reporting requirements.

The proposed rule requires that Title X projects comply with all state and local reporting laws and provide satisfactory documentation to the Deputy Assistant Secretary for Population Affairs that it has complied, as a condition of receiving Title X funding.

- Current Title X guidelines clearly stipulate that information on clients cannot be disclosed, “except as required by law” which establishes the necessity of compliance with all state/federal reporting requirements. In addition, a current legislative mandate clearly outlines the requirements the reporting of any suspected child abuse or maltreatment by Title X grantees, subrecipient agencies, and their employees. The clarity of this mandate ensures consistent application among programs while allowing providers to develop and implement strategies to meet these needs that are tailor made for the individual circumstances of their own patients. Routine program monitoring includes chart reviews, a required number of which must be adolescent charts, which are specifically assessed to demonstrate compliance with these legislative mandates.
- Per NYS law all NYS licensed physicians, mid-level providers, and nurses serve as “Mandated Reporters” of any suspected of child abuse or neglect. Professionals providing services in Title X-funded sites are aware of their reporting obligations, already receive training on them, and make reports in compliance with these requirements. Health care professionals take seriously their reporting obligations and their obligations to their patients to protect them from real risks of exploitation and abuse.
- The proposed rule requires providers to conduct preliminary screening of any teen who presents with a sexually transmitted disease to rule out victimization. In addition, the proposed rule requires providers to document the age of minor patients as well as the age of the minor patient’s sexual partners. Not only does this require a Title X project to maintain detailed records that include this highly personal information but it would require providers to collect that information no matter what the surrounding circumstances which could scare away, or at a minimum, disturb minor patients and cause them to no longer seek care in a Title X setting.
- The proposed rule also seeks to expand HHS’ authority to inspect patient records for the sole purpose of ensuring compliance with reporting obligations. The proposed rule would thus allow HHS to substitute its own judgment for that of the state (or locality) that is actually responsible for determining compliance with these laws and is in the best position to make determinations about whether a Title X project or its individual providers are in compliance with them.

- NYSDOH contends that increased oversight by HHS, together with the addition of new requirements to collect and document specific information in Title X records, will prompt inappropriate screening and over-reporting by providers that will harm patients and undermine the provider/patient relationship.

Recommendation:

We strongly recommend this proposed rule not be enacted as part of the Title X program. Given that a Title X legislative mandate already exists, addition of this rule is not necessary, will compromise patient confidentiality (particularly for adolescents), and will drive patients away from critical health services.

Section 59.18. Appropriate use of funds

The proposed rule outlines the prohibition on use of funds to build infrastructure for abortion providers, or for activities that promote support or opposition to any legislative proposals or candidates for office. In addition, the proposed rule requires full accounting for charges against the Title X grant.

- NYSDOH contends that the addition of this rule is unnecessary within the scope of the current Title X program. Based on current statute and regulations, Title X providers are already prohibited from using funds to support abortion services for family planning, and any kind of infrastructure building for such services are outside the scope of allowable activities. Furthermore, as stated in the response to Section 59.16, in order to be eligible for the NYS FPP, organizations must be 501c3 or other eligible groups and as such, are already prohibited from engaging in any form of lobbying for proposals or candidates. Finally, the additional requirement of full accounting for Title X expenses is unnecessary as fully accounting for expenses is a key principle of any general rules of accounting and is mandatory for all NYSDOH funded programs. Current NYSFPP funded organizations are required to maintain a record of all grant related expenses, are expected to produce that information upon request, and undergo periodic audits to ensure that information is kept and can be made available when necessary.

Recommendations:

We strongly recommend this proposed rule not be enacted as part of the Title X program.

Section 59.19. Transition provisions

The proposed rule requires that entities comply with physical separation requirements within one year of publication of the final rule, and comply with financial separation and all other requirements within sixty days of publication of the final rule.

- NYSDOH contends that the aforementioned new rules regarding physical separation are unnecessary and present a substantial administrative and financial burden to agencies being required to operationalize these changes. As written, these changes would undermine the financial stability of numerous organizations throughout the NYSD FPP Provider Network and would likely result in several hundred thousand NYS residents being forced to go without life changing family planning services.

Even the addition one year's time frame in which to make these changes does nothing to effectively ease this burden, as the ongoing operational costs to maintain duplicative systems and locations would be substantial. Furthermore, many subrecipient agencies are small, not-for-profit organizations which lack the capital on hand, or the ability to raise the amount of capital needed to fund these changes within such a short window of time.

Recommendations:

We strongly recommend this proposed rule not be enacted as part of the Title X program.

II. Responses to HHS Specific Requests for Comments:

The following section summarizes NYSDOH's response to HHS' specific requests for comment that appear in the preamble of the Notice of Proposed Rulemaking (NPRM). When comments relate to specific proposed rule changes the applicable sections are referenced.

