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ESSENTIAL ACCESS HEALTH, INC. and
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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ESSENTIAL ACCESS HEALTH, INC.; MELISSA MARSHALL, M.D.,

Plaintiffs,

v.

ALEX M. AZAR II, Secretary of U.S. Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOES 1-25,

Defendants.

Case No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Administrative Procedure Act Case

Trial Date: None set

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INTRODUCTION

1. Title X of the Public Health Service Act of 1970 is the nation's only federal program dedicated to the provision of family planning services and is a vital component of the nation's public health safety net. Under Title X, the federal government provides grants to public agencies and private nonprofits to fund family planning services for low-income individuals. Over the last four decades, the Title X program has given rise to a vast network of family planning health centers that provide critical reproductive health services to millions of individuals across the country. In 2017 alone, health centers that received Title X funding served four million patients in need of subsidized family planning services. These family planning services include education and advice regarding reproductive health, contraceptive services, pregnancy testing, basic infertility services, and referrals for other health and social services. Because Title X requires that health centers provide related preventative health services to patients requesting contraceptive care, Title X funding also supports basic primary care services such as lifesaving cervical and breast cancer screenings, testing for sexually transmitted infections and HIV, and screenings for high blood pressure. In many places throughout the country, Title X-funded clinics and health centers are the only source of quality contraceptive, reproductive, and sexual health care for underserved populations.

2. Today, Title X is under assault. On March 4, 2019, Defendants issued a new rule governing Title X grants. The new rule seeks to inject ideological beliefs into the provider-patient relationship and impose draconian conditions on Title X funding aimed at stifling constitutionally protected conduct. The rule, if implemented, would jeopardize the nation's network of family planning health centers and deprive millions of individuals access to quality sexual and reproductive health care. Plaintiffs bring this action for declaratory and injunctive relief to prohibit implementation of the new rule and to ensure that quality sexual and reproductive health care at Title X-funded health centers remains available to the millions of individuals who depend on it.

3. In 2017, Plaintiff Essential Access Health ("Essential Access") helped over one million low-income patients obtain life-changing family planning and related services with Title

X grants. Essential Access administers California's Title X system, supporting the delivery of family planning and related preventive health services through a vast, diverse network of Title X-funded health centers that includes federally qualified health centers, city and county health departments, hospitals, standalone family planning and women's health centers, and an Urban Indian Health Center. This network, in turn, serves more than one million low-income California residents every year—over 25% of patients served by the Title X program nationwide.

4. The new rule will change all of that. The new rule is purportedly designed to implement Section 1008 of the Title X statute, which prohibits Title X projects from using Title X funds to provide abortions. But the new rule goes far beyond Section 1008, seeking instead to "prohibit Title 10 [sic] funding from going to any clinic that performs abortions,"[1] even though Congress has always understood that recipients of Title X funds may provide abortion-related services using non-Title X funds.

5. To accomplish its goal of preventing Title X funding from going to any clinic that provides abortion-related services using non-Title X funds, the new rule imposes sweeping physical and financial separation requirements for family planning health centers. These centers will now have to divert a significant portion of their already limited budgets toward complying with these new requirements, which effectively demand that Title X services be provided in facilities totally separate from the many activities that are now prohibited under the new rule.

6. Moreover, in a departure from decades of settled practice and well-established medical ethics, the new rule prohibits Title X-funded health centers from referring patients for abortions, even in response to a direct request from a pregnant patient. By contrast, all pregnant patients must be referred to prenatal care under the new rule.

7. These new requirements go beyond the Title X statute's prohibition on using Title X funds to perform abortions, imposing conditions that distort the patient-provider relationship, dictating the very advice that a medical provider may offer a patient. Ultimately, the rule will

[1] President Donald Trump, Remarks by President Trump at the Susan B. Anthony List 11th Annual Campaign for Life Gala, May 22, 2018, *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trump-susan-b-anthony-list-11th-annual-campaign-life-gala.

dramatically limit patient access to family planning and reproductive health care, and will thus have a devastating impact on millions of patients in California and beyond.

8. Plaintiffs face an unacceptable choice: either comply with an unlawful rule that intrudes on the provider-patient relationship and conditions Title X funding on the cessation of constitutionally protected conduct, or forfeit critical funds necessary to provide quality sexual and reproductive health care for millions of women.

9. Plaintiffs accordingly seek declaratory and injunctive relief to prohibit implementation of the new rule and to ensure that quality sexual and reproductive health care at Title X-funded clinics remains available to the millions of individuals who depend on it.

JURISDICTION AND VENUE

10. This Court has jurisdiction under 5 U.S.C. §§ 703–706 and 28 U.S.C. § 1331, and further remedial authority under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

11. The new Title X rule (attached hereto as **Exhibit A** and hereinafter referred to as the "Final Rule") constitutes final agency action under the Administrative Procedure Act, 5 U.S.C. § 704. Plaintiffs are aggrieved and wronged by this agency action. The Final Rule is therefore subject to judicial review under 5 U.S.C. § 702.

