XAVIER BECERRA
Attorney General of California
MICHAEL L. NEWMAN
Senior Assistant Attorney General
KATHLEEN BOERGERS
Supervising Deputy Attorney General
ANNA RICH, State Bar No. 230195
KARLI EISENBERG
BRENDA AYON VERDUZCO
Deputy Attorneys General
1515 Clay Street, 20th Floor
P.O. Box 70550
Oakland, CA 94612-0550
Telephone: 510-879-0296
Fax: 510-622-2270
E-mail: Anna.Rich@doj.ca.gov
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX AZAR, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,

Defendants.

DECLARATION OF JULIE RABINOVITZ IN SUPPORT OF A MOTION FOR A PRELIMINARY INJUNCTION

Date:	April 18, 2019
Time:	12:30 p.m.
Dept:	Courtroom 5, 17th Floor
Judge:	The Honorable Edward M. Chen
Trial Date:	Not set
Action Filed:	March 4, 2019

I, Julie Rabinovitz, declare that if called as a witness, I would testify competently to the following:

1. I am President and Chief Executive Officer CEO of Essential Access Health, Inc. ("Essential Access"). I have held this position since January of 2011. In this role, I lead the nation's largest and most diverse Title X federal family planning program and partner with 70 health care agencies across California to ensure access to quality, comprehensive sexual and reproductive health care for more than 1 million women, men, and teens each year. Essential Access is committed to ensuring that all individuals have access to affordable, high-quality family planning and sexual and reproductive health services, including, but not limited to, contraceptives, screenings for sexually-transmitted diseases (STDs), breast exams, and Pap tests.

2. I hold a Master's Degree in Public Health Management and Policy from the University of Michigan School of Public Health and a Bachelor of Arts in Political Science in History from Northwestern University. I have over 20 years of experience in public health administration. Prior to serving as President and CEO at Essential Access Health, I led comprehensive family planning and reproductive health programs at a wide range of health settings; including federally-qualified health centers, Planned Parenthood League of Massachusetts, academic medical centers such as the University of Illinois at Chicago Medical Center, and Brigham and Women's Hospital, Harvard Medical School, and Planned Parenthood of Illinois. I have also served as Board Chair and member of the Board for the National Family Planning & Reproductive Health Association and Family Planning Councils of America.

3. I am familiar with the rule entitled "Compliance with Statutory Program Integrity Requirements" (the "Final Rule"), 84 Fed. Reg. 7,714, issued by the Department of Health and Human Services ("HHS") on March 4, 2019. Prior to its publication in the Federal Register on March 4 2019, I submitted comments on behalf of Essential Access to HHS's Notice of Proposed Rule, entitled "Compliance with Statutory Program Integrity Requirements," published in the Federal Register on June 1, 2018 (the "Proposed Rule"). There, I shared Essential Access's significant concerns about the Proposed Rule, including that it would significantly impede access to time-sensitive family planning and reproductive health services, eliminate highly-qualified

family planning providers from the program, and result in diminished access to care, higher unintended pregnancy rates, and higher STD rates.

4. Though the Proposed Rule received overwhelmingly negative responses from several legislators, major medical associations, Title X providers, and distinguished policy and research organizations working in the reproductive health care field, the Final Rule is largely identical to the Proposed Rule. The Final Rule reflects an unprecedented attack on the Title X program, toppling decades of established practice that has allowed thousands of Title X-funded health centers to provide quality, comprehensive family planning services to millions of low-income individuals.

I. ESSENTIAL ACCESS HEALTH AND TITLE X

5. Essential Access Health was founded in 1968 as the Los Angeles Regional Family Planning Council, later merged to become California Family Health Council, and then Essential Access Health in 2016. Essential Access is a California nonprofit 501(c)(3) corporation. Every year, HHS distributes Title X funding to support family planning programs and related reproductive care in service areas throughout the country. Since the inception of the program nearly fifty years ago, Essential Access has been California's primary Title X Family Planning Services Grantee.

6. Essential Access's mission is to champion and promote quality sexual and reproductive health care for all. Essential Access achieves that mission by supporting the delivery of core family planning and related preventative health services through its 70 sub-recipient health care agencies; by serving as a nationally-recognized resource for training health care professionals in best practices in the delivery of sexual and reproductive health care; by conducting advanced clinical research on contraceptives; and by advocating for the expansion of access to sexual and reproductive health care, with a focus on reaching low-income and uninsured populations disproportionately impacted by unintended pregnancy and high STD rates.

7. Currently, Essential Access oversees the largest and most diverse Title X provider network in the country, contracting with sub-recipient health care organizations in 38 out of 58 California counties. This robust network of Title X-funded organizations—including 356 clinic

sites and formalized partnerships with non-traditional referral sources, community groups, and faith- and community-based education and outreach organizations—currently serves more than one million patients annually, representing more than 25% of the patients served by the Title X program nationwide. Fifty-nine percent of Essential Access's Title X sub-recipients are federally-qualified health centers ("FQHCs") and community health centers; 13% are faith- and community-based education and outreach organizations; 11% are family planning and women's health centers; 10% are city and county health departments; 3% are community action partnerships and economic opportunity commissions; 3% are Native American health centers and outreach organizations; and 1% are hospitals.

