American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

July 31, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: HHS-OS-2018-0008; Compliance with Statutory Program Integrity Requirements

Dear Secretary Azar:

The American Academy of Pediatrics and the Society for Adolescent Health and Medicine write in response to the proposed rule, "Compliance with Statutory Program Integrity Requirements" (Proposed Rule), published in the Federal Register on June 1, 2018 by the Department of Health and Human Services (HHS). The Proposed Rule would fundamentally alter the Title X Family Planning Program (Title X), and put at risk nearly 50 years of progress in public health.

The American of Pediatrics (AAP) is a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. Reproductive health care is a necessary component of overall health care for adolescents and young adults, and the AAP is committed to ensuring access to this care, including family planning services, sexual health screenings, and contraception. Pediatricians believe that the Title X Family Planning Program is critical to the goal of securing access to these services for this population, providing low-cost or no-cost access to reproductive health care for adolescents and low-income young adults and ensuring that cost and confidentiality are not barriers to care for this population. The AAP believes that Title X has been of enormous benefit to this population for over four decades.

The Society for Adolescent Health and Medicine (SAHM) is a multidisciplinary organization that promotes optimal health, well-being, and equity for all adolescents and young adults by supporting adolescent health and medicine professionals through the advancement of clinical practice, care delivery, research, advocacy, and professional development. SAHM is keenly aware of the vital role the Title X Family Planning Program has played in making sure that adolescents and young adults, especially those with low incomes, are able to receive the full spectrum of family planning services, including contraception and other services such as testing and treatment for sexually transmitted infections (STIs) and cancer screening that are essential to protecting their health.

The Proposed Rule undermines the patient-provider relationship. Contrary to the preamble of the Proposed Rule, which states that "the new regulations would contribute to more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission

of the Title X program,"[1] the proposed changes to the program would jeopardize access to family planning and preventive health care for more than four million low-income women, men, and adolescents, and put at risk patient access to high-quality care. We therefore call for the Proposed Rule's immediate and complete withdrawal.

I. The Title X Family Planning Program plays a critical role in our nation's public health safety net.

As the only federal grant program dedicated exclusively to providing low-income patients with essential family planning and preventive health services and information, Title X plays a vital role in ensuring that safe, timely, and evidence-based care is available to women, men, and adolescents, regardless of their financial circumstances. Rates of adverse reproductive health outcomes are higher among low-income women and women of color, and unintended pregnancy rates are highest among those least able to afford contraception.[2] According to the HHS Office of Population Affairs website, "Access to quality family planning and reproductive health services is integral to overall good health for both men and women. Few health services are used as universally. In fact, more than 99 percent of women aged 15–44 who have ever had sexual intercourse have used at least one contraceptive method."[3]

In addition to pregnancy prevention, Title X projects meet other reproductive health needs. In 2016, Title X projects provided nearly five million STI tests, more than 700,000 Pap tests, and 900,000 clinical breast exams.[4] Further, it is estimated that in 2010 alone, services provided by Title X projects helped avert 53,450 chlamydia infections, 8,810 gonorrhea infections, 250 HIV infections, and 6,920 cases of pelvic inflammatory disease.[5]

Unintended pregnancy and STIs are of particular concern for adolescents and young adults. Among 15-19 year-olds, three quarters of pregnancies are unintended as are nearly 60 percent of pregnancies among 20-24 year-olds.[6] Teen-aged birth rates in the United States have declined to the lowest rates seen in seven decades yet still rank highest among industrialized countries.[7] Research suggests that the decline is largely due to increased use of contraception.[8] Youth are also disproportionately impacted by STIs. Data from the Centers for Disease Control and Prevention indicate that adolescents and young