Page 21-22 of NPRM

Re: HHS request for comment on the proposed rule to prohibit providers from promoting, referring for, or supporting the provision of abortion services.

NYSDOH strongly opposes the addition of this language. The current Title X statute has been in place for over 40 years to ensure that Title X funds are not used to support the provision of abortion as family planning and this statute and implementing regulations do not require updating. If enacted, the proposed regulation would compromise provider ethics, and all but end the ability of health care providers to provide care within the limits of their clinical judgment. Furthermore, this proposed rule would deny Title X patients their right to informed consent on medical services as well as medically necessary information on legally available health care procedures. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 39-40 of NPRM

Re: HHS Request for Comment on changing the regulatory review criteria of applications to clarify “confusion” among Title X providers and the public.

NYSDOH strongly opposes the addition of this proposed rule change. As an original Title X grantee and applicant of the most recent Title X FOA, NYSDOH contends that confusion, either among clients, the general public, or potential grantees about the inclusion of abortion related activities in the Title X program does not exist. Information provided throughout the Notice of Proposed Rule Making fails to demonstrate any confusion among patients, grantees, subrecipient agencies, or the public about the appropriateness of abortion related services under the Title X program. Years of statute and regulation have clearly articulated the prohibition of using Title X funds to support the provision of abortion services and as such, this proposed rule is unnecessary. Furthermore, in applying retroactively to the currently pending FOA the proposed rule would undermine the fairness of the FOA and ensure that current applicants would be scored on criteria they were previously unaware. NYSDOH contends that the late inclusion of these measures, well after the application due date, would create a fundamentally unfair scoring process that would unjustly weight funding to organizations not capable of providing the full range of comprehensive services that have long been the benchmark of Title X care.

Page 45-46 of NPRM

Re: HHS request for comment on eliminating specific regulations as they apply to “contracts.”

NYSDOH supports fair contracting practices completed through open procurement procedures and scored in alignment with Title X program guidelines as the most appropriate method to distribute federal Title X program funds. NYSDOH strongly opposes any effort to circumvent fair contracting rules to expedite allocation of funds to organizations and programs that do not submit applications as part of a competitive procurement or, as “contracts” that will not be required to follow program regulations, including basic eligibility guidelines. If implemented, this change could drastically alter the landscape of Title X providers, potentially allowing, among other things, for-profit organizations and health care providers that

do not meet the highest standards of quality care to be awarded federal funds through a non-competitive process. This would result not only in the loss of long standing provider organizations with a proven track record for contract management, but the award of public funds to organizations who may opt to use federal money to profit from serving limited income individuals seeking family planning services. NYSDOH is committed to ensuring the fair and equitable distribution of public funds to communities who through a competitive process, fairly scored, adequately demonstrate both a compelling need for funds and the ability to utilize those funds in alignment with program regulations and guidelines.

Page 50-51 of NPRM

Re: HHS request for comment on the proposed rule to expand the reporting requirement and oversight of grantee and sub-recipient agencies to all referral partner organizations of each grantee/subrecipient agency.

NYSDOH strongly opposes the implementation of this proposed rule. As written, this additional requirement would dramatically expand the oversight and reporting requirements of the Title X program to include a wide range of organizations partnering with subrecipient agencies to establish referral networks. These collaborative partnerships are non-funded partner and referral agreements, established between subrecipient agencies and their partners across the state who do not receive any federal Title X funds. This proposed rule demonstrates several fatal flaws that would make its implementation not only overly burdensome and financially unsound, but call into question the legal authority of both HHS and grantee organizations in inserting themselves into the contractual relationship of two organizations, one of whom they will have no legal or contractual relationship. NYSDOH contends that neither HHS, nor the NYSDOH as its grantee organization, can claim a legal right of oversight on the operations and activities of non-funded referral partner organizations. Lacking any legal authority to dictate the scope or type of activities, the NYSDOH would be unable to enforce the minute requirements and/or require the reporting of data as outlined in the proposed rule. Therefore, this rule is unacceptable and would be impossible to implement at any provider level. Furthermore, should there arise contractual relationships that give grantees this level of oversight, the sheer volume of analysis of all referral partners within a large Title X program would necessitate increased staff time, data processing ability, and the subsequent increase of grant funds used to support administrative overhead at the expense of funds supporting clinical patient care. For example, the NYSDOH Title X network consists of 48 subrecipient agencies, with over 170 individual clinical sites that each may have dozens of referral partner organizations. It would be impossible for the NYSDOH to maintain oversight of this large number of referral partners. Additional comments can be found under § 59.5(a)(13), discussion *supra* pages 11-12.

Page 62-63

Re: HHS request for comment on whether the additional requirements related to abortion are necessary to protect the individual right to decline participation in abortion-related activities and alleviate current confusion.