12. Plaintiff Essential Access timely submitted detailed comments on the proposed Title X regulations.

13. Venue properly lies within the Northern District of California under 28 U.S.C. § 1391(b) and (e), because a substantial part of the events or omissions giving rise to this act occurred in this District and the Defendants are agencies and officers of the United States acting in their official capacity.

INTRADISTRICT ASSIGNMENT

14. Under Civil Local Rule 3-2(c), this case may be assigned to either the San Francisco or Oakland Divisions of this Court.

THE PARTIES

15. Essential Access is a California nonprofit corporation. Founded in 1968 as the Los Angeles Regional Family Planning Council, Essential Access oversees the delivery of critical

sexual and reproductive health care services throughout California with its network of Title X sub-recipients. Essential Access is California's sole Title X grantee and administers the state's Title X program, which is the nation's largest and most diverse. Essential Access's Title X network encompasses every health center that currently receives Title X funds in California. Essential Access's network of Title X-funded health centers includes federally qualified health centers, city and county health departments, hospitals, standalone family planning and women's health centers, and an Urban Indian Health Center. This network, in turn, serves more than one million low-income California residents every year, which accounts for more than 25 percent of Title X patients in the United States. Essential Access also trains medical providers, advocates for expanded access to sexual and reproductive health care on a public policy level, and conducts advanced clinical research on contraceptive methods.

16. Plaintiff Melissa Marshall, M.D., suing in her individual capacity, is Chief Executive Officer and acting Chief Medical Officer of CommuniCare Health Centers ("CommuniCare") in Yolo County, California. CommuniCare has been part of the Title X network since 1993. In 2017, CommuniCare served over 26,000 patients—nearly 80 percent of whom live on income below the federal poverty level. CommuniCare served 4,081 Title X patients in 2017, primarily through a drop-in healthcare clinic for teens. In addition to overseeing CommuniCare, Dr. Marshall personally sees 300 to 500 patients per year. Dr. Marshall earned her medical degree from the Washington University School of Medicine in Saint Louis, and completed a residency at the University of California at Davis Medical School. Dr. Marshall, who is board-certified in family medicine, has been practicing medicine for over 17 years and has seen thousands of patients.

17. Defendant U.S. Department of Health and Human Services ("HHS" or "the Department") is a cabinet-level agency of the U.S. federal government.

18. Defendant Alex M. Azar ("the Secretary") is the Secretary of Health and Human Services. He is sued in his official capacity.

19. The true names and capacities of Defendants identified as DOES 1–25 are unknown to Plaintiffs, and Plaintiffs will amend this Complaint to insert the true names and capacities of those fictitiously named Defendants when their identities are ascertained.

STATEMENT OF FACTS

A. Title X of the Public Health Service Act of 1970

20. In 1969, President Richard M. Nixon called on Congress to "establish as a national goal the provision of adequate family planning services within the next five years to all those who want them but cannot afford them." Congress responded by enacting Title X of the Public Health Service Act of 1970, 42 U.S.C. §§ 300 *et seq.*, with broad bipartisan support. Title X authorized the Secretary of Health, Education, and Welfare (now the Secretary of Health and Human Services) to make grants to, or contract with, public or nonprofit private entities to establish and operate "voluntary family planning projects."

21. Congress made clear in the plain text of the statute that in order to receive Title X funding, a family planning project must "offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a).

22. Congress also required the Secretary to consider certain statutory criteria when making grants and contracts under Title X. Specifically, Congress directed the Secretary to consider: (1) the number of patients that a project would serve; (2) the degree of local need for family planning services; (3) the relative need of the applicant; and (4) the applicant's capacity to rapidly and effectively use Title X assistance. 42 U.S.C. § 300(b).

23. The Senators who passed Title X explained that family planning is not "merely a euphemism for birth control." Rather, "family planning" is "properly a part of comprehensive health care and should consist of much more than the dispensation of contraceptive devices." Specifically, "a successful family planning program must contain . . . medical services, including consultative examination, prescription, and continuing supervision, supplies, instruction, and ***referral to other medical services as needed***."[2]

24. In response to concerns that Title X funding would be used to pay for abortions, the late Representative John D. Dingell proposed to amend the Act by adding Section 1008, entitled

[2] S. Rep. No. 91-1004, p. 10 (1970) (Senate Report summarizing committee's view) (emphasis added); S. Rep. No. 1004, 91st Cong., 2d Sess., reprinted in 116 Cong. Rec. 24094–96 (1970).

"Prohibition of Abortion."[3] Section 1008 provides that "[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6.

B. Congress's Intent Behind Title X

25. Congress has repeatedly rejected the notion that Title X grantees should be barred from counseling on, referring for, or performing abortion. The plain language of Section 1008 limits its application to Title X ***programs***, not the Title X funding recipients themselves or programs they may operate using non-Title X funds. Congress understood that some recipients of Title X funds would, in the course of carrying out their respective missions, also provide abortions and abortion-related services (subject to applicable legal restrictions). Accordingly, Section 1008 did not altogether preclude such recipients from receiving Title X funds. Instead, it simply prohibited those recipients from using Title X funds to support any programs in which abortion was a method of family planning. Thus, Title X recipients have been historically free to provide abortions and abortion-related services so long as they use non-Title X funds to do so.

26. Congress has repeatedly rejected proposed amendments to HHS appropriations bills that would have prohibited the use of federal funds for abortion referral services or the promotion or encouragement of abortion.[4] For example, in 1974, then-Representative Roncallo proposed an amendment in the House that "[n]o part of [Title X] funds . . . shall be used in any manner directly or indirectly to pay for abortions or abortion referral services, abortifacient drugs or devices, the promotion or encouraging of abortion, or the support of research designed to develop methods of abortion, or to force any State, school or school district or any other recipient of Federal funds to provide abortions or health or disability insurance abortion benefits."[5] The House rejected the amendment by a two-to-one margin.

[3] See H.R. Rep. No. 1472, 91st Cong., 2d Sess. 4 (1970).

[4] *See* 120 Cong. Rec. 21687–95 (1974), 121 Cong. Rec. 20863-64 (1975); 30 Cong. Quart. Almanac 97 (1974).

[5] 120 Cong. Rec. 21,687–95 (1974).

27. When Congress reauthorized Title X in 1975, it again rejected an amendment prohibiting Title X recipients from "pay[ing] for abortions, . . . promot[ing,] or encourag[ing] abortions."[6] In fact, the Senate Labor and Public Welfare Committee explained that it encouraged the use of Title X funds "not only in specialty clinics, but, where such facilities do not exist or are impractical, in entities devoted to comprehensive health care for low-income families."[7] As the Committee explained, "it is essential that there be close coordination and, whenever possible, integration of family planning services into all general health care programs."[8] The Committee Reports from that time repeatedly observed that the Title X program was effective and should continue as it had previously operated.

28. In 1978, Congress again debated whether to amend Title X in order to exclude entities that "directly or indirectly provide[d] abortions." Congress resoundingly rejected the proposed amendment. Specifically, then-Representative Robert Dornan was concerned about the alleged "difficult[y] of segregat[ing] funds" given to grant recipients such as Planned Parenthood. He therefore proposed an amendment that would have prevented organizations with family planning programs and abortion referral services from "redirect[ing] funds."[9] His amendment would have provided: "No grant or contract authorized by this Title may be made or entered into with an entity which directly or indirectly provides abortion, abortion counseling, or an abortion referral services."[10] In effect, it would have "allow[ed] no Federal funding to such groups."[11]

29. Congress rejected Representative Dornan's proposed amendment by almost a two-to-one margin.[12] During debate, it was clear that some Title X programs with larger family

[6] 121 Cong. Rec. 20863–64 (1975).

[7] S. Rep. No. 63, 94th Cong., 1st Sess. 65–66 (1975), *reprinted in* 1975 U.S. Code Cong. & Admin. News 469, 528.

[8] *Id.*

[9] 124 Cong. Rec. 37046 (1978).

[10] 124 Cong. Rec. 37045 (1978).

[11] 124 Cong. Rec. 37046 (1978).

[12] 124 Cong. Rec. 37048-49.

planning clinics were often "down the hallway" from abortion providers."[13] Congress concluded that it was unnecessary to amend the statute because Section 1008 already prohibited the use of Title X funds for abortion services. As Representative Paul Grant Rogers, who sponsored the reauthorization, explained: "[t]he point of what we are doing in title X . . . is to let people know how to avoid pregnancy. We cannot use any funds for abortion. The amendment is not needed."[14]

30. In 1981, Congress extended Title X's funding to 1984.[15] In 1982, the Comptroller General issued a report finding no evidence of any grantees using Title X funds to perform, promote, or encourage abortions.[16]

31. In 1985, Congress again extended Title X's funding. The House Energy and Commerce Committee report explained, "Title X has included a prohibition on the use of family planning funds for abortion since its enactment in 1970. The Committee . . . is satisfied that Title X grantees are complying with this prohibition" and thus "overwhelmingly rejected proposed amendments that would affect the interpretation and implementation of this section."[17] The Committee was emphatic that it did "not intend—and would discourage—regulatory efforts to modify restrictions that the Committee has chosen to retain." Indeed, as the Committee explained "[p]revious efforts to create restrictions beyond the original intent of the law have been unnecessary and without statutory foundation."[18]

32. In the mid- to late 1980s, Senators and Representatives proposed new amendments and bills that sought to restrict abortion counseling or referrals under Title X. All failed.[19]

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[13] *See*, 124 Cong. Rec. 37046 ("But you mean to say, here is a good institution and they cannot run a family planning clinic because somewhere down the hallway—somewhere in an operating room—they might have at some time or other performed an abortion or they might perform an abortion.") (statement of Rep. Rogers).

[14] 124 Cong. Rec. 37046 (1978).

[15] The Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, 95 Stat. 357.

[16] *See* Report by the Comptroller General of the United States, "Restrictions on Abortion and Lobbying Activities in Family Planning Programs need Clarification." (Sept. 24, 1982).