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[1] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25505.
[2] Access to contraception. Committee Opinion No. 615. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015;125:250–5.
[3] Family Planning Guidelines. Office of Population Affairs. Department of Health and Human Services. https://www.hhs.gov/opa/guidelines/program-guidelines/index.html
[4] Fowler CI, Gable J, Wang J, Lasater B. Family Planning Annual Report: 2016 national summary. Research Triangle Park, NC: RTI International (August 2017). https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf
[5] Sonfield A. Beyond Preventing Unplanned Pregnancy: The Broader Benefits of Publicly Funded Family Planning Services. Guttmacher Policy Review 17, issue 4 (2014). https://www.guttmacher.org/sites/default/files/article_files/gpr170402.pdf.
[6] Finer LB, Zolna MR. Declines in Unintended Pregnancy in the United States, 2008-2011. N Eng J Med 2016 Mar 3;374(9):843-52. doi: 10.1056/NEJMsa1506575.
[7] Santelli JS, Song X, Garbers S, Sharma V, Viner RM. Global Trends in Adolescent Fertility, 1990-2012, in Relation to National Wealth, Income Inequalities, and Educational Expenditures. J Adolesc Health 2017 Feb;60(2):161-168. doi: 10.1016/j.jadohealth.2016.08.026. Epub 2016 Nov 15.
[8] Lindberg L, Santelli J, Desai S. Understanding the Decline in Adolescent Fertility in the United States, 2007-2012. J Adolesc Health 2016 Nov;59(5):577-583. doi: 10.1016/j.jadohealth.2016.06.024. Epub 2016 Aug 29.

adults account for half of all STI diagnoses in the United States despite only making up a quarter of the sexually active population.[9] Sixty-five percent of reported chlamydia and 50 percent of reported gonorrhea cases occur among 15-24 year-olds.[10] Untreated STIs can lead to long-term reproductive health consequences. Pregnancy and birth are significant contributors to high school dropout rates among female youth; only approximately 50 percent of teen-aged mothers earn a high school diploma by 22 years of age versus approximately 90 percent of females who did not give birth during adolescence.[11] Title X not only improves the health and lives of women and their families and enables them to achieve greater educational, financial, and professional success and stability. It also saves taxpayer dollars. Taxpayers save an estimated $7.09 for every dollar invested in the Title X program.[12]

If implemented, the Proposed Rule would limit access to vital preventive services for the more than four million patients seeking care annually at a Title X project, including many adolescents and young adults, increasing rates of unplanned pregnancy and other adverse sexual and reproductive health outcomes, undermining public health and turning back the clock on women's health.

II. The Proposed Rule would interfere with the patient-provider relationship and restrict the information available to patients.

The provision of safe and quality medical care relies on a strong patient-provider relationship free from political interference. Patients expect medically accurate, comprehensive information from their providers; this dialogue is imperative to the integrity of the patient-provider relationship. If implemented, the Proposed Rule would drive a wedge between patients and their providers by placing restrictions on the counseling and referrals that can be provided to patients, in some instances directing providers to withhold information critical to patient decision-making.

Specifically, the Proposed Rule removes requirements that patients be offered nondirective counseling on the full range of reproductive health options, instead placing vague and confusing restrictions on the counseling that can be provided to patients.[13] In addition, the Proposed Rule directs providers to withhold full and accurate information and to include referrals to providers that do not offer the service requested by the patient.[14] For example, the Proposed Rule requires that even those patients who specifically state their intention to obtain an abortion must be given a list of referrals that includes providers who do not offer abortions and that does not identify those who do, stating: "The list shall not identify the providers who perform abortion as such."[15] This obstacle to nondirective options counseling conflicts with medical practice guidelines, including those of the American Academy of Pediatrics.[16] The

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[9] Centers for Disease Control and Prevention. STDs in Adolescents and Young Adults. https://www.cdc.gov/std/stats16/adolescents.htm.

[10] Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2015. Atlanta, GA:US Department of Health and Human Services; 2016. www.cdc.gov/std/stats15/default.htm.

[11] Perper K, Peterson K, Manlove J. Diploma Attainment Among Teen Mothers. Fact Sheet. Publication #2010-01. Washington, DC: Child Trends; 2010.

[12] Frost JJ et al., Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program. Milbank Quarterly 2014 Dec;92(4):696–749. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4266172/.

[13] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530.

[14] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25531.

[15] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25531.

[16] Hornberger LL and AAP Committee on Adolescence. Diagnosis of Pregnancy and Providing Options Counseling for the Adolescent Patient. Pediatrics 2017 Dec 140(3):e20172273.

Proposed Rule would also require Title X providers to refer all pregnant patients to "appropriate prenatal and/or social services (such as prenatal care and delivery, infant care, foster care, or adoption)"[17] even if the patient has indicated a clear decision to terminate her pregnancy.

Access to medically accurate, comprehensive guidance based on a clinician's expertise, experience, and best judgment is of particular importance for adolescents, and interference in the relationship between a provider and an adolescent patient is highly concerning. Adolescents may experience heightened obstetric risk as compared with women who experience pregnancy at a later age.[18] Several studies have found that adolescents are at a higher risk of complications, such as preterm delivery, small-for-gestational-age infants, and neonatal death, though the evidence is inconclusive. However, the psychosocial risks associated with adolescent parenting are well-established, including a lower likelihood of adolescent mothers receiving a high school diploma, an increased chance of living in poverty during adulthood, poorer academic performance and increased likelihood of dropping out of high school among children of adolescent mothers, and increased risk for daughters of adolescent mothers to become adolescent mothers themselves.[19] Given the weight of the evidence and the serious implications of adolescent pregnancy and parenthood, it is critical that health care providers be able to engage in open dialogue around the health risks and potential outcomes of adolescent pregnancy.

Moreover, the restrictions on counseling and referral information that can be shared by Title X providers may put them at increased risk of medical liability. The decision in the case of *Wickline v. State of California* found that "it is no defense in a medical liability case to argue that physicians simply have followed a payer's instructions."[20] By restricting the provision of clear, direct referrals to patients, the patient is faced with unnecessary barriers and delayed access to care, putting the patient at risk of undiagnosed medical conditions, and placing Title X providers at elevated risk of liability.

Efforts to regulate the way in which Title X providers talk to their patients are inappropriate and prevent access to complete and accurate medical information necessary to ensure that patients are able to make timely, fully informed medical decisions. We reject this intrusion into the patient-provider relationship.

III. The Proposed Rule threatens patient confidentiality, will cause harm to patients, and will lead patients to avoid seeking care.

Family planning services address some of the most sensitive and personal issues in health care and therefore require strong confidentiality protections. Patients seeking family planning services encompass a broad spectrum of patient populations.[21] Certain groups, including adolescents and young adults and people at risk of domestic or intimate partner violence, have special privacy concerns that

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[17] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25531.
[18] Hornberger LL and AAP Committee on Adolescence. Options Counseling for the Pregnant Adolescent Patient. Pediatrics. 2017;140(3):e20172274.
[19] Hornberger LL and AAP Committee on Adolescence. Options Counseling for the Pregnant Adolescent Patient. Pediatrics. 2017;140(3):e20172274.
[20] Rosenbaum S et al. The Title X Family Planning Proposed Rule: What's at Stake for Community Health Centers? Health Affairs Blog, June 25, 2018.DOI: 10.1377/hblog20180621.675764.
[21] Gold RB. A New Frontier in the Era of Health Reform: Protecting Confidentiality for Individuals Insured as Dependents. Guttmacher Policy Review 2013; 16(4):2.
https://www.guttmacher.org/pubs/gpr/16/4/gpr160402.pdf.

require particularly strong protection.[22] The Title X confidentiality regulations[23] are among the strongest in current law, and research shows these confidentiality protections are one of the reasons individuals choose to seek care at Title X sites.[24] The current regulations contain exceptions that allow health providers to disclose patient information without documented consent only if necessary to provide services to the patient or if the disclosure is required by law; but even then appropriate safeguards for confidentiality must be in place.[25]

The need for Title X's strong confidentiality protections is supported by both research and medical practice standards. Of particular relevance, the Title X confidentiality protections are grounded in research about the effect of confidentiality on patients' health care access. Decades of research findings have shown that privacy concerns influence the behavior of patients, particularly adolescents and young adults, with respect to whether they seek care, where they do so, which services they accept, and how candid they are with their health care providers.[26] Adolescents are especially concerned about disclosures to their parents of their use of family planning services: numerous studies demonstrate that requiring parental notification would drive minors out of family planning clinics and away from critical health care including contraception and testing and treatment for STIs. [27]

Cognizant of the key role confidentiality plays in access to health care and in the provision of high quality health care services, numerous medical organizations have issued ethical guidelines, practice standards, and policy statements highlighting the necessity of protecting confidentiality for adolescents. More than 20 organizations of medical and health care professionals have issued such documents, many of which specifically address family planning services.[28] In particular, the organizations of medical and health professionals most often directly involved in the care of adolescents, such as the American Academy of