NYSDOH strongly opposes the implementation of any additional requirements in this area, for reasons previously stated, which include: a failure of HHS to demonstrate any “confusion” regarding the nature of Title X services or an individual provider’s role, the longstanding provision of abortion services which has successfully ensured that no Title X funds have supported the provision of abortion for nearly forty years, and unethical, potentially illegal, and contrary to medical ethics limits on physician speech that would be required to implement this rule. If enacted, this rule has the potential to jeopardize the health and well-being of women accessing reproductive health services through a Title X provider. For example, this rule could cause women seeking care through Title X providers to miss timely access to key reproductive health care services including identification of and treatment for ectopic pregnancy, molar

pregnancies, or other abnormal products of conception. Should a woman present with a medically nonviable pregnancy, this rule would allow a physician to inform her that she may opt to terminate the pregnancy, but would prohibit that provider from assisting her in obtaining and accessing a timely referral for medically necessary care. The guidance issued along with this proposed rule stipulates that this physician could only give the patient a list of alternative health service providers some (but not all) of which provide abortion and the physician would be specifically barred from indicating which providers offer abortion care. This lack of clear information, the additional burden of time required to contact and verify which provider offers her required medical service could result in a delay in accessing care which would jeopardize the health and well-being of women receiving medical care through the Title X program.

An additional concern also lies with the regulatory definition of “physician” as the sole individual permitted to provide information on abortion to any Title X patients. As with many other types of health care facilities, the vast majority of “providers” who regularly seeing patients are highly trained mid-level clinicians (i.e. Nurse Practitioners, Physician’s Assistants, Nurse-Midwives) and not physicians. Therefore, the language in this rule calls into question whether or not mid-level clinicians would be prohibited from acting within their scope of practice and expertise to inform patients of the availability of abortion care when medically necessary and/or requested by a patient. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 69-70

Re: HHS request for comment on the inclusion of additional requirements to demonstrate segregation of abortion services in any Title X program.

NYSDOH strongly opposes the inclusion of these factors within any new Title X regulations. The NYSDOH continues to be confident the long existing Title X statutory and regulatory language do ensure the separation of funds supporting Title X activities and those funding the provision of any abortion services, and those regulations have successfully ensured that segregation for well over forty years. These unnecessary, burdensome, and seemingly arbitrary points of separation included in the proposed rule will not, in any meaningful way, go further to ensure the separation of Title X fund from abortion care than current legal requirements and annual provider attestations do. The proposed rule includes onerous requirements created with a clear design to establish additional Title X regulations that would effectively prohibit any Title X funded provider from also providing abortion care even through a separate source of funding as is currently permissible within the existing Title X regulations and statute. These new rules would be difficult to implement and oversee, unfairly target specific provider types to the benefit of organizations incapable of providing a high level of quality medical care to patients, and serve to dramatically limit the number of eligible Title X subrecipient agencies. Implementation of this rule could result in the closure of family planning clinics across NYS, resulting in loss of access to essential health care services by as many as 300,000 patients across NYS. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 70

Re: HHS request for comment on the impact of the proposed rules requiring physical and organizational separation of Title X providers and abortion care.

NYSDOH strongly opposes the implementation of this rule and is incredibly concerned about the potential impact of this proposed rule if enacted. Opposition comes not only from the substance and content of the rule itself, but the HHS contention that confusion currently exists within the public about the separation of Title X services and abortion care. It is the position of NYSDOH that no such public confusion exists, that all currently funded Title X subrecipient agencies have an excellent track record

ensuring the separation of Title X funds from any abortion related services and that this misplaced concern demeans not only the understanding and intelligence of family planning clients, but demonstrates a fundamental lack of understanding from HHS on how most patients choose to access family planning services. Similar to the rule referenced in the section above (pgs. 69-70 of NPRM document) this new rule would create an undue burden on certain types of Title X providers, many of whom serve the bulk of Title X clients in any given service area. The new proposed requirements around financial and physical separation are not only unnecessary (as all Title X programs already clearly pro-rate space, administrative, and staff expenses to ensure separation of abortion funds) but are anathema to every other trend in health care service delivery, especially in NYS. Over the past several years billions of dollars have been spent to reform the health care service delivery system in NYS, emphasizing increased collaboration, shared administrative services, as well as opportunities for increased shared spaces among different types of community providers. This proposed rule would undue nearly a decade's worth of effort to better streamline health care delivery in NYS, would undue work to avoid administrative duplication, and would create an unfair financial burden on only some Title X providers to the detriment of the communities and patients that they serve. Additional comments can be found under **Sections §59.13 – §59.16, discussion *supra* pages 15-21.**

Page 80

Re: HHS request for comment on the value of cost/benefit of proposed rule changes.

NYSDOH strongly disagrees with the HHS proposed cost/benefit assessment of the proposed rule changes. The included analysis fails to adequately calculate the devastating financial impact of physical and administrative separation for organizations that will continue to provide legal abortion services and does not account for the likelihood that these organizations may have to decline Title X funding and/or cease operations with the addition of these arbitrary and unnecessary new rules. That lack of service providers would devastate the current landscape of Title X services across NYS and could result in up to half of all current NYS FPP clients (nearly 300,000 individuals annually) no longer being able to access Title X funded services. Furthermore, HHS has provided no factual basis for their continued assertion that there is confusion regarding the separation of abortion funds from Title X funded services or that the currently accepted safeguards (in place within the Title X program for over 40 years) have not sufficiently ensured the effective separation of funds supporting abortion care with those supporting Title X services. Without establishing the necessity of these rules to remedy confusion, HHS's claim of an added benefit of clarity to the Title X program, to the residents of NYS, or to other stakeholders if these proposed rules are adopted is not convincing.

Page 100-101

Re: HHS request for comment on the proposed rules requiring additional separations between Title X service provision and the provision of abortion services.

NYSDOH strongly opposes the additional separations between Title X services and the provision of abortion services outlined in this rule. Not only has HHS failed to meaningfully demonstrate that such separation is necessary or beneficial to the implementation of Title X, the proposed additional requirements would add significant administrative burdens to Title X programs which have already proven their ability to comply with statutory language regarding prohibition on funds supporting abortion services. Further, new requirements regarding oversight go well beyond the scope of the Title X program to implement.

While purporting to support "holistic" family planning services, the HHS proposed rule does, in fact, only serve to dramatically limit both the scope and quality of family planning services required under this program. Rather than recognizing the way in which women and men currently access family planning

services, the proposed rules draw arbitrary distinctions between allowable and unallowable services that do not align with any known standards of care or medical practice. By prohibiting the provision of any post-conception care as part of the Title X program, HHS is not only limiting the ability of agencies to provide abortion care (something already restricted by 42 U.S.C. § 300a-6) but is working contrary to medical science and best practice to increase barriers high risk women experience to accessing needed prenatal and postpartum care services in a timely manner.

Other approaches to ensure compliance with statutory language would be the continued use of attestations submitted annually detailing agency understanding and responsibility to ensure the segregation of Title X funds from the provision of abortion services combined with regular cycles of onsite program monitoring and reporting at both the grantee and subrecipient agencies. Other approaches to providing holistic services that would better align with nationally accepted standards of care and best practice in family planning would include the expansion of services of within the Title X setting to promote easier access to prenatal care, abortion care, or adoption services based on the wishes of individual patients.

Page 104

Re: HHS request for comment on the proposed annual reporting changes along with their respective impact on the Title X program.

NYSDOH strongly opposes the implementation of this rule change proposed by HHS. NYSDOH contends that the proposed rule and its associated documentation are unnecessary, undesirable, and would only serve to increase costs for Title X funded organizations and subsequently decrease availability of services. The burden detail developed by HHS fails to fully describe the total cost in both financial and labor terms of all associated changes. For example, nowhere in the provided estimation did HHS include funds to support the creation of new patient intake/consent forms with updated program language in all required languages produced by NYSDOH, per NYS Executive Order³⁶ and per HHS Office for Civil Rights³⁷

Additionally, the current calculation fails to consider regional variations in provider salary, type and function when establishing a base salary rate for individuals who will be primarily responsible for implementing changes. Additional comments can be found under **Sections 59.3, 59.5, 59.7, 59.13, and 59.18 discussions *supra* pages 4-6, 12-13, 15, and 22.**

III. Legal Shortfalls of the Proposed Rules

The proposed rule changes, issued under Title X of the Public Health Service Act would include, among other things, restrictions on the use of funds received by grantee providers. Specifically, such grantees would be prohibited from utilizing any disbursement from this program for services associated with abortion – not merely the performance of such a procedure, but medical providers would also be prohibited from even mentioning the option of abortion to a patient during an examination/consultation. Furthermore, if a provider’s menu of services includes abortion, that entire portion of services must be completely cleaved from other medical services offered if the provider wishes to be a recipient of Title X funds. This separation extends so far as to preclude maintaining patient record databases or housing administrative services within the same building. The fallout from such restrictions could include (1) a

³⁶ NYS Executive Order No. 26 (Oct. 6, 2011), <https://www.governor.ny.gov/news/no-26-statewide-language-access-policy>

³⁷ Executive Order No. 13166, 65 Fed. Reg. 50121 (Aug. 11, 2000), <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html>

serious reduction in the amount of funding received by providers as any award will reflect a perceived “reduced need” if abortion services are not to be included in appropriate “family planning” options, and (2) some providers not receiving funds at all if they either cannot or will not separate abortion from other services offered as part of its family planning services.