8. Essential Access assumes the administrative burden of applying for Title X funding, and is accordingly the Title X grantee or recipient. The Title X Family Planning Services Grant application process is initiated once the Funding Opportunity Announcement ("FOA") is released. The application package includes a project narrative, budget narrative, budget attachments, and a host of federal forms and appendices.

9. Upon receiving its Title X funding award, Essential Access contracts with sub-recipient health care organizations, to which it distributes Title X funds. Essential Access sub-recipients use Title X funding to create Title X programs at their agencies, consistent with the Title X statute, regulations, and program priorities.

10. These sub-recipients rely upon Essential Access's substantial experience administering Title X benefits, allowing them to devote their limited resources to providing family planning services, rather than applying directly for Title X funding themselves. Without Essential Access, many of those sub-recipients would lack the staffing or resources to apply for Title X funding on their own.

11. Title X programs administered by Essential Access sub-recipients provide a broad range of family planning services and are the access point through which one million residents across California receive quality sexual and reproductive health care. Sub-recipients also provide preventive care services related to sexual and reproductive health, like screening for breast and cervical cancer, and prevention education for sexually transmitted infections and HIV.

12. In 2017 alone, Essential Access sub-recipients served more than one million patients and provided more than 1.6 million family planning visits that included more than 148,000 Pap tests, more than 118,000 clinical breast exams, more than 642,000 chlamydia screenings, more than 700,000 gonorrhea screenings, and more than 341,000 HIV tests.

II. ESSENTIAL ACCESS HEALTH'S TITLE X GRANTS

13. The Title X program is administered by the Office of Population Affairs ("OPA"), which operates under the Office of the Assistant Secretary for Health within HHS. Title X is a competitive grant program, meaning that eligible entities must apply to OPA for Title X grants. In 2017, Essential Access received $20.5 million in grant funding.

14. On February 23, 2018, OPA published a Funding Opportunity Announcement announcing the anticipated availability of "approximately $260 million for competing grants" under the Title X program for Fiscal Year 2018, and soliciting applications from entities to provide Title X family planning services throughout geographical services areas, including California.[1] On September 4, 2018, OPA notified Essential Access that it would again be the sole grantee for Title X in California and awarded Essential Access Title X funding in the amount of $14,360,000 from September 1,2018 through March 31, 2019.

15. On October 22, 2018, OPA published FOA Number PA-FPH-19-001, entitled "Announcement of Availability of Funds for Title X Family Planning Services Grants" for Fiscal Year 2019 (the "2019 FOA"). The 2019 FOA again solicited applications from entities to provide family planning services, and announced OPA's intention to make available "approximately $260 million for competing grants in 60 service areas and/or populations," including California.[2] The 2019 FOA provides that "estimates funds available" for California total $22 million, but also that "[a]ward amounts made to a successful applicant or applicants that provide Title X services within the same area or areas may be greater or less than the estimated funds presented in Table 1."[3] The 2019 FOA further provides that "[a]ll activities funded under this announcement must be

[1] Funding Opportunity Number PA-FPH-18-001 (https://www.hhs.gov/opa/sites/default/files/FY18-Title-X-Services-FOA-Final-Signed.pdf).

[2] https://www.hhs.gov/opa/sites/default/files/FY2019-FOA-FP-services.pdf

[3] *Id.* at 6.

in compliance with the Title X statute, any legislative mandates, and any program regulations, as of the time the requirement is applicable and in effect."[4] On January 10, 2019, Essential Access submitted its application in response to the 2019 FOA.

16. OPA provides strict oversight of Title X grantees, including Essential Access, to ensure that federal funds are used appropriately and that funds are not used for any prohibited activities, such as abortion services. OPA's oversight mechanisms include independent financial audits to examine whether there is a system to account for program-funded activities and non-allowable program activities; yearly comprehensive reviews of the Essential Access's financial status and budget report; and periodic and comprehensive program reviews and site visits by OPA regional offices.

17. OPA's Title X Regional Offices conduct a Comprehensive Program Review of Essential Access every three years. The review includes an assessment of compliance with Title X statutes and regulations and Essential Access's progress in carrying out the plan laid out in its Title X grant application, as well as verification of Essential Access's expenditure of funds and services offered. As part of the review, personnel and/or consultants from the Regional Offices conduct on-site visits of Essential Access and certain sub-recipients. The reviewers use OPA's "Program Review Tool" to evaluate compliance with respect to administration, finance, clinical services, and community outreach and education.

18. OPA also receives annual detailed data from Essential Access for compilation in the Family Planning Annual Report ("FPAR"). This includes data on users, providers, services offered, and providers' sources of revenue.

19. Essential Access also monitors sub-recipients' financial and program compliance on an ongoing basis. Essential Access conducts Program Evaluations of its Title X sub-recipients every three years. As part of the evaluation, Essential Access conducts on-site visits and evaluates sub-recipients' compliance with Title X statutes, regulations, and program priorities. The on-site

[4] *Id.*

visits include, among other things, staff interviews, reviews of medical charts, and direct clinical observations. There are three main aspects of every Program Evaluation:

i) The administration evaluation, in which Essential Access reviews the sub-recipient's administrative policies, procedures, manuals, training requirements and tracking. As part of this evaluation, sub-recipients must demonstrate that their protocols to combat child sexual abuse and human trafficking are comprehensive, up-to-date, and accurately reflect actual practice. Essential Access also audits medical records to ensure that whenever abuse is identified, the sub-recipient has documented any appropriate action taken in response;

ii) The clinical evaluation, in which Essential Access ensures, among other things, that the sub-recipient's treatment and counseling services are aligned with current, evidence-based standards of care and Title X's statutory and regulatory requirements. Essential Access's evaluators observe counseling sessions and ensure that pregnancy counseling in particular is factual, neutral, and nondirective; and

iii) The financial evaluation, in which Essential Access reviews the sub-recipient's policies, procedures, and documents to ensure compliance with applicable federal standards and sound accounting principles. Essential Access maintains specific operational procedures to verify that funds for abortion activities are separated from Title X funds.

20. Essential Access also monitors compliance by regularly collecting data from its sub-recipients. For example, Essential Access collects monthly or quarterly electronic health record data, along with bi-annual aggregate clinical and outreach data, from all its sub-recipients for the OPA's annual FPAR. Likewise, Essential Access reviews sub-recipients' financial data on a quarterly basis. Through all of these data sources and others, Essential Access continually monitors its sub-recipients for compliance with Title X statutory and regulatory requirements, as well as compliance with applicable standards of care.

III. ESSENTIAL ACCESS HEALTH'S TITLE X-FUNDED WORK

21. Essential Access's sub-recipient agencies serve more than one million patients annually, providing family planning and related services to otherwise underserved or vulnerable communities, including low-income individuals, teens, and women of color. Title X programs

administered by Essential Access sub-recipients provide a broad range of family planning services and are the access point through which one million residents across California receive quality sexual and reproductive health care. Title X funds have never been available to pay for abortion services, and Essential Access sub-recipients do not use Title X funds to pay for abortion services.[5]

22. In 2017, Essential Access's sub-recipient network provided services to 1,018,978 patients. These patients were 88% female, 12% male, and 66% under the age of thirty. Seventy-three percent of those patients had family incomes below the federal poverty line. In 2017, 93% of Title X patients served by Essential Access's sub-recipients had family incomes below 250% of the Federal Poverty Level, and 50% were uninsured.

23. Sub-recipients also provide preventive care services related to sexual and reproductive health, like screening for breast and cervical cancer, and prevention education for sexually transmitted infections and HIV. In 2017 alone, Essential Access's sub-recipients provided more than 1.6 million family planning visits that included more than 148,000 Pap tests, more than 118,000 clinical breast exams, more than 642,000 chlamydia screenings, more than 700,000 gonorrhea screenings, and more than 341,000 HIV tests.

24. Essential Access's administration of Title X funding reduces barriers to patient access to comprehensive, high-quality family planning services and related preventive health care. For example, Title X funding allows Essential Access's sub-recipient health centers to extend clinic hours, target hard-to-reach populations through outreach and education, provide bilingual or interpreter services for clients not proficient in English, and improve technologies such as web-based appointment systems and text or email appointment reminders. Evening and weekend clinic hours enhance access for low-income men and women who may be hesitant or

[5] According to OPA, "family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion." Congressional Research Services August 31, 2017 report (see fn 10 of Maine complaint).That restriction is set forth in section 1008 of Title X, which provides that Title X funds would "be used only to support preventative family planning services, population research, infertility services, and other related medical, information, and educational activities." H.R. Rep. No. 91-1667, at 8 (1970).

unable to take time off from work or other responsibilities for non-emergency health care. Outreach and marketing strategies can also facilitate patient access by generating awareness about the availability of no- or low-cost reproductive health care services.

25. Essential Access sub-recipients also use Title X funding to facilitate the delivery of high-quality sexual and reproductive health care by providing expanded clinical training opportunities to enhance the capacity of Title X-funded health care sites to integrate best practices into their service delivery. A higher proportion of clinicians working at Title X clinics participate in clinical training opportunities as compared with non-Title X providers. Web-based trainings are particularly helpful in developing the skills of clinicians at rural and/or small sites, who otherwise may be less available to participate in in-person training opportunities. Between 2015 and 2018, Essential Access administered trainings on critical health care issues to more than 7,500 Title X-funded health center staff. These included trainings on Sexual and Reproductive Health for Adolescents, California Mandatory Child Abuse Reporting Laws, STD Management Strategies, Best Practices for Services Providers Supporting LGBTQ Youth, Talking With Patients About Permanent Contraception, and Zika Prevention Updates for Providers, among others. In addition, in 2017, Essential Access staff provided more than 1,000 hours of technical assistance to Title X sub-recipients on quality improvement, work flow, patient-centered and team-based care, documentation, and integrating family planning services into primary care settings.