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[22] Ford C, English A, Sigman G. Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine**.** J Adoles Health 2004;35(2):160–167; National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care Settings. San Francisco: Family Violence Prevention Fund, 2004. http://www.futureswithoutviolence.org/userfiles/file/HealthCare/consensus.pdf.
[23] 42 C.F.R. § 59.11.
[24] Frost JJ, Gold RB, Bucek A. Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs. Women's Health Issues 2012;22: e519-e525.
[25] 42 C.F.R. § 59.11.
[26] Burke PJ et al. Sexual and Reproductive Health Care: A Position Paper of the Society for Adolescent Health and Medicine. J Adolesc Health 2014;: 491-496, https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf; Salganicoff A, Ranji U, Beamesderfer A, Kuran N. Women and Health Care in the Early Years of the ACA: Key Findings from the 2013 Kaiser Women's Health Survey. Menlo Park, CA: Henry J. Kaiser Family Foundation, May 2014: 28, 38-39, https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8590-women-and-health-care-in-the-early-years-of-the-affordable-care-act.pdf.
[27] Reddy DM, Fleming R, Swain C. Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services. JAMA 2002;288(6):710–714; Jones RK, et al. Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception. JAMA 2005;293(3):340–348; Fuentes L, Ingerick M, Jones R, Lindberg L. Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services. J Adolesc Health 2018;62(1):36-43; Leichliter JS, Copen C, Dittus PJ. Confidentiality Issues and Use of Sexually Transmiiteed Disease Sservices Among Sexually Experienced Persons Aged 15-25 Years – United States, 2013-2015. MMWR Morb Mortal Wkly Rep 2017;66:237-241. DOI: http://dx.doi.org/10.15585/mmwr.mm6608a1.
[28] Policy Compendium on Confidential Health Services for Adolescents, 2d Ed. Chapel Hill, NC: Center for Adolescent Health & the Law, 2005. http://www.cahl.org/PDFs/PolicyCompendium/PolicyCompendium.pdf.

Pediatrics and the Society for Adolescent Health and Medicine, have repeatedly stressed the importance of confidentiality.[29]

The Proposed Rule undermines patient confidentiality and access to care in two primary ways: by exerting increased and inappropriate pressure on adolescent patients and their Title X providers to involve family members including parents or guardians in virtually all cases; and by inserting the HHS Secretary improperly into the enforcement of state reporting laws, impacting all Title X patients.

Congress already requires that Title X providers encourage family participation "where practicable."[30] Title X providers, guided by their expertise, training, and experience, as well as extensive practice standards and recommendations, already assist adolescents to involve their families in decisions about family planning services and other key health care matters when realistic and appropriate. For example, the AAP highly encourages the involvement of families in the care of adolescents and young adults as much as possible but recognizes that the confidential provision of sexual and reproductive health care services is important and makes adolescents more likely to access health care, communicate about sensitive topics openly with the provider, and return for follow-up care.[31]

As a consequence, most adolescents already involve their families in decisions about family planning or seek family planning services with their parents' or guardians' knowledge.[32] However, when taking a health history, careful clinicians sometimes learn of circumstances (short of abuse) in a minor's family that make it not "practicable," or unrealistic or even harmful, to encourage the minor to involve their parents or guardian. In these situations, they should not be required to take "specific actions" to encourage the minor to do so (and then document those specific actions) as the Proposed Rule requires.[33] Doing so is not only contrary to medical ethics, but it also undermines the relationship between the minor and the health care professional and is likely to drive some minors away from returning for critical health care services, including contraception and testing and treatment for sexually transmitted infections.[34]

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[29] E.g., Contraception for Adolescents. Committee on Adolescence. Pediatrics. Sep 2014, peds.2014-2299; DOI: 10.1542/peds.2014-2299; Ford C, English A, Sigman G. Confidential Health Care for Adolescents: Position Paper of the Society for Adolescent Medicine**.** J Adoles Health 2004;35(2):160–167. Burstein GR, Blythe MJ, Santelli JS, English A. Confidentiality Protections for Adolescents and Young Adults in the Health Care Billing and Insurance Claims Process," J Adolesc Health 2016; 58:374-377.

[30] 42 U.S.C. 300.

[31] Marcell AV, Burstein GR, AAP COMMITTEE ON ADOLESCENCE. Sexual and Reproductive Health Care Services in the Pediatric Setting. *Pediatrics*. 2017;140(5):e20172858; Ford CA, Millstein SG, Halpern-Felsher BL, Irwin CE Jr. Influence of Physician Confidentiality Assurances on Adolescents' Willingness to Disclose Information and Seek Future Health Care. A Randomized Controlled Trial. JAMA 1997;278(12):1029–1034.pmid:9307357.