The Scope of Regulatory Authority Under Title X

Where Congress has delegated rulemaking authority to a federal agency, such as HHS, that agency is granted deference in how it interprets and implements a statute. If it determined that Congress has not addressed an issue within a statute “unambiguously”, then deference is given to the federal agency’s interpretation of the provision in question. However, that deference is not without limits. First, an agency’s rulemaking must be based upon a statutory interpretation that is “rational” or “reasonable,” as well as not inconsistent with clear statutory language. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 468 U.S. 837 (1984). Second, an agency’s rulemaking will be struck down if it is “arbitrary, capricious, [or] an abuse of discretion.” Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A). To survive a review under the APA, an agency “must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983). The proposed rule changes go well beyond previous regulations proposed or implemented under the Title X program and stretches the reasonable bounds of Congress’ intent for the Title X program.

Rust v. Sullivan, 500 U.S. 173 (1991) involved a challenge to regulations enacted by Congress to administer the Title X statutory program, and is of particular interest in the current instance as the rules proposed now share the primary goal of the 1988 rules challenged in the Rust case: the exclusion of abortion services from funding under the federal grant program designated for family planning programs for the fraction of our population with limited access to healthcare services. However, the new proposed rules exceed the scope of the 1988 rules challenged in Rust. Most significantly, the newly proposed rules:

- Alter the scope of family planning services provided to no longer require that family planning methods be “medically approved”, as discussed *supra* page 6.
- Require all pregnant people be referred for prenatal care, without full options counseling, regardless of their wishes for their pregnancy, as discussed *supra* pages 8 and 16.
- Restrict not only whether providers may refer for abortion, but *how* abortion & prenatal care can be discussed as discussed *supra* pages 16-17.
- Alter the decades-long existing criteria for grants as discussed *supra* page 13.
- Add extensive reporting requirements about subrecipient’s referral networks, entities not receiving Title X funds or currently within the scope of Title X regulations, as discussed *supra* page 12.
- Threaten patient confidentiality – especially for minors as discussed *supra* pages 4 and 21.
- Add vague and confusing prohibitions on activities associated with abortion, as discussed *supra* pages 20-21.
- Add confusing requirements for compliance with its proposed physical separation requirement, as discussed *supra* page 19.
- Twist the definition of low-income to enable and possibly require Title X programs to provide free services to women *regardless of income* whose employers provide insurance but object to that coverage including contraceptives, as discussed *supra* page 5.

The new proposed rules, in their difference from the 1988 rules, go beyond the outer bounds of Congress’ intended scope of delegated authority to HHS, contravening the intent and mission of the program and thus the principles of legislative control in Chevron. Furthermore, HHS has failed to

articulate a satisfactory explanation linking the proposed rules to any facts or data that might justify those rules, violating the APA's prohibition on arbitrary and capricious rulemaking. For example, HHS has offered no facts or data that provide a rationale to substantially broaden the requirements to separation of Title X family planning services from abortion services; there is no rational connection between the needs of Title X patients and the proposal to no longer require that family planning services be "medically approved;" and it is not a reasonable interpretation of Title X, a statute intended to provide services to low-income, uninsured, underserved individuals of reproductive age, to require that free services be provided to women regardless of income and insurance status.

Additionally, the new rules are proposed in a radically changed healthcare landscape. For example, the proposed §59.15, discussed *supra* pages 18-20, requiring separate personnel and health records for Title X services and abortion services, is both more proscriptive on its face from the 1988 rule, and the legal and practical landscape of healthcare provision now makes integrated, electronic health records (EHR) the default and the best practice for providers. Separating these records does not mean having two separate file cabinets or rooms, but instead needing to build entirely separate EHR systems, which is one of the most significant expenses for any family planning provider. This changed landscape renders HHS' rationale for the proposed rules even more suspect.

Finally, the APA requires that prior to adopting a rule, notice and opportunity to comment is afforded to the public, and that such notice be provided at least 30 days in advance of the rules effective date. 5 U.S.C. 553. An exception to this general rule permits the notice period to be waived when the agency finds that notice is "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b). In this case, HHS is seeking to impose these proposed rules retroactively on the Title X FOA that was released in February 2018. As discussed, *supra* page 13-14, changing the rules and scoring criteria of an FOA after applications have been submitting would be, at the very least, unfair to applicants that applied and to entities that decided not to apply. In the absence of any indication that providing prospective notice of these rule changes is impracticable, unnecessary or in some way contrary to the public interest, it violates HHS's obligations under the APA.

The Constitutional Issues Raised by the Proposed Rules

A. THE PROPOSED RULES THREATEN TITLE X PROVIDERS FIRST AMENDMENT SPEECH RIGHTS

In addition to failing to conform the requirements of Chevron and the APA, the differences in the current proposed rules and the 1988 proposed rules, as well as recent developments in case law, open up questions of constitutionality.