26. Essential Access sub-recipients also use Title X funding to increase patients' access to family planning services in rural areas. In California, rural counties have the highest teenage birth rates. Teenagers living in these counties are less likely to receive family planning services because there are a limited number of providers—and in any event, they often have to travel much farther than their urban counterparts to access such services. Essential Access's sub-recipients are often the only providers of Title X services in their county. Without those sub-recipients, patients in many rural areas would lack access to family planning services.

27. The work of Essential Access sub-recipients in California's Central Valley provides just one illustration of the impact Title X funding can have on a community. The Central Valley

faces several critical disparities in sexual and reproductive health. For example, among the counties with above-average teenage birth rates in California, eight are in the Central Valley. Central Valley residents also have higher rates of chlamydia compared to the rest of the state. Accordingly, for the past several years, Essential Access has focused efforts on expanding access to family planning services in the Central Valley. From 2013 to 2017, Essential Access added eleven Title X-funded clinics in the Central Valley, increasing the network of Central Valley Title X-funded clinics from 52 to 63. These new clinic sites saw an average of more than 200,000 patients annually during this time period.

28. In many cases, Essential Access's Title X-funded network is a critical access point to quality reproductive care and related services for low-income individuals. For example, twelve counties in California—including Humboldt, Imperial, Kern, Kings, Lake, Mendocino, Merced, Napa, Nevada, Placer, Stanislaus, and Sutter counties—have only one Title X-funded clinic. If, for instance, the Title X-funded clinic in Humboldt county were to close, its patients would have to drive up to 150 miles to reach the next closest Title X-funded clinic in Shasta county.

29. Access to Title X-funded clinics matters to the patients those clinics serve. Patients rely on Title X-funded clinics to provide high-quality sexual and reproductive health care consistent with clinical best practices. Title X-funded clinics must comply with recommendations for Providing Quality Family Planning ("QFP") as determined by the Centers for Disease Control and OPA in 2014, developed in collaboration with individual clinical experts and professional medical associations including the American College of Obstetricians and Gynecologists ("ACOG"). The QFP recommendations set forth broadly accepted, evidence-based standards for high-quality clinical practice regarding the provision of family planning services based on a rigorous, systematic, and transparent review of existing clinical guidelines published by federal agencies, such as the CDC and U.S. Preventive Services Task Force.

30. The QFP recommendations are considered by the public health community to be the standard of care for all family planning practitioners. Contraceptive services are a cornerstone of the reproductive care offered by Essential Access sub-recipients. Nearly half (40%) of all pregnancies in California are unintended, resulting in over 306,070 unintended pregnancies in

2014 alone. Contraceptives help women time and space their pregnancies, or prevent pregnancies altogether, in accordance with their own desires and to improve maternal, child, and family health outcomes. In addition, access to birth control is particularly critical for women with underlying chronic, physical, and psychological conditions that can be exacerbated by pregnancy, and can also help reduce rates of maternal mortality and morbidity.

31. The QFP recommendations Title X-funded clinics comply with provide that contraceptive services should include consideration of a full range of FDA-approved contraceptive methods, a brief assessment to identify the contraceptive methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it effectively and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary. The recommendations emphasize that providers should inform clients about ***all*** contraceptive methods that can be used safely, including long-acting reversible contraceptives ("LARC") like IUDs and implants. The QFP recommendations also recommend providing contraceptive care in line with the U.S. Medical Eligibility Criteria for Contraceptive Use, released by the CDC, and its companion U.S. Selected Practice Recommendations for Contraceptive Use, which provides guidance on how to use contraceptive methods safely and effectively once they are deemed medically appropriate.

32. The QFP recommendations also explain that pregnancy testing and counseling services are a core part of family planning services, and recommend that providers give patients referrals to appropriate providers for follow-up care upon client request as needed, and that every effort should be made to expedite and follow through on all referrals.

33. When referring pregnant clients, Essential Access's Title X-funded health centers act in accordance with evidence-based clinical standards for nondirective counseling. These standards were developed to provide quality family planning services in a safe, effective, and client-centered manner. The American Medical Association (AMA), the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American Academy of Family Physicians all endorse nondirective options counseling as the most clinically appropriate course for providers caring for a patient who is facing an unexpected pregnancy.

These standards allow patients to trust that Title X medical providers and health centers will provide unbiased information regarding their reproductive and sexual health. Medical providers at Essential Access's Title X-funded health centers understand that nondirective counseling requires the presentation of neutral, factual, and nondirective information about all legal and medically indicated options for pregnancy, including abortion. Nondirective counseling also requires nondirective referrals for particular services—including abortion—upon request of the patient.