[32] Diane M. Reddy, Raymond Fleming, and Carolyne Swain, "Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services," *JAMA* 288, no. 6 (2002): 710–714; Rachel K. Jones, et al., "Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception," *JAMA* 293, no. 3 (2005): 340–348; Liza Fuentes, Meghan Ingerick, Rachel Jones, and Laura Lindberg, "Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services," *Journal of Adolescent Health* 62, no. 1 (2018):36-43.

[33] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530.

[34] Reddy DM, Fleming R, Swain C. Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services. JAMA 2002;288(6):710–714; Jones RK, et al. Adolescents' Reports of Parental Knowledge of Adolescents' Use of Sexual Health Services and Their Reactions to Mandated Parental Notification for Prescription Contraception. JAMA 2005;293(3):340–348; Fuentes L, Ingerick M, Jones R, Lindberg L. Adolescents' and Young

Not only does the Proposed Rule impose excessive requirements related to encouraging family involvement, it would empower HHS to engage in compliance efforts with respect to state reporting laws that exceed the purview of HHS. This could lead to incorrect reporting and confusion by medical providers in ways that would lead adolescent patients to avoid seeking care.

Title X providers are required by state law to comply with a variety of reporting requirements, including child abuse reporting laws. Professionals providing services in Title X-funded sites are aware of these reporting obligations, receive regular training on them, and make reports to comply with these requirements. Health care professionals take seriously not only their reporting obligations but also their obligations to their patients to protect them from real risks of exploitation and abuse.[35]

The reporting laws are complex, nuanced, and varied and are enforced by state authorities. Some state laws include both specific requirements that clearly trigger an obligation to make a report and others that allow for the exercise of discretion by health care professionals. For example, determinations of "reasonable suspicion" and "likelihood of harm" may be within the purview of health care providers who are mandated reporters.[36] However, the Proposed Rule gives HHS substantial oversight over compliance by Title X providers with these complicated state reporting requirements, and the authority to impose harsh penalties if HHS (not the state) believes a Title X project is out of compliance.[37]

Given the complexity, nuances, and variations, HHS has not and should not oversee compliance with state (or local) reporting laws, as doing so is both outside HHS' authority and expertise and is likely to harm patients. Nevertheless, the Proposed Rule would prohibit projects from receiving Title X funds unless the project provides "appropriate documentation or other assurance satisfactory to the Secretary" of HHS that it has met the compliance requirements[38] and states that continuation of funding "is contingent upon demonstrating to the satisfaction of the Secretary" that the requirements have been met.[39]

Providers should use their best clinical judgment about the right time to ask adolescents about victimization as it can take time to develop a relationship of trust between a provider and a patient who has been victimized. The Proposed Rule requires that, irrespective of state requirements, Title X entities commit to "conduct a preliminary screening" of all teens who present with an STD or pregnancy in order to rule out victimization of a minor. Requiring a provider to affirmatively rule out victimization, even when there is no indication of abuse, has the real potential to leave a patient feeling stigmatized and judged simply for seeking family planning care. Patients who feel judged by their health care provider are less likely to return for care.

Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services. J Adolesc Health 2018;62(1):36-43.

[35] Protecting Adolescents: Ensuring Access to Care and Reporting Sexual Activity and Abuse—Position Paper of the American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, Society for Adolescent Health and Medicine. Journal of Adolescent Health 2004;35(5):420-423.

[36] *See e.g*. Rebecca Gudeman and Erica Monasterio, Mandated Child Abuse Reporting Law: Developing and Implementing Policies and Training. National Center for Youth Law and Family Planning National Training Center for Service Delivery, 2014, http://www.cardeaservices.org/documents/resources/Mandated-Child-Abuse-Reporting-Law-GUIDE-20140619.pdf.

[37] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532-25533.

[38] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25532-25533.

[39] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25533.

The increased oversight by HHS, together with the addition of new requirements to collect and document specific information in Title X records, is likely to cause Title X providers to conduct screenings and make reports to authorities against their best clinical judgment, which will harm patients and undermine the provider-patient relationship, driving some patients away from critical health services. It also turns health care providers into interrogators and directs Title X funds toward unduly excessive policing and record-keeping, rather than toward providing evidence-based care.

Collectively, the onerous and invasive requirements undermine trust in the provider-patient relationship and could cause patients to avoid seeking care in Title X settings, if they seek care at all. AAP and SAHM are deeply committed to protecting adolescent and young adult patients who may be victims of abuse or other criminal activity and our members who are health care professionals take their roles as mandatory reporters very seriously. None of these goals can be achieved if the trust our patients have in their providers is so eroded by unnecessary and prescriptive regulations that patients are no longer comfortable seeking care at all. It is unclear why HHS is trying to inject itself even more into the realm of state law enforcement and to create these additional, unnecessary hurdles for patients and for Title X entities that are already required to ensure their compliance with reporting requirements. There is no evidence that they are not doing so.