The impact of the proposed rules on First Amendment-protected speech is of particular concern. While Rust upheld the 1988 rules against a First Amendment challenge, the Court's recent decision in Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361 (2018) casts the application of Rust into doubt. In Becerra, the Supreme Court ruled against a California State law that mandated that "crisis pregnancy centers" provide information about abortion services. Justice Thomas, writing for the majority, applied strict scrutiny standard of review, noting that "this Court has stressed the danger of content-based regulations in the fields of medicine and public health, where information can save lives," and that "regulating the content of professionals' speech poses the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information." Id. (internal citations omitted). In the case of the rules proposed here, by prohibiting a Title X provider from even

mentioning the availability of abortion services and restricting the format of any information a Title X provider may give about abortion providers, HHS is clearly intending to burden content based speech. Given the broad scope of the proposed rulemaking and the lack of a compelling rationale, it is doubtful whether the federal government can demonstrate narrow tailoring to meet a compelling government interest, as is required under strict scrutiny.

Additionally, although the Supreme Court upheld the 1988 rules as valid, the decision was based upon challenges under the First and Fifth Amendments. There are other Constitutional grounds not raised by the complainants and not contemplated by the Court in its decision in *Rust* that serve to call into question the legality of the proposed legislation. We discuss these items below.

B. THE PROPOSED RULES DEMONSTRATE AN ACTION WITHIN THE FEDERAL LEGISLATIVE BRANCH THAT EXCEED THE AUTHORITY GRANTED BY THE SPENDING CLAUSE

“The Spending Clause grants Congress the power ‘to pay the debts and provide for the...general welfare of the United States.’” National Federation of Indep. Bus. v. Sebelius, 567 U.S. 519, 576 (2012) (citing U.S. Constitution Art. 1, §8, cl. 1). Furthermore, it is well-established by case law at various levels within the federal court system that “Congress may attach conditions on the receipt of federal funds” pursuant to the Spending Clause and “use this power to grant federal funds to the States, and may condition such a grant upon the States taking certain actions that Congress could not require them to take.” N.Y. v. U.S., 505 U.S. 144, 166 (1992) (citing South Dakota v. Dole, 483 U.S. 203, 206 (1987) and Sebelius, 567 U.S. 519). However, there are limitations on this power that can cause an enacted law to be struck down as an impermissible use of authority granted pursuant to the Spending Clause if the federal government is seeking to improperly coerce the State.

Time and again, the Supreme Court has ruled that legislation enacted pursuant to the Spending Clause is contractual in nature and that the “legitimacy of Congress’s exercise of the spending power...rests on whether the State *voluntarily* and knowingly accepts the terms of the contract.” Sebelius, 567 U.S. at 577 (emphasis added) (citations omitted). This rationale grounds the Court’s review by acknowledging that “this limitation is critical to ensuring that Spending Clause legislation does not undermine the status of the States as independent sovereigns in our federal system ... [a system that rests on the] insight that ‘freedom is enhanced by the creation of two governments, not one.’” Id. As a result, the Supreme Court has stricken “federal legislation that commandeers a State’s legislative or administrative apparatus for federal purposes.” Id.

Also, while Congress “may use its spending power to create incentives for States to act in accordance with federal policies ... [b]ut when ‘pressure turns into compulsion’ the legislation runs contrary to our system of federalism.” Id. at 577-578. This holds true whether “Congress directly commands a State to regulate or indirectly coerces a State to adopt a federal regulatory system as its own.” Id. at 578.

The proposed changes to the rules and regulations related to the Title X funding program are a clear example of the federal government using the spending power to infringe upon the State’s sovereignty via impermissible coercion and should be rejected or significantly revised to preserve states’ sovereignty.

1. The proposed regulatory action fails to satisfy the three-prong test established by the Supreme Court for determination as to a permissible use of the Congress’s power under the Spending Clause

As previously discussed, the power(s) granted to Congress under the Spending Clause are rather broad, but not without limitation. In South Dakota v. Dole, 483 U.S. 203 (1987), the Supreme court discussed three (3) points to be examined when determining whether or not legislation enacted by Congress via its spending power is legally valid. The questions to be answered are (1) is the spending power “in pursuit of the ‘general welfare’”; (2) are condition(s) placed upon the State receiving the federal funds “unambiguously...enabling the States to exercise their choice knowingly, cognizant of the consequences of their participation”; and (3) are the conditions “unrelated to the federal interest in particular national projects or programs.” Id. at 207-208. An “unofficial” additional prong is that “other constitutional provisions may provide an independent bar to the conditional grant of federal funds.” Id. at 208.

There is no question that as to the first prong of review that, in passing the Title X statute and delegating authority to HHS to implement the statute, the federal government is utilizing its spending power “in pursuit of general welfare.” The funds disbursed under the Title X program assists providers in the ability to serve members of the population who may otherwise not have access to quality and safe care relative to assistance with decisions and options for family planning – low-income, uninsured and underinsured women and men of reproductive age, including adolescents.