[17] H.R. Rep. No. 99-159, June 4, 1985, 6-7. (H.R. Rep. No. 159, 99th Cong., 1st Sess. 6-7 (1985).

[18] *Id.*

[19] In 1985, Senator Orrin Hatch attempted to add a Title X provision to the appropriations bill which would specifically prohibit abortion counseling and referral. 131 Cong. Rec. 28166 (1985) (statement of Sen. Hatch). The amendment failed. Representative Kemp proposed language that

33. Every year since 1996, Congress has passed a requirement as part of Title X appropriations that "all pregnancy counseling shall be nondirective."[20] This further demonstrates Congress's longstanding commitment to ensuring that patients receive unbiased, nondirective pregnancy options counseling and underscores the principle that Title X-funding recipients should not be barred from counseling on abortion services or from providing referrals to health centers that provide abortion services.

34. In sum, for nearly 50 years, Congress has authorized Title X funds again and again. Title X regulations have consistently required that Title X projects remain separate from abortion-related services, without mandating complete physical separation between facilities that receive Title X funds and facilities that provide or refer patients to abortion services.

C. The Title X Patient Population

35. Through Title X, Congress intended to provide family planning services to those who cannot afford them. Federal regulations require that Title X programs prioritize the delivery of care to persons from low-income families. These regulations specify that individuals served by the program with family incomes at or below the federal poverty level must receive services at no charge, unless a third party is authorized or obligated to pay for these services. In 2018, the federal poverty level was $12,140 for an individual and $25,100 for a family of four in the 48 contiguous states and the District of Columbia.

36. Essential Access's network provides family planning and related services to otherwise underserved or vulnerable communities. In 2017, 93% of Title X patients served by Essential Access's sub-recipients had family incomes below 250% of the Federal Poverty Level,

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would have prohibited the use of Title X funds for abortion referrals. *See* Congressional Quarterly Weekly Report 2,589-90 (Dec. 7, 1985) (reporting on H.J. Res. 465). The House Committee on Appropriations rejected the proposal.

In 1987, three bills designed to end abortion counseling and abortion referral under Title X failed to be voted out of committee: the President's Pro-Life Bill of 1987, S. 1242, 100th Cong., 1st Sess. (1987); the Unborn Children's Civil Rights Act, S. 381, 100th Cong., 1st Sess. (1987); and the Preborn Children's Civil Rights Act of 1987, H.R. 720, 100th Cong., 1st Sess. (1987).

[20] *See, e.g.*, Consolidated Appropriations Act, 2018, Public Law 115-141, Div. H, Title II, 132 Stat. 348, 716-17 (2018).

and 50% were uninsured. 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, ten counties in California have only one Title X-funded clinic. If that Title X-funded clinic were to close, patients would have to drive up to 131 miles to reach the next closest Title X-funded clinic.

37. In 2017, 90% of Title X patients—approximately 3.6 million people—had family incomes that qualified them for either subsidized or no-charge services. Sixty-seven percent of Title X patients, or 2.7 million individuals, had family incomes at or below the federal poverty level, and 42% were uninsured. Title X also serves populations that have historically faced significant barriers to care, including people of color and youth. In 2017, approximately one-third (1.3 million) of Title X patients nationwide identified as Hispanic or Latino, 22% (over 860,000 people) identified as black or African American, and 4% (143,215) as Asian. Nearly two-thirds of Title X patients, or 2.5 million people, were under the age of thirty.

38. Section 1006 of Title X provides that "priority will be given in [a Title X] project or program to the furnishing of [family planning] services to persons from low-income families[.]" The Senate Report confirmed that Congress's focus was on the "more than 5 million poor and near-poor women who, for the most part, have not been given the opportunity to avail themselves of family planning services in order to exercise their right to determine the size and spacing of their families."[21]

39. The legislative history further confirms that Congress intended Title X[22] to help low-income families. As then-Representative George H.W. Bush put it, "this legislation is a

[21] S. Rep. No. 91-1004, at 12 (1970).

[22] *See e.g.*, 116 Cong. Rec. 37375 (1970) ("Our Committee . . . has . . . given priority in the family planning services to low-income families which may not otherwise be able to secure them.") (statement of Rep. Nelsen); 116 Cong. Rec. 37386 (1970) ("I am also concerned over the discrepancy that exists in the availability of family planning services for low-income citizens. Low-income families without access to private medical care are often denied the opportunity to determine the number and spacing of their children.") (statement of Rep. Cohelan); 116 Cong. Rec. 37370 ("The necessity of this legislation arises from the lack of attention and funding in the past given to fertility control in providing health care to the poor.") (statement of Rep. Bush); 116 Cong. Rec. 37380 ("[This legislation] will make an important contribution to the health of American mothers and children. This bill will make family planning services available to low-

definite congressional mandate in support of family planning services for low-income families." Similarly, the House Report noted that "[n]inety percent of the approximately 4,000 nonprofit general care hospitals in the United States in which low-income mothers deliver babies offer[ed] no family planning programs at all," and that "[o]f the estimated 5 million medically indigent women who could probably use subsidized family planning services, if available, only one out of four now receive them."[23] And in 1975, a Senate Report reiterated that Title X's intent "was to greatly expand the availability of voluntary planning services with priority on low-income individuals."[24]

D. Previous Title X Regulations

40. In enacting Title X, Congress authorized the Secretary to promulgate regulations governing the award of Title X funding and contracts.[25]

41. In 1971, the first regulations promulgated under Title X took effect ("the 1971 Regulations").[26] The 1971 Regulations, among other things, defined which projects would be eligible for Title X funding: those which "assist[ed] in the establishment and operation of voluntary family planning projects consisting of the educational, comprehensive medical, and social services necessary to aid individuals freely to determine the number and spacing of their children." The 1971 Regulations also set forth project requirements. For example, Title X funding recipients had to provide "for the effective usage of contraceptive devices and practices," and for the "use of a broad range of medically approved methods of family planning." Recipients also had to provide assurances that low-income families would receive priority in the provision of services, and that projects would "not provide abortions as a method of family planning."

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income women who presently want and need but cannot afford them and will increase the federal role in population research.") (statement of Rep. Kyros); 116 Cong. Rec. 24093 (legislation "moves toward providing much needed medical family planning services to millions of women who cannot afford them, and it provides for the research that will help us better to understand the phenomena of population growth and enable all couples to regulate fertility according to their individual consciences.") (statement of Sen. Hart).

[23] H. Rep. No. 91-1472, at 5071.

[24] 1975 Code Cong. & Admin. News 469, 515.

[25] 42 U.S.C. § 300a-4(a).

[26] *See* 36 Fed. Reg. 18465.

42. HHS promulgated revised regulations in 1980 ("the 1980 Regulations"),[27] which reflected certain amendments made to Title X in the 1970s. The 1980 Regulations, for example, required eligible projects to provide assurances "that economic status [would] not be a deterrent to receiving services."

43. HHS again promulgated new regulations in 1988 ("the 1988 Regulations").[28] The 1988 Regulations prohibited Title X-funded projects from providing counseling or referrals for "the use of abortion as a method of family planning." The 1988 Regulations also required Title X-funded health centers to organize themselves so their Title X-funded activities were "physically and financially separate" from prohibited abortion activities. Under this separation requirement, "[m]ere bookkeeping separation of Title X funds from other monies [was] not sufficient." Instead, Title X-funded health centers had to maintain an "objective integrity and independence from prohibited activities," which required separate accounting records, facilities, personnel, and signage.

44. The same month that HHS promulgated the 1988 Regulations, a group of Title X grantees and doctors filed a lawsuit contending that the regulations violated Title X and were unconstitutional.[29] That lawsuit culminated in the Supreme Court decision *Rust v. Sullivan*.[30] In *Rust*, the Supreme Court noted that the doctor-patient relationship may require "protection under the First Amendment from Government regulation, even when subsidized by the Government." But the Court held that the 1988 Regulations did not "significantly impinge upon the doctor-patient relationship" because nothing in the regulations required "a doctor to represent as his own any opinion that he does not in fact hold." Thus, the Court determined that the 1988 Regulations were "a permissible construction of the statute as well as consistent with the First and Fifth Amendments to the Constitution."

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[27] *See* 45 Fed. Reg. 37433.

[28] *See* 53 Fed. Reg. 2922.

[29] *See State of N.Y. v. Bowen*, 690 F. Supp. 1261 (S.D.N.Y. 1988).

[30] 500 U.S. 173 (1991).

45. Although the Supreme Court in *Rust* upheld the 1988 Regulations, they were never fully implemented because of subsequent litigation and a change in presidential administrations. On January 22, 1993, shortly after taking office, President William J. Clinton directed the Secretary to suspend the 1988 Regulations "as soon as possible."[31] Subsequently, in February 1993, the Secretary proposed new regulations[32] that HHS ultimately promulgated in 2000 ("the 2000 Regulations").[33]

46. The 2000 Regulations "readopt[ed] the regulations, with one revision, that applied to" Title X funding recipients before 1988. In keeping with the purpose and text of Title X, the 2000 Regulations required eligible health centers to "[p]rovide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including infertility services and services for adolescents)."

47. The 2000 Regulations required Title X projects to provide nondirective counseling to pregnant women. Specifically, the 2000 Regulations required Title X-funded projects to "[o]ffer pregnant women the opportunity to be provided information and counseling regarding each of the following options: (A) Prenatal care and delivery; (B) Infant care, foster care, or adoption; and (C) Pregnancy termination." 42 C.F.R. § 59.5(a)(5) (2007). The 2000 Regulations further required that, "[i]f requested to provide such information and counseling," Title X projects "provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling." *Id.* This requirement was consistent with the ethical duties of medical professionals to provide all information necessary for patients to make informed choices about their medical care. *See* AMA Principles of Medical Ethics 2.1.3; American College of Obstetricians & Gynecologists, "The Limits of Conscientious Refusal in Reproductive Medicine," ACOG Committee Op. No. 385 (Nov. 2007).