IV. The Proposed Rule undermines access to the most effective evidence-based family planning methods.

Title X has contributed to the dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low.[40] Improved access to contraception and information for adolescents, including those served by Title X projects, has contributed to a record low teen pregnancy rate.[41] The services provided by Title X projects help prevent nearly one million unintended pregnancies each year.[42] The Proposed Rule threatens to reverse this historic progress.

The Proposed Rule removes the requirement that methods of family planning be "medically approved," instead placing increased emphasis on the provision of natural family planning and "other fertility-awareness based methods."[43] Indeed, the Proposed Rule encourages the inclusion of more providers within a Title X project that only offer a single method or very limited methods, and shows a clear preference for organizations providing these less effective methods. Thus, the Proposed Rule would permit entities to participate in Title X that refuse to provide the broad range of contraceptive methods that have been a core part of Title X-funded services since the program's inception, putting at risk access to the most effective forms of contraception, such as long-acting reversible contraception (LARC).[44] Limiting access to the most effective methods of family planning is especially harmful to adolescents and young adults, an age group in which LARC and other hormonal contraceptive methods have been

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[40] Finer LB, Zolna MR, Declines in Unintended Pregnancy in the United States, 2008–2011. N Engl J Med 2016; 374:843–852.
[41] Martin JA, Hamilton BE, Osterman MJ, Driscoll AK, Drake P. (2018). Births: Final data for 2016. Hyattsville, MD: National Center for Health Statistics. https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf – PDF.
[42] Guttmacher Institute. Fact Sheet: Publicly Funded Family Planning Services in the United States. September 2016. *Available at* https://www.guttmacher.org/sites/default/files/factsheet/fb_contraceptive_serv_0.pdf
[43] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530.
[44] Secura G et al., The Contraceptive CHOICE Project: Reducing Barriers to Long-Acting Reversible Contraception. Am J Obstet Gynecol. 2010 Aug; 203(2): 115.e1–115.e7. http://doi.org/10.1016/j.ajog.2010.04.017

associated with decreased rates of teen and unintended pregnancy.[45] Additionally, this provision of the Proposed Rule directly contravenes AAP and SAHM policy regarding contraception for adolescents. It is AAP and SAHM policy that adolescents have access to the full range of contraceptive services that are safe and appropriate for them, including the most highly effective LARC.[46]

The preamble of the Proposed Rule appears to justify this new emphasis by stating that "it has become increasingly difficult and expensive for a Title X project to offer all acceptable and effective forms of family planning."[47] However, the Proposed Rule does not provide evidence to support this statement. In fact, a recent study by the Kaiser Family Foundation and George Washington University found that Title X-funded health centers are far more likely than non-Title X-funded health centers to provide effective family planning methods onsite and to offer services associated with high quality care.[48]

All people seeking care from Title X projects, including adolescents and young adults, should have access to the contraceptive method that works best for their individual circumstances. We are concerned that the Proposed Rule lowers the threshold on the contraceptive services available at Title X-funded sites, restricting access to safe and effective contraception, and negatively impacting the quality of care provided to patients. If implemented, the Proposed Rule threatens to reverse decades of progress, including our nation's historic achievements in reducing unplanned and teen pregnancy rates.

V. The Proposed Rule excludes qualified providers, putting at risk access to quality family planning services for millions of patients.

The Proposed Rule seeks to exclude certain qualified providers from the Title X program by imposing a broad range of financially and administratively burdensome regulatory requirements that are completely unrelated to the goals of the Title X program, putting at risk access to critical primary and preventive care services for more than 40 percent, or nearly two million Title X patients.[49] The government has no role in picking and choosing among qualified providers.