34. Absent Essential Access's Title X-funded network, the sexual and reproductive health care needs of many low-income individuals will be at risk . In 2014, 2.6 million California women needed publicly-funded family planning, and the State's family planning network could meet only 50% of that need. Essential Access and its network of sub-recipients work to fulfill that need with Title X-funded services.

IV. THE FINAL RULE WILL IRREPARABLY HARM ESSENTIAL ACCESS HEALTH AND TITLE X PATIENTS

35. If the Final Rule is implemented, Essential Access sub-recipients will be forced to comply with the Final Rule's onerous and arbitrary restrictions, or decline Title X funding because the costs of compliance are too great to bear. Either option will result in immediate, irreparable harm to Essential Access and the millions of patients who benefit from Title X family planning services.

36. Implementation of the Final Rule will frustrate Essential Access Health's mission to champion and promote quality sexual and reproductive health care for all and cause it substantial, irreparable harm, in at least the following ways: (1) by decimating the network through which it supports the delivery of core family planning and related preventative health services, resulting in diminished access to quality care for patients served by Title X; (2) by interfering with the patient-provider relationship and diminishing patient access to time-sensitive and comprehensive care, putting patients at risk; (3) by forcing Essential Access to cease its *non*-Title X-funded training, education, and advocacy efforts promoting quality sexual and reproductive care, or else conduct those activities out of a "mirror" office that uses separate facilities, staff, email addresses, and phones; and (4) by requiring enormous financial

expenditures by Essential Access and its sub-recipients to ensure compliance with the Final Rule, with no public health benefit and significant public health cost.

A. The Final Rule will devastate Essential Access Health's Title X network and decrease access to care

37. If implemented, the Final Rule will jeopardize the nation's network of family planning health centers and deprive millions of individuals access to quality sexual and reproductive health care.

38. The harm to Californians will be particularly pronounced. Essential Access's Title X network serves one million patients annually—representing more than 25% of the patients served by the Title X program nationwide. This robust network of 70 Title X sub-recipient agencies includes 356 clinic sites and formalized partnerships with non-traditional referral sources, community groups, and faith- and community-based education and outreach organizations.

39. Essential Access has strategically used Title X funds to strengthen the organizational capacity of California's Title X provider network to (1) ensure continued access for the one million low-income women, men, and teens that depend on them each year, and (2) increase the number of patients that receive quality family planning services from Title X-funded health centers—particularly in regions like the Central Valley that are home to the highest rates of unintended pregnancies, teen births, and STDs in the state. Essential Access achieves its mission through the distribution of Title X funds in a manner that will ensure comprehensive and quality care for all served by the program.

40. However, faced with the choice of either complying with the Final Rule's unlawful and draconian conditions or foregoing Title X funds altogether, many of Essential Access's sub-recipients confirm they will be forced to forfeit Title X funds, drastically reducing the number of Title X family planning clinics and decimating Essential Access's Title X network, through which it supports the delivery of core family planning and related preventative health services.

41. Essential Access surveyed its Title X sub-recipients to better understand the impact the new regulations would have on its Title X network, if implemented. Seventy-six percent of

Essential Access's sub-recipients—representing 47 health care agencies operating 313 clinic sites, and serving over 867,000 patients—responded.

42. Sub-recipients representing 233 clinic sites serving over 774,000 patients said they would leave or consider leaving the program if their medical providers would be prohibited from giving patients referrals for abortion services. Sub-recipients representing 194 clinic sites that serve over 682,000 patients report they will leave or consider leaving the program if the provision requiring medical providers to promote family involvement where an adolescent seeks confidential services is implemented. Eighty-five percent of responding sub-recipients said those restrictions would worsen the quality of patient care, and more than half reported that prohibiting referrals for abortion services would make it more difficult for clinics to recruit medical providers, such as doctors and nurses. If required to implement the Final Rule's requirement that medical providers promote family involvement where an adolescent seeks confidential services, over half of responding sub-recipients would leave or consider leaving the Title X program. Sub-recipients that are unable to comply with the Final Rule will become ineligible for Title X funds, mid-grant, on May 3, 2019.

43. In most cases, the cost of complying with the Final Rule's reporting and separation requirements will be impossible for Essential Access's sub-recipients to afford, leaving them with no choice but to forego Title X funds. Without Title X funding, health centers vital to their communities will be forced to reduce access to services, reduce staff positions, and close satellite sites. Without Title X funding, members of Essential Access Health's Title X provider network would also have limited capacity to conduct the community outreach and education activities that increase awareness about Title X services and connect patients to care. In addition, if all qualified family planning abortion providers in California were to close, 18 counties would be left without a Title X-funded health center.