[31] 58 Fed. Reg. 7455.

[32] *See* 58 Fed. Reg. 7464.

[33] *See* 65 Fed. Reg. 41270.

48. The 2000 Regulations also eliminated the physical separation requirement, determining that it was sufficient for a Title X project to maintain a financial firewall between its abortion and Title X activities.

49. In 2014, the Centers for Disease Control ("CDC") and the Department's Office of Population Affairs ("OPA")—which administers the Title X program—jointly released recommendations for Providing Quality Family Planning ("QFP"), which set forth broadly accepted, evidence-based standards for high-quality clinical practice regarding the provision of family planning services. These recommendations are 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, and were developed in collaboration with individual clinical experts and professional medical associations including the American College of Obstetricians and Gynecologists ("ACOG"). In its program guidance for Title X service projects, OPA required these recommendations to be incorporated into standards of care provided at Title X-funded clinic sites.

50. Among other provisions, the QFP recommendations establish that contraceptive services should include consideration of a ***full rang***e 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.

51. 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.

52. When referring pregnant clients, 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.

53. These standards allow patients to trust that Title X medical providers and health centers will provide unbiased information regarding their reproductive and sexual health. This evidence-based nondirective standard of care helps patients make the best decisions for themselves and their loved ones when assessing contraceptive options, facing an unintended pregnancy, or making other time-sensitive decisions about their sexual and reproductive health.

E. Plaintiffs' Roles in California's Title X Landscape

54. For nearly fifty years, Essential Access Health has been California's primary Title X Family Planning Services Grantee. Essential Access's mission is to champion and promote quality sexual and reproductive health care for all. Currently, Essential Access oversees the largest and most diverse Title X provider network in the country, contracting with 70 sub-recipients in 38 out of 58 California counties. This robust network of Title X sub-recipient agencies—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.

55. 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.

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

57. 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 to OPA for Title X funding. Without Essential Access, many of those sub-recipients would lack the staffing or resources to apply for Title X funding on their own.

58. 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.

59. 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.

60. 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 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 infrastructure by introducing new 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 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.

61. Title X funding also facilitates the delivery of high-quality sexual and reproductive health care by providing expanded clinical training opportunities. 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.

62. Title X funding also increases 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 have no access to family planning services.

63. The work of Essential Access's 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.

64. 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.

65. Dr. Marshall's experience further illustrates how Title X funding is critical to providing high quality family planning services to low-income patients. Title X funds allow Dr. Marshall's health center, CommuniCare, to provide sexual and reproductive healthcare to thousands of patients every year. In 2018, CommuniCare served 3,622 Title X patients, many through CommuniCare's drop-in teen clinic.[34] Many of these teen clinic patients subsequently visit CommuniCare for general healthcare. Without Title X funding, CommuniCare could not run the outreach services that inform young people of its teen clinic services, nor could it provide teen clinic services at all.

[34] CommuniCare strives to meet patient needs immediately. For example, if a clinic patient wants an intrauterine device ("IUD") and it is clinically appropriate, CommuniCare may provide it at that same visit. This is consistent with the CDC's QFP recommendations.

66. The majority of CommuniCare's Title X patients are low-income. Over 80% of CommuniCare's Title X patients in 2018 had income under the federal poverty level. In 2018, CommuniCare's Title X patients received over 1,000 Pap tests for cervical cancer, nearly 1,000 clinical breast exams, and more than 8,300 tests for sexually-transmitted infections. CommuniCare's Title X patients included individuals who are homeless, individuals with substance use diagnoses, individuals with disabilities, and individuals with limited English proficiency.

67. In addition to overseeing CommuniCare as CEO, Dr. Marshall personally provides her patients comprehensive family planning services. She treats between 300 and 500 patients per year, including Title X patients she sees through the teen clinic.

68. When Dr. Marshall sees a pregnant patient who chooses to continue the pregnancy, Dr. Marshall coordinates with CommuniCare's award-winning, nationally recognized Perinatal Program.[35] If a pregnant patient wants or needs to terminate the pregnancy, Dr. Marshall provides a referral for the patient.

69. Dr. Marshall has an obligation to provide unbiased options counseling to all of her patients. In some instances, Dr. Marshall may determine that it is medically advisable to terminate the pregnancy, particularly when the life of the mother is at risk. Potentially life-threatening conditions include decompensated cardiac conditions, renal failure, and some untreated cancers. In other instances, pregnancy may be especially risky because of the ways in which it can exacerbate existing medical conditions such as heart disease, hypertension, diabetes, sickle cell anemia, cancer, or AIDS, and Dr. Marshall must advise patients accordingly. In these circumstances especially, nondirective options counseling is an essential part of Dr. Marshall's practice and ensures her patients' health and well-being.

70. Dr. Marshall, as well as all licensed medical providers practicing in the state, must provide enough information for patients to exercise informed consent. As a provider under

[35] CommuniCare's Perinatal Program includes comprehensive services for prenatal and postpartum care. The Perinatal Program is run by Certified Nurse Midwives who collaborate with physicians and others to provide holistic maternity care. The Midwives have a collaborative practice with a nearby hospital. In 2017, 619 patients gave birth through the Perinatal Program.