On the second point, Title X makes clear that Title X funds shall not be used “in programs where abortion is a method of family planning”. 42 U.S.C. § 300a-6. In fact, as already mentioned, under the proposed rules, a provider may not even mention the option of abortion when counseling or treating a patient. Hence, Congress has clearly indicated there is a condition attached to the usage of the Title X funds. More serious questions arise involving consideration of the third prong and the “unofficial” fourth prong of review, and the failure to pass these two points vitiates the legitimacy of the proposed regulations, as all the prongs of this test are construed as a collective that must be satisfied *in toto*. South Dakota v. Dole, 483 U.S. at 208.

a. The specifics of the conditions placed upon receipt of funds by the federal government in the proposed new regulations are unrelated to a federal interest in particular projects and programs

Certainly, the regulations associated with the Title X statutory body, generally speaking, are related to a valid federal interest in particular projects and programs. The objective of this federal grant program as stated throughout the comments herein, is to assist providers in reaching and serving an otherwise underserved faction of the population to ensure access to quality care and healthy family planning services – both medical and consultative/educational services. Regulations are necessary to provide clarity and guidance for the disbursement of funds from this program to ensure the attainment of that objective. Where these proposed regulations go awry of that valid federal interest, however, is the arbitrary exclusion of abortion from the list of services deemed “appropriate” for those patients or clients in need of either counsel or medical services relative to family planning needs. This exclusion goes so far as to essentially place a “gag rule” on medical professionals and facilities brick-walling off any feature of its practice or program that is associated with abortion. Instead, the proposed regulations lean heavily toward options historically deemed “morally acceptable”.

This is no place for governmental intervention. If the purpose is to ensure this vulnerable population receives medical and educational services from competent professionals regarding the aspects of family planning, this arbitrary restriction on the discussion of abortion services is not in furtherance of a legitimate and authorized federal interest in conjunction with the federal funding program. The federal government “may condition grants under the spending power *only in ways reasonably related to the purpose of the federal program.*” South Dakota v. Dole, 483 U.S. at 213 (Justice O’Connor, dissenting opinion) (emphasis added). In this instance, the proposed regulations are contrary to the “purpose of the federal spending”. The statute enacted for the Title X program seeks to fund programs that will serve an “at risk” population with quality and accessible family planning services. There is no reasonable basis found within the proposed new rules which proves that the exclusion of all items of service associated with abortion – including what a doctor may counsel the patient on in the course of treatment – furthers that purpose. In fact, these rules run contrary to that purpose as access to crucial treatment and services will be unduly hampered by the delay caused by providers having to refer patients out to other providers.

b. Other constitutional provisions provide an independent bar to the conditional grant of federal funds

Tenth Amendment

The State’s sovereignty is guaranteed by the Tenth Amendment of the United States Constitution, and a federal law must be struck down if in a balancing of the federal interest against this Tenth Amendment right of the State, the law “would prevent the State from functioning as a sovereign”. N.Y. v. U.S., 505 U.S. at 177.

“Regulating matters of health is among the historic police powers of a state ... and [b]ecause such regulation is primarily a matter of local concern, ‘States traditionally have had great latitude under their police powers to legislate under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons.’” Zahl v. Harper, 282 F.3d 204, 211 (U.S. Ct. App. 3d Cir. 2002) (citing DeBuono v. NYSA-ILA Med. & Clinical Svcs. Fund, 520 U.S. 806 (1997) and Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996)).

Pursuant to that inherent police power, New York State did indeed enact a body of law regulating the practice of medicine within the State – including regulating the standards of practice that must be adhered to in the treatment of patients and such. The enforcement of the standards of practice is achieved by the provisions of N.Y. Pub. Health Law § 230 *et seq.* which is found in Title II-A of that section of the State’s statutes and is entitled “Professional Medical Misconduct.” Section 230 establishes the state board of professional medical conduct, sets forth its function and purpose and how proceedings against medical professionals alleged to have violated the standards established by the State.

The proposed new regulations for the Title X program include a prohibition on what a medical professional may discuss with a patient in the course of treatment and how they must discuss it – most notably abortion care. In certain instances, a medical professional practicing within the State of New York may be required as a matter of law to advise and counsel a patient on such an option in order to fulfill the obligation to adhere to a standard of care set forth by State law and consistent with nationally accepted standards of medical ethics, *see supra* pages 8-9. If the medical professional is affiliated with a program that receives funding under the Title X program, the medical professional would be prohibited from such a discussion. Such an omission could be deemed negligent and/or below the established standard that would cause the State to initiate a misconduct proceeding against the professional. Were the medical

provider to rely on the Title X regulation as a defense, it would interfere with the State's right to enforce a standard set pursuant to its police power, when the "state regulation of the medical profession is in the public interest [and the] power to establish and enforce health standards 'is a vital part of a state's police power.'" Zahl, 282 F.3d at 211.