When qualified providers are excluded from publicly funded programs serving low-income patients, other providers are unable to adequately fill the gap, creating barriers to care for patients. When certain qualified providers were excluded from a state program serving low-income patients, the number of

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[45] Secura GM, Madden T, McNicholas C, Mullersman J, Buckel CM, Zhao Q, Peipert JF Provision of No-cost, Long-acting Contraception and Teenage Pregnancy. N Engl J Med 2014 Oct 2;371(14):1316-23. doi: 10.1056/NEJMoa1400506. Ricketts S, Klingler G, Schwalberg R. Game Change in Colorado: Widespread Use of Long-acting Reversible Contraceptives and Rapid Decline in Births Among Young, Low-income Women. Persp Sex Reprod Health 2014 Sep;46(3):125-32. doi: 10.1363/46e1714. Epub 2014 Jun 24.

[46] AAP Committee on Adolescence. Contraception for Adolescents. Pediatrics. 2014. doi:10.1542/peds.2014-2299; Burke PJ et al. Sexual and Reproductive Health Care: A Position Paper of the Society for Adolescent Health and Medicine. J Adolesc Health 2014;: 491-496, https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/Apr-14-Sexual-Repro-Health.pdf.

[47] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25516.

[48] Wood SF et al., George Washington University. Community Health Centers and Family Planning in an Era of Policy Uncertainty. Kaiser Family Foundation. March 2018. http://files.kff.org/attachment/Report-Community-Health-Centers-and-Family-Planning-in-an-Era-of-Policy-Uncertainty

[49] Frost J, Frohwirth L, Blades N, Zolna M, Douglas-Hall, A, Bearak, J. Publicly Funded Contraceptive Services at U.S. Clinics, 2015. Guttmacher Institute. April 2017. https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf

women using the most effective methods of birth control decreased by 35 percent and the number of births covered by Medicaid increased by 27 percent.[50]

When qualified providers in rural and medically underserved communities are forced to close, public health suffers. In addition to losing access to family planning services, communities also lose access to STI testing and treatment. In 2015, closure of a qualified provider in a rural midwestern town coincided with an alarming HIV outbreak, with reduced access to HIV testing that could have minimized or even prevented the outbreak.[51]

The Proposed Rule would exacerbate racial and socioeconomic disparities in access to care by leaving Title X patients, who are disproportionately black and Latinx, without alternate sources of care. It would also limit access to Title X sites for young low-income patients who have few other options. Restricting access to qualified providers will increase rates of unplanned pregnancy, pregnancy complications, and undiagnosed medical conditions, leaving patients worse off than they are today.

VI. The Proposed Rule redefines "low-income family" to fill a contraceptive coverage gap created by the administration's own actions.

The Proposed Rule would redefine "low-income family" to include women whose employer-based health insurance coverage does not cover contraception due to the employer's religious or moral objections.[52] The Affordable Care Act requires that all non-grandfathered health plans cover an HHS-designated list of women's preventive services, which includes contraceptive services. The administration created a significant gap in that coverage in its interim final rules of October 13, 2017, regarding religious[53] and moral[54] objections to contraceptive coverage, which allow virtually any employer to claim an exemption from the contraceptive coverage requirement.

The Proposed Rule's expanded definition would potentially require Title X providers to fill that gap and provide free contraceptive services to women of all incomes. The Title X program is already underfunded, and the Proposed Rule would result in even fewer resources to serve low-income patients, including adolescents and young adults.

VII. The Proposed Rule radically changes the Title X program and jeopardizes public health and the health of adolescents and young adults.

Policy decisions about public health must be firmly rooted in science, and increase access to safe, effective, and timely care. The Proposed Rule would interfere with the patient-provider relationship, exacerbate disparities for low-income and minority women, men, and adolescents, and harm patient

[50] Stevenson AJ, Flores-Vazquez IM, Allgeyer RL, Schenkkan P, Potter JE. Effect of Removal of Planned Parenthood from the Texas Women's Health Program. N Engl J Med. 2016 Mar 3;374(9):853-60. DOI: 10.1056/NEJMsa1511902.
[51] Peters PJ, Pontones P, Hoover KW, Patel MR, Galang RR, Shields J, et al. Indiana HIV Outbreak Investigation Team. HIV Infection Linked to Injection use of Oxymorphone in Indiana, 2014-2015. N Engl J Med 2016; 375:229-239. DOI: 10.1056/NEJMoa1515195.
[52] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. at 25530.
[53] Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act. 82 Fed. Reg. at 47792 (October 13, 2017).
[54] Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act. 82 Fed. Reg. at 47838 (October 13, 2017).

health. In particular the Proposed Rule would harm the health of young patients by limiting confidentiality protections and driving them away from care.

We urge HHS to immediately withdraw the Proposed Rule. Thank you for your full consideration of our comments.

Sincerely,

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