California's family planning services program Family PACT and Medi-Cal, Dr. Marshall is subject to an agreement to abide by California law and adhere to Family PACT's minimum clinical standards. Dr. Marshall also has professional and ethical obligations to provide transparent and comprehensive medical advice. Dr. Marshall honors and supports her patients' autonomy. She provides accurate factual information, and as a doctor has a legal, ethical, and moral obligation to do so.

71. In many cases, Dr. Marshall's patients have had negative interactions with the healthcare system in the past. Most of her patients also face one or more challenges—low income levels, linguistic barriers, behavioral health issues, substance use—and many have experienced trauma. Her patients are often afraid to speak openly. To care effectively for these patients, Dr. Marshall must build trust and ensure that her patients are comfortable sharing their concerns with her. If a patient were to detect any hint of being judged, maligned, or misled, it would unravel Dr. Marshall's relationship with that patient, undermining her effectiveness as a health care provider.

F. The New Title X Regulations

72. On June 1, 2018, the Secretary proposed a new rule governing Title X grants, titled "Compliance with Statutory Program Integrity Requirements." 83 Fed. Reg. 25502 (June 1, 2018) (attached hereto as **Exhibit B**). In the following weeks, Essential Access, along with thousands of other interested parties, submitted comments opposing the rule.

73. On March 4, 2019, Defendants published the Final Rule. 84 Fed. Reg. 7714.[36]

74. The Final Rule imposes draconian and unnecessary conditions on Title X grants, toppling decades of established practice that has allowed thousands of Title X-funded health centers to provide consistent and comprehensive family planning services to millions of low-income individuals. With these new conditions, Defendants seek to leverage Title X funding to improperly micro-manage the provider-patient relationship and stifle constitutionally protected activity, both within and outside Title X programs. In doing so, Defendants undermine

[36] The Final Rule was posted on the federal register's website on March 2, 2019, but identifies the publication date as March 4, 2019. 84 Fed. Reg. 7714.

Congress's intent for the Title X program, disregard well-established clinical guidelines, and upend well-founded prior agency rules and guidance.

75. While the 2000 Regulations simply echoed Section 1008 of Title X by prohibiting Title X projects from "provid[ing] abortion as a method of family planning," 42 C.F.R. § 59.5(a)(5) (2007), the Final Rule far exceeds the mandate of the statutory language by prohibiting Title X projects from "perform[ing], promot[ing], refer[ring] for, or support[ing] abortion as a method of family planning."[37] § 59.5(a).[38]

1. Restrictions on Abortion Counseling and Ban on Abortion Referral

76. The Final Rule narrowly circumscribes who may provide a woman with pregnancy counseling and what information she may be given about her options. In place of the previous, statutorily-prescribed requirements of neutral, factual information and nondirective counseling about all pregnancy options (including abortion), the Final Rule requires providers to withhold relevant information from patients and steer pregnant women towards prenatal services without their informed consent, regardless of the doctor's professional judgment or whether the pregnant woman, once fully informed of her options, would choose that course.

77. Under the Final Rule, "once a client served by a Title X project is medically verified as pregnant, she ***shall*** be referred to a health care provider for medically necessary prenatal health care." § 59.14(b) (emphasis added). These referrals are required regardless of the wishes of the pregnant woman or the medical judgment of her doctor, and even though the definition of "family planning" in the Final Rule "does not include postconception care (including obstetric or prenatal care)." § 59.2.

78. In addition to providing the mandatory referral to prenatal care, the Title X provider "may also choose to provide . . . [n]ondirective pregnancy counseling," but only if the provider is

[37] The Final Rule defines "family planning" to mean "the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved." § 59.2. Under this new definition, any abortion could be characterized as a "method of family planning," regardless of the reason or need for the abortion.

[38] For ease of reference, the provisions of the Final Rule are cited by their section number (e.g., "§ 59.5" or "§59.14"). The provisions of the 2000 Regulations are cited according to their section in the 2007 version of the Code of Federal Regulations (e.g., "42 C.F.R. § 59.5 (2007)").

a "physician[] or advanced practice provider," which is defined as a medical professional who "receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients." §§ 59.2, 59.14(b)(1). This is a significant departure from established practice, under which much of Title X counseling is provided directly by non-physician and non-advanced practice provider staff, such as registered nurses, health educators, licensed clinical social workers, and licensed vocational nurses. There has been no evidence of complications from this practice. By restricting who can deliver nondirective pregnancy counseling, the Final Rule restricts patients' access to that information.[39]

79. Further, even if the Title X provider chooses to provide "nondirective pregnancy counseling," the Final Rule restricts the information the provider may give the patient with respect to abortion. Although the Rule states that "nondirective pregnancy counseling . . . may discuss abortion," it does not specify what that discussion may include. § 59.14(e)(5). The only example the Rule provides regarding discussion of abortion is a provider telling a patient that abortion is not a "method of family planning." *See id.* At the same time, the Rule prohibits providers from "promot[ing]," "encourag[ing]," or "support[ing] abortion as a method of family planning," but does not specify what it means to "promote," "encourage," or "support" abortion. § 59.14(a), (c)(1); *see also id.* § 59.5(a)(5). Because of the vagueness of § 59.14, a Title X provider must take the most cautious approach possible by avoiding any suggestion that abortion is an appropriate option for the patient, lest the Secretary deem the Title X project out of compliance with § 59.14. Thus, the Final Rule effectively restricts Title X providers from counseling pregnant patients on all options available to them.

80. The Final Rule also prohibits Title X medical providers from "refer[ring] for" abortion. § 59.14(a); *see also id.* § 59.5(a)(5). Indeed, even if a pregnant patient directly "requests information on abortion and asks the Title X project to refer her for an abortion," the Final Rule states that the proper course is for the provider to "tell[] her that the project does not consider

[39] Notably, the Final Rule does not impose this requirement for providers who opt to give the patient a "[r]eferral to social services or adoption agencies[] and/or [i]nformation about maintaining the health of the mother and unborn child during pregnancy" alongside the referral to prenatal care. *See* § 59.14(b).

abortion a method of family planning and, therefore, does not refer for abortion," and further explain that, instead, "the project can help her to obtain prenatal care and necessary social services." § 59.14(e)(5). If the provider is a physician or advanced practice provider, he or she may also offer "nondirective pregnancy counseling" which may "discuss abortion," but, in so doing, cannot "refer[] for, nor encourage[], abortion." *Id.* The Rule provides no further explanation of what this "discussion" may include without running afoul of the prohibition on promoting or supporting abortion. *See id.*

81. If a pregnant patient directly requests a referral to an abortion provider, the counselor may also offer her "a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) . . . , which is not presented as a referral for abortion." *Id.*; *see also* § 59.14(b)(2), (c)(2). However, that list "may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services." § 59.14(c)(2). "Neither the list nor project staff may identify which providers on the list perform abortion." *Id.* In addition, the requirement that any abortion providers also provide "comprehensive primary health care" drastically limits the number of abortion providers that can be included on the list. A provider of abortion services which does not also provide primary care could not be placed on the list, even if it were the closest available provider and otherwise qualified to provide the services the patient has requested.

82. Thus, even when a patient directly requests a referral to an abortion provider, the Title X provider must refer the patient instead to what the Final Rule describes as "medically necessary prenatal health care." The provider may also provide a list of "licensed, qualified, comprehensive primary health care providers," but that list need not include any abortion providers. If the provider chooses to include abortion providers on the list, those providers must be "comprehensive primary health care providers" in addition to providing abortion services, and at least half or more of the list must be comprehensive primary health care providers that do ***not*** perform abortions. The Title X project may not identify which providers on the list perform

abortions, leaving the patient to find the needle in the haystack—the burden falls wholly on the patient to figure out which providers, on the list provide abortion services (to the extent any such providers are even included on the list).

83. Although the Final Rule purports to allow Title X projects to provide "nondirective pregnancy counseling" by physicians and advanced practice providers, § 59.14(b)(1), the Rule's prohibition on referral for abortion, and the Rule's limitations on the parameters of discussions with respect to abortion, render the allowance for "counseling" illusory. In the medical field, counseling a patient means informing the patient of all options available to the patient, as well as referrals for those options when requested. Indeed, as the Department's proposed rule acknowledged, "referral is an integral part of the provision of any method of family planning." 83 Fed. Reg. 25502, 25506. Without the ability to refer patients to an abortion provider upon request, Title X providers cannot truly give their patients nondirective counseling.

84. By requiring providers to refer patients to prenatal services, while allowing providers to withhold information concerning options for terminating the pregnancy, the Final Rule sets up a scheme for directive counseling, steering patients toward prenatal care and/or social services, and steering them away from abortion.[40]

85. In addition to requiring Title X providers to withhold relevant information from patients and steer them toward prenatal care and/or social services, the Final Rule's prohibition on abortion referrals does not clearly delineate an exception for instances where a medical provider determines that continuing a pregnancy could have adverse health effects for the pregnant patient. Instead, the Final Rule merely states that "[i]n cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency." § 59.14(b)(4). The Final Rule provides only one example of an emergency warranting such care: an ectopic pregnancy. § 59.14(e)(2). But there are many circumstances other than ectopic pregnancy for which termination of the

[40] Contrary to what the Department claims in the preamble to the Final Rule, the Final Rule's reference to prenatal health care as "medically necessary" does not inoculate the Rule from the conclusion that it establishes directive counseling. 84 Fed. Reg. 7714, 7761-62. Prenatal services are not medically necessary if a patient has chosen to terminate the pregnancy.

pregnancy may be advisable, even if it is not an emergency—such as where the patient has a pre-existing condition exacerbated by the pregnancy, or if the pregnant woman unexpectedly experiences a life-threatening illness