Takings Clause

Under the principles of the Fifth Amendment of the US Constitution, the federal government is prohibited from taking a property right without due process of law. In the case of Omnia Commercial Co. v. U.S., 261 U.S. 502 (1923), the Supreme Court ruled that contractual rights are indeed "property" allowing for scrutiny of federal legislation producing an impact on those rights. If the legislation is found to "appropriate" the contractual right, then the law must be deemed invalid.

"To prevail on a claim that federal economic legislation unconstitutionally impairs a private contractual right, the party complaining of unconstitutionality ... [must demonstrate] first, that the statute alters contractual rights or obligations." National R. Passenger Corp. v. Atchison, T & SFR Co., 470 U.S. 451, 472 (1985) (citing Trust Co. v. New Jersey, 431 U.S. 1 (1977)). Thereafter, if "impairment is found ... [it must be determined] whether the impairment is of constitutional dimension." Id. (citing Allied Structural Steel Co. v. Spannus, 438 U.S. 234 (1978)). Finally, "[w]hen the contract is a private one, and when the impairing statute is a federal one, ... [there is a question of whether] the legislature has acted in an arbitrary and irrational way." Id. (citing Pension Benefit Guaranty Corp. v. R.A. Gray & Co., 467 U.S. 717 (1984)).

NYSDOH, as a Title X grantee contracts with subrecipient agencies to deliver family planning services for those individuals contemplated within the establishment of the Title X program. With these contracts in place up to this point in time, if the proposed rules are implemented, the contractual rights and obligations between the NYSDOH, as a grantee, and its various subrecipient agencies will be negatively impacted. Several subrecipient agencies may decide to no longer contract with the grantee if they must restructure their programs to ensure separation of abortion services from any family planning services. Additionally, the grantee will have to adjust the compensation contracted for in order to reflect its inability to expend Title X funds that may be used by the subrecipient for education on, or referrals for, pregnancy abortion. This end result – without question – amounts to an impairment.

This impairment is of constitutional proportions because the parties negotiated terms and conditions that would be economically feasible for the subrecipient agency to gain the requisite level of services for the grantee at crucial points in time to ensure that the needs of the underserved are met without any interruption or lack of service availability by the grantee. Each party in this contract have rights severely trampled and vitiated by the proposed rules, i.e., taken.

As these private contracts will be impaired by the proposed rules, the final question is whether HHS, in interpreting the legislature's actions, is acting in an arbitrary and irrational way. The answer to this is in the affirmative. As discussed earlier, the federal government is seeking to single out one type of service that has historically been accepted as a medically appropriate health care option without providing a rational basis for doing so, and instead choosing to attempt to exert a moral restriction upon the use of funding.

2. The financial inducement offered by Congress is so coercive as to evidence undue influence and compulsion

As discussed previously, a review of an action by Congress pursuant to its spending power includes whether or not the resultant “financial inducements” are not used to “exert a ‘power akin to undue influence’ ...and ‘pressure turns into compulsion’ [thereby running] contrary to our system of federalism.” *Sebelius*, 567 U.S. at 577-578. The extent of the fallout of the regulations is so severe that the acceptable “mild inducement,” permitted of the federal government’s spending powers, is surpassed to an unacceptable level of compulsion.

Since at least 1971, States have relied upon the receipt of grant funds to supplement funds garnered through budgetary appropriations each year. With the inclusion of the federal monies, the States have had more funds available so as to allow more subrecipients to receive the crucial funding needed to develop programs that provide an appropriate quality of care. These disbursements have flowed without unduly burdensome restrictions and monitoring required by the States. However, under the newly proposed rules, if the States wish to receive grant money under Title X, they would not only be compelled to comply with the condition that no aspect of services associated with abortion may receive any funding from that program, but also required to monitor subrecipients to ensure that abortion services are not even located within the same premises. If the State does not have the means to enforce these new provisions – or chooses not to do so – then it is placed in the predicament of either refusing to participate and seeking to fund all applicable programs solely from its coffers, or accepting the award and still having to seek funding sources within itself in order to help those providers that will be forced to make drastic changes due to the reduction in funding. Either option places an extreme burden on the taxpayers of the State, and of course will serve to deny those the program was meant to serve and protect of much needed care and services.

IV. CONCLUSION

As set forth above, the results of implementing the proposed rules could be devastating to providers who will be forced to reduce or eliminate services and staff in response to a reduction or complete eradication of funding. The losers in either of these scenarios are not just the providers, but more importantly the millions of women and men who rely upon providers who are to be found in the roster of Title X funding recipients: low income members of society who do not have access to insurance plans or sufficient funds to seek adequate services to address needs for safe, effective contraception options, along with associated counseling and primary care services. What is proposed by the federal government in the new rules and regulations, not only serves to seriously debilitate access to quality care for a section of the population who are the intended beneficiaries of programs like Title X, but is also contrary to established principles of constitutional law.

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