44. Essential Access sub-recipients confirm that a reduction in the number of providers participating in California's Title X program will impede access to care and disproportionately harm individuals with limited resources. Eighty-five percent of responding sub-recipients, representing over 250 clinic sites that serve over 690,000 patients, report that without Title X

funding, they would be forced to lay off staff and cut staff training and continuing education on the provision of quality family planning services. Eighty-seven percent, which includes sub-recipients representing 258 clinic sites serving over 656,000 patients, would be forced to reduce outreach and education activities that connect community members to their family planning services. Over a third, representing 90 clinic sites serving over 300,000 Title X patients, would be forced to reduce clinic hours.

45. These reductions will result in immediate, significant harms to patients. In the absence of Title X funding, clinics will be unable to provide many services that they currently offer to low-income and underserved populations. In many cases, patients will lose access to extended clinic hours, bilingual or interpreter services, or technology improvements. Where outreach and education resources are cut, access to primary care services will also be diminished, as family planning outreach activities often lead patients to access primary care services as well. Survey respondents confirm that the regulatory changes will impact the total number of patients clinics see, increasing wait times and the duration between patients' family planning appointments.

46. Reducing access to Title X-funded health centers will also reduce access to quality reproductive care, including contraceptives. Studies show that when patients have access to all medically-approved contraceptive methods, they are more likely to find a method that is right for them, and thus more likely to effectively and consistently use it. In 2016, patients served by Title X-funded health centers in California were more likely to adopt or continue the use of LARCs when compared to patients served by non-Title X funded health centers. LARCs are highly effective because they obviate the need for daily administration or use at the time of intercourse. Diminishing access to LARCs may result in a greater number of unintended pregnancies. Some clinics that do not adhere to the Quality Family Planning Guidelines have expressed interest in obtaining Title X funds if the Rule takes effect and are now more likely to qualify for Title X funding. These lower-quality providers do not offer comprehensive contraception services, and staff at these facilities are often trained to delay women's decisions so that abortion becomes a less safe and accessible alternative.

47. This disruption of services will have profound short- and long-term consequences for Title X patients, their children, and society. Women who experience an unintended pregnancy are more likely than those with an intended pregnancy to receive inadequate or delayed prenatal care and experience poor outcomes, such as preterm births and low-birth-weight babies. Low-income women will be especially at risk, as they have historically suffered from a higher proportion of unintended pregnancies in relation to the general population.

B. Compliance with the Final Rule will interfere with the provider-patient relationship and harm patients

48. For Essential Access sub-recipients who feel they have no alternative but to remain in the program and comply with the Final Rule, the effects on providers and the patients they serve are similarly devastating.

49. If the Final Rule is implemented, medical providers in Essential Access's network will be forced to choose between continuing to provide services at a Title X-funded health care center and accepting the Rule's interference with candid, transparent provider-patient communication around pregnancy options counseling, and abortion in particular. Under the Final Rule, medical providers are allowed to tell pregnant patients about only *some* of their options, and must exclude any information about abortion. Even where a patient says that she is only interested in information and counseling on abortion, the Final Rule requires medical providers to disregard that patient's decision and compels them to discuss other options the patient does not want. In fact, while banning abortion referrals, the Final Rule affirmatively requires prenatal referrals, providing that a Title X provider "*shall*" provide referrals for prenatal health care once a client is verified as pregnant—even if the patient has expressly said she does not want it.

50. The prohibition on discussing abortion and providing abortion referrals prevents medical providers from providing comprehensive, quality medical care to their patients. Forcing medical providers to give a woman seeking an abortion a list that includes *non*-abortion providers wrongly burdens the patient with investigating and discovering which providers perform abortions. That charade imposes an unreasonable barrier to patients' ability to access appropriate medical care, and impedes access to time-sensitive family planning and reproductive health care

services. Title X patients seeking an abortion referral will be misled into scheduling one or more unnecessary in-person office visits for unwanted services, only to learn they must again arrange transportation and time off from work or school to actually obtain an abortion referral.

51. The Final Rule's requirement that the list of providers given to a woman who has requested a referral for abortion include only abortion providers who also offer "comprehensive primary health care" exacerbates this problem. This requirement will exclude many abortion providers who are otherwise qualified to provide the services requested by the patient. In some areas, the only qualified abortion provider is a specialized facility that does not provide primary care services. Omitting these providers from the list will leave patients who wish to terminate their pregnancy without any local referral options, increasing the delay in their receiving the requested care. For example, California women in rural parts of Northern California will have to travel more than five hours in order to visit a provider that qualifies for the list and offers abortion services. Women in the Central Valley, central coast, and southeastern regions of California will have to drive 2–4 hours to visit a provider that qualifies for the list and offers abortion services.

52. The Final Rule also drastically limits who can provide "nondirective pregnancy counseling," banning all medical professionals other than doctors or "advanced practice providers" (as defined by HHS) from providing that pregnancy counseling. That restriction excludes vast numbers of medical professionals—including registered nurses and health care assistants who regularly work alongside physicians and advanced practice providers from providing such counseling, further diminishing patients' access to care.

53. The Final Rule further harms patients by failing to explicitly allow for abortion referrals when abortion is medically necessary. Instead, the Final Rule appears to preclude *all* medically necessary referrals for abortion, except for in documented emergency situations. However, an abortion referral may be medically necessary even in situations where the pregnant woman need not be sent immediately to an emergency room, but the risk to her health is nonetheless time-sensitive. The lack of an explicit exception for abortion referrals in medically necessary or other threatening situations threatens to chill provider speech and impede patients'

timely access to the full range of information they need to make informed decisions about their health.

54. The Final Rule will also undo years of investment Essential Access and its network have made in establishing a "no wrong door" approach to reproductive healthcare. Under this approach, the goal is to ensure that regardless of which provider a patient initially sees for their sexual and reproductive health care, he or she is given access to, and information regarding, the full range of available services from local providers. Integral to such an approach is the provider's ability to make referrals to all needed reproductive services and related care. By limiting providers' ability to make referrals, the Final Rule impedes efforts to offer seamless reproductive healthcare.

55. Abiding by the Final Rule will fundamentally alter the relationships between patients and their medical providers by requiring providers to remain silent or misrepresent pregnancy options to patients seeking referrals for abortion services. The majority of sub-recipient survey respondents confirm that if the Final Rule is implemented and they elect to continue receiving Title X funds, it will be more difficult to recruit and retain medical providers to work in Title X programs because of the Final Rule's interference with the provider-patient relationship.

56. The Final Rule will also limit the ability of clinical staff other than doctors—such as nurse practitioners and administrative staff—from adequately serving their clients. The Final Rule allows only "Advanced Practice Providers," *i.e.*, professionals with graduate degrees such as Certified Nurse Practitioners, to provide counseling to pregnant patients, even though the majority of counseling in Title X programs is provided directly by non-physician and non-Advanced Practice Providers such as registered nurses, licensed clinical social workers, medical assistants, family planning health workers, and licensed vocational nurses. This added restriction further impedes patients' access to family planning services.

57. Adolescent patients who seek care at clinics that are forced to comply with the Final Rule's family involvement requirements will also suffer. The majority of Essential Access sub-recipient survey respondents confirm that, if these requirements were implemented, fewer

adolescent patients will speak honestly with their medical providers, fewer adolescent patients will seek care at their clinics, and these requirements would disrupt the confidential provider-patient relationship. In addition, fewer adolescents will seek care if sub-recipients are required to screen any adolescents for abuse when those individuals test positive for pregnancy or for STDs.

C. The Final Rule will force Essential Access to cease non-Title X-funded activities or conduct them through a "mirror" organization

58. The current Title X regulations—with which Essential Access and its sub-recipients fully comply—already ensure that no Title X funds are used for abortion. If an entity provides both abortion and Title X care, its Title X finances are completely separate. Title X funding (and the Title X project budget) pays only Title X expenses.

59. However, under the Final Rule, the separation requirement goes much further. Under the Final Rule, an entity that engages in so-called "prohibited activities" in its *non*-Title X-funded work must be organized so that it is physically *and* financially separate from a Title X project. "Prohibited activities" is defined so broadly as to cover virtually *anything* abortion-related, from providing abortion with non-Title X funds, providing abortion referrals, or even allowing abortion-related brochures to sit on a table within the same space where Title X services are provided. The Final Rule fails to give explicit guidance on how an organization achieves physical and financial separation and instead invokes a boundless standard of "objective integrity and independence" while noting that factors relevant to HHS's compliance determination include the existence of separate, accurate accounting records, the degree of separation from physical facilities in which prohibited activities occur, and the existence of separate personnel, health care records, and work stations, among other things.

60. This provision of the Final Rule puts Essential Access in an impossible position, as it would require Essential Access to expend substantial resources to separate its *non*-Title X-funded training, advocacy, and public awareness activities that discuss abortion.

61. For example, Essential Access's training arm, the Learning Exchange, is a nationally recognized leading resource for health care professionals across the country. The Learning Exchange offers learning opportunities in multiple formats, including in-person and

customized on-site trainings, webinars, and an annual clinical conference, the Women's Health Update. In 2017, Essential Access's Learning Exchange trained more than 6,000 clinicians and allied health professionals from forty-nine states on providing quality sexual and reproductive health care in diverse health settings.

62. Through the Learning Exchange, Essential Access offers training on pregnancy options, including how to provide patients with medically accurate, unbiased, non-judgmental information about abortion, adoption, and parenting. Essential Access's trainings include "Family Planning Health Worker" certification program, and in-person trainings on "Pregnancy Options Counseling," "Integrating Sexual and Reproductive Health Into Primary Care Settings," and "Motivational Interviewing," and other webinars and online trainings discuss these topics in an evidence-based, unbiased manner.

63. Essential Access also engages in substantial *non*-Title X-funded advocacy and public policy efforts that seek to expand and protect access to comprehensive sexual and reproductive health care for all, including abortions. These efforts include conducting meetings with health care policy decision-makers, drafting letters of support and providing public testimony on reproductive health care issues, participation in ballot initiative campaigns, and strategic engagement with partners on sexual and reproductive health care initiatives. For example in 2013, Essential Access publicly expressed support of AB 154, later signed into law, which authorized advance practice clinicians to provide first trimester abortions. In 2016, Essential Access sponsored AB 1954, which sought to provide patients direct access to comprehensive sexual and reproductive health care, including abortion, without first needing to obtain a referral from a primary care provider. This measure was chaptered and took effect on January 1, 2017.

64. *Non*-Title X-funded public education and awareness efforts conducted by Essential Access are similarly extensive. Essential Access creates and shares information and resources about comprehensive sexual and reproductive health, including where to access care, through its online adolescent health programs, such as TeenSource.org, Hookup, and TalkWithYourKids. These programs have a combined reach of over 650,000 individuals. Essential Access actively

posts information and resources about comprehensive sexual and reproductive health care on its social media accounts. Essential Access representatives, including myself, also regularly discuss sexual and reproductive health care issues in the media.

65. To the extent any of these activities discuss abortion, the Final Rule would require Essential Access to conduct those activities with a separate staff, under a separate roof, using separate workstations, email addresses, and phone numbers.

66. The Final Rule would effectively require Essential Access to either abandon the training, advocacy, and educational efforts described above—in additional to any other activities that discuss or could be construed as supporting abortion—or open a "mirror" office to continue to participate in the Title X program. Even though the physical and financial separation requirements do not take effect until a year after the Final Rule's effective date, opening a "mirror" office would be time-consuming and complex, requiring Essential Access to expend resources on planning and implantation of operational changes immediately after the Final Rule takes effect. Essential Access estimates that the cost of separating its non-Title X-funded training, advocacy, and public education and information activities would be approximately $325,000 for the first year, and $212,500 every year after. Those numbers reflect an extraordinary expense to the organization, and confirm that maintaining full separation between Essential Access's Title X programs and "prohibited activities" would be too costly for Essential Access to comply.

D. The Final Rule will require Essential Access and its sub-recipients to spend enormous sums on compliance, with no public health benefit

67. The massive disruption that implementation of the Final Rule will cause in Essential Access's network will, and already has, diverted resources away from Essential Access's mission of championing and promoting quality sexual and reproductive health care for all. Implementation of the Final Rule's separation and reporting requirements will further require Essential Access and its sub-recipients to devote extraordinary financial resources toward compliance.

68. The harm attendant to compliance is immediate. Despite the unprecedented changes to the Title X program mandated by the Final Rule, its "transition provisions" require that

providers comply with many of its provision within 60 days of its issuance—that is, May 3, 2019. The new requirements are so onerous that Essential Access and its sub-recipients must begin compliance efforts now. For instance, Essential Access must prepare and administer trainings and create new policies and workflows to instruct sub-recipients that intend to remain in the Title X program on implementation of the Final Rule.

69. Sub-recipients must, in turn, update their medical record systems and financial records, undertake extensive renovations, and hire new staff and personnel to implement the required changes. Sub-recipient estimate that implementing these changes would cost an average of more than $119,000 per agency. Money siphoned for compliance with the vague and onerous separation requirements will mean less money for patients, resulting in fewer services, reduced clinic hours, and staff layoffs. Additionally, under the Final Rule's new physical separation requirements, sub-recipients that wish to provide comprehensive counseling options and abortion referrals in compliance with clinical best practices would have to build "mirror" organizations with separate physical facilities operated by separate staff.

70. In addition to being costly, compliance with the Final Rule's separation and reporting requirements compromise quality of care and put patients at risk. For example, the Final Rule's physical separation requirement provides that a Title X project's "objective integrity and independence" from prohibited activities—such as unbiased, nondirective pregnancy options counseling and referral for abortion services in compliance with best practices—shall be determined by evaluating factors including the degree of separation between facilities, including "treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services and websites," as well as the "existence of separate personnel, electronic or paper-based health care records, and workstations." But separating the workspace, staff, and financial systems of Title X projects from non-Title X-funded activities will impede patients' timely access to care, contrary to best practices and the QFP recommendations. Separating medical records systems will put patients at risk. Non-integrated medical records systems are contrary to best medical practices and increase the risk of error. Multiple medical records systems can result in maintenance of incomplete medical

histories, missing data, lost medical tests or test results, missing or incorrect medication or dosage instructions, missing allergy warnings, and other miscommunications across patient records that threaten patient health and well-being.

71. Despite the harm resulting from the separation and reporting requirements mandated by the Final Rule, Essential Access will be forced to devote substantial financial resources toward educating its sub-recipients on compliance, to the detriment of Essential Access, it sub-recipients, and the patients they serve.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on March 21, 2019 in Berkeley, California.

JULIE RABINOVITZ

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