

May 17, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services
(RIN 0937-AA11), 86 Fed. Reg. 19812 (April 15, 2021)

Dear Secretary Becerra:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments to the U.S. Department of Health & Human Services (HHS) in response to the Notice of Proposed Rulemaking (Proposed Rule or NPRM) on “Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services” issued by HHS’ Office of Population Affairs (OPA). The Proposed Rule would revoke the rules issued on March 4, 2019, (the 2019 rule) establishing standards for compliance by family planning services projects authorized by Title X of the Public Health Service Act and reissue the 2000 regulations, with several modifications. The AMA applauds HHS for taking these actions to restore the Title X program, a vital public health program that has provided critical care to millions of people each year, to its mission of ensuring that all individuals have access to family planning care, regardless of their income or where they live.

The 2019 rule made sweeping and harmful changes to Title X programmatic requirements by: restricting counseling by physicians and other health professionals about abortion services and prohibiting in most cases programs receiving that money from referring clients for abortion; withholding federal funds from qualified family planning providers that also offer abortion services; requiring Title X providers to physically and financially separate divisions that counsel clients about family planning from those that provide abortion; eliminating previous requirements that Title X sites offer a broad range of medically-approved family planning methods and nondirective pregnancy options counseling; and directing new funds to faith-based and other organizations that promote fertility awareness and abstinence as methods of family planning rather than the full range of evidence-based family planning methods. All of the major medical associations, including [the AMA](#), strongly opposed the 2019 Rule, and the agency was sued by 23 states, numerous major medical organizations, Title X grantee organizations, and individual grantees. As a result of a split in decisions about whether to uphold the Final Rule between the Courts of Appeals for the Ninth and Fourth Circuits, the U.S Supreme Court granted certiorari on February 22, 2021, consolidating the cases. On March 12, 2021, the parties stipulated to dismiss the cases under Supreme Court Rule 46.1; the Court dismissed the case on May 17, 2021.

As discussed in more detail below, the 2019 changes have significantly undermined Title X’s mission as the only federal program that provides taxpayer money for family planning programs intended to help low-income people, and weakened patients’ access to high-quality, affordable medical care and information, dangerously interfered with the patient-physician relationship and conflicted with

physicians' ethical obligations, excluded qualified providers, and jeopardized the public's health. **The AMA strongly supports HHS' proposal to revoke the 2019 rule and urges the agency to finalize its NPRM as expeditiously as possible.**

Impact of the 2019 Rule on Access to Title X Providers Demonstrates Why the NPRM is Needed

The substantial impact of the 2019 Rule on access to Title X providers and services demonstrates by itself why the NPRM is needed. After the rule was implemented in August of 2019, grantees immediately began to withdraw from Title X rather than comply with the 2019 Rule's requirements. As HHS summarizes in the NPRM's preamble, the number of family planning services grantees has decreased significantly. Overall, as the proposed rule notes, the Title X program lost more than 1,000 service sites, representing approximately one quarter of all Title X-funded sites in 2019. Title X services currently are not available at all in six states (HI, ME, OR, UT, VT, and WA) and an additional eight states lost over half of their Title X network (AK, CT, IL, MA, MD, MN, NH, and NY). Contrary to projections by the previous administration, OPA has been unable to find new grantees to fill the gaps created by the 2019 Rule. The number of clients served by the program dropped from 3,939,749 clients in 2018 to 3,095,666 clients in 2019 (a 21 percent decrease), and then further decreased to 1,536,744 clients in 2020, a 60 percent decrease compared to those served in 2018 (in part due to fewer people seeking care due to the pandemic).

Of particular concern to the AMA, a breakdown of the decrease in the number of clients served shows that the 2019 Rule had a notable impact on access to Title X services by minoritized and marginalized communities. OPA data show that individuals in the following racial and ethnic groups received fewer Title X services in 2019 compared to 2018: 128,882 African Americans; 50,039 Asians; 6,724 American Indians/Alaska Natives; 7,218 Native Hawaiians/Pacific Islanders; and 269,569 Hispanics/Latinos. In addition, compared to 2018, there was a decrease in over 800,000 low-income clients (incomes less than 250 percent of the Federal Poverty Level (FPL)) and over 300,000 uninsured clients. As noted by HHS, this contradicts the purpose and intent of the Title X program, which is to increase and prioritize family planning services to low-income individuals.

As further noted by HHS, hundreds of thousands of Title X clients have lost access to critical family planning and related preventive health services due to service delivery gaps created by the 2019 Rule. More specifically, according to [OPA's Family Planning Annual Report: 2019 National Summary Report](#), compared to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008 fewer clients received IUDs. Additionally, 90,386 and 188,920 fewer Papanicolaou (Pap) tests and clinical breast exams respectively were performed in 2019 compared to 2018. Confidential human immunodeficiency virus (HIV) tests decreased by 276,109. Sexually transmitted infection (STI) testing decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis. Furthermore, 71,145 fewer individuals who were pregnant or sought pregnancy were served. The AMA agrees with HHS's statement that the 2019 Final Rule "undermined the mission of the Title X program by helping fewer individuals in planning and spacing births, providing fewer preventive health services, and delivering fewer screenings for STIs." Moreover, as HHS acknowledges in the Proposed Rule's preamble at 19815, the true impact of the 2019 Rule in terms of long-term reproductive and sexual health repercussions is difficult to quantify, but the agency estimated that it is estimated that the 2019 Rule may have led to up to 181,477 unintended pregnancies.

It is clear that the numbers alone on the impact on access to Title X providers and family planning and preventive health services demonstrate that continued enforcement of the 2019 Rule will harm more individuals seeking family planning services. In a 2016 study, six in ten women seeking contraceptive services at a Title X-funded health center reported that to be their only source of medical care in the past year. The lack of access to such critically needed services has been exacerbated by the decreased lack of

access to medical care due to the COVID-19 pandemic, and the increased number of uninsured individuals. The Proposed Rule will help alleviate these issues.

The NPRM Removes Inappropriate Interference with the Patient-Physician/Provider Relationship

The AMA strongly opposes any government interference in the exam room, especially legislation or regulations that attempt to dictate the content of physicians' conversations with their patients.

Protecting the sanctity of the patient-physician relationship, including defending the freedom of communication between patients and their physicians, is a core priority for the AMA. The ability of physicians to have open, frank, and confidential communications with their patients has always been a fundamental tenet of high-quality medical care. The 2019 Rule inappropriately prohibited, yet also compelled, certain pregnancy-related speech between a Title X physician/provider and her patient, proscribing abortion-related information and most abortion referrals but requiring information about non-abortion options—regardless of what the patient wants. The AMA supports the removal by the NPRM of this interference in the patient-physician relationship.

From ancient times, physicians have recognized that the health and well-being of patients depends upon a collaborative effort between physician and patient. Patients share with physicians the responsibility for their own health care. The patient-physician relationship is of greatest benefit to patients when they bring medical problems to the attention of their physicians in a timely fashion, provide information about their medical condition to the best of their ability, and work with their physicians in a mutually respectful alliance. This relationship is built upon trust. A physician must always have the ability to freely communicate with his or her patient, providing information to patients about their health and safety, without fear of intrusion by government and/or other third parties. Regulations that restrict the ability of physicians to explain all options to their patients and refer them, whatever their health care needs, compromise this relationship and force physicians and other health care providers to withhold information that their patients need to make decisions about their care. Likewise, requiring physicians to share information about specific options, particularly those that may be contrary to their medical judgment or their patient's needs, infringes on the physician's freedom to communicate.

Prior to the issuance of the 2019 Rule, HHS had long recognized the importance of full, open communication to the patient-physician/provider relationship through its interpretation of section 1008 of the Title X statute, which provides that no program funds “shall be used in programs where abortion is a method of family planning,” and by administering the Title X program to require that providers offer pregnant patients the opportunity to receive nondirective counseling on all their medical options, including abortion. This position respects the integrity of the patient-provider relationship and is consistent with both medical ethics and HHS' own standards of care for all family planning professionals. The 2019 Rule violated these core principles by restricting the counseling and referrals that can be provided to patients and by directing clinicians to withhold information critical to patient decision-making. Specifically, the 2019 Rule eliminated the longstanding requirement that Title X projects provide neutral, factual, nondirective options counseling regarding all of a pregnant patient's options—including abortion—upon request.

In contrast, the Proposed Rule is similar to the regulations that were in place from 1993 to 2019. It allows Title X funded sites and providers to discuss and refer clients to abortion services when they wish to terminate a pregnancy but maintains the longstanding prohibition on the use of Title X funds to pay for abortions. The NPRM once again requires, “upon request of the client, nondirective counseling and referral, regarding any option requested: (1) prenatal care and delivery; (2) infant care, foster care, or adoption; and (3) pregnancy termination.” (section 59.5(a)(5)) However, a physician or other health care provider would no longer be required to discuss any option(s) about which the patient indicates she does not want information and counseling.

The changes on counseling and referral in the 2019 rule not only undermined the patient-physician relationship, but also contravened physicians' ethical obligations. The inability to counsel patients about all of their options in the event of a pregnancy and to provide any and all appropriate referrals, including for abortion services, are contrary to the AMA's [Code of Medical Ethics](#), which provides that patients have the right

“to receive information from their physicians and to have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives...patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment.” AMA, *Code of Medical Ethics*, Opinion E-1.1.3.

Moreover, the AMA's *Code of Medical Ethics* states that providers must “present relevant information accurately and sensitively, in keeping with the patient's preferences (Opinion 2.1.1) and that “withholding information without the patient's knowledge or consent is ethically unacceptable (Opinion 2.1.3). Physicians' inability to comply with their ethical obligations not only undermines the patient-physician relationship, but also harms their pregnant patients, especially when patients are delayed in finding abortion providers.

The 2019 Rule violated fundamental principles of medical ethics. **The AMA supports the Proposed Rule's changes that restore the patient-physician/provider relationship of open dialogue and candor and allow physicians and providers to follow their codes of ethics without being afraid that they might violate the law.**

The NPRM Restores Access to Evidence-Based Family Planning Methods

The Title X statute requires projects to “offer a broad range of acceptable and effective family planning methods and services.” Prior to the 2019 Rule, Title X regulations required funded projects to provide medical services related to family planning and to offer a broad range of acceptable and effective medically-approved family planning methods. The 2019 Rule eliminated the requirement that projects offer the full range of family planning methods and removed “medically-approved” from the previous regulatory requirement. The 2019 Rule also no longer required that Title X sites follow the nationally recognized Quality Family Planning (QFP) clinical guidelines published by the Centers for Disease Control and Prevention and the OPA in 2014. Instead, HHS emphasized non-medical services, such as abstinence, natural family planning, and adoption as a way to manage infertility, which allowed organizations to qualify for Title X funding even though they only offered a single method such as fertility awareness-based approaches or abstinence, which is not an FDA-approved method. These provisions changed the historic emphasis under both the Title X statute and previous regulations that projects must provide a broad range of acceptable and effective medically-approved family planning methods. In addition, HHS's emphasis on non-medical services was contradicted by data showing that fertility awareness methods are among the least effective methods of family planning, and the Food and Drug Administration has warned that these are not reliable forms of contraception.

All individuals seeking care in Title X programs should have access to the contraceptive method that works best for their circumstances. Evidence shows that women who have access to and are able to use the contraceptive method of their choice are more likely to use contraception consistently and effectively, thereby reducing their risk of unintended pregnancy. Contrary to HHS' assertion in the 2019 Rule that its revisions would improve access to and the quality of care at Title X projects, the revisions have undermined the quality and standard of care upon which millions of women depend for their reproductive health care. Moreover, the 2019 Rule has threatened to reverse decades of progress in reducing unintended and teen pregnancy; prior to adoption of the 2019 Rule, the United States currently had a

30-year low in unplanned pregnancy and an all-time low in teen pregnancy. Access to affordable contraception, including through programs funded by Title X, has helped make these results possible.

The Proposed Rule will again base the standards of care for the Title X program on the QFP guidelines and require that Title X clients receive high-quality, client-centered care that includes comprehensive, medically accurate counseling and information, and referrals for any other services sought. The NPRM restores the term “medically-approved” and adds “FDA-approved contraceptive services” to the proposed definition of family planning services; requires that Title X service sites refer patients if the site does not offer the contraceptive method of the patient’s choice; and provides services “in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with national recognized standards of care.” (proposed section 59.5(a)(3)) The AMA supports these proposals and urges they be adopted.

The NPRM Restores Access to Qualified Providers

The statute governing Title X requires that program funds can only go to entities where abortion is not a method of family planning. Under regulations from 2000 to 2019, Title X projects were banned from using Title X funds to pay for abortions and had to keep any abortion-related activities financially separate from their Title X activities. The 2019 Rule, however, required that Title X activities have full physical and financial separation from abortion-related activities. In addition to separate accounting and electronic and paper health records, providers were required to have separate treatment, consultation, examination and waiting rooms, office entrances and exits, workstations, signs, phone numbers, email addresses, educational services, websites, and staff. These requirements led long-serving Title X providers, such as Planned Parenthood, to leave the program, harming patients and the public’s health. The NPRM once again permits family planning services to be co-located with abortion services and removes the onerous and cost-prohibitive accounting, record-keeping, and other requirements. The AMA supports these changes, which we hope will be a significant step forward in rebuilding the Title X provider network to its pre-2019 numbers and in restoring access to care for Title X clients.

Advancing Health Equity

The AMA is pleased that the NPRM emphasizes advancing health equity in the Title X program, both as a goal and a new criterion for awarding grant funds. We believe this is consistent with the mission and statutory language of Title X, which prioritizes serving people with low-incomes and provides care regardless of ability to pay. The impact that the 2019 Rule has had on marginalized and minoritized individuals’ access to critical family planning and preventive health services has been devastating. The AMA is strongly committed to advancing health equity, embedding racial justice, and addressing health disparities, and we recently released our first [strategic plan](#) to guide our efforts. The Title X program has a significant role to play in combating systemic barriers to care and ensuring that all people, regardless of their race, ethnicity, age, sexual orientation, gender identity, immigration status, employer, insurance status, or any other demographic, have timely access to comprehensive, high-quality family planning and sexual health services. We believe that the proposed revisions to the Title X regulations will help advance Title X’s mission to provide equitable, affordable, client-centered, quality family planning and sexual health services.

Conclusion

Title X is the only federal program dedicated specifically to providing low-income patients with essential family planning and preventive health services and information. As such, it plays a vital role in the nation’s public health safety net by ensuring that timely, safe, and evidence-based care is available to people, regardless of their financial circumstances. In addition to pregnancy prevention, Title X projects

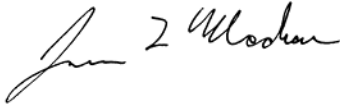
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provide other important health services, including sexually transmitted infection testing and treatment, Pap tests, and clinical breast exams. We strongly support the Proposed Rule's revisions to the 2019 Rule, which we believe will restore the Title X Program's ability to meet its statutory mandate. We urge HHS to finalize this proposal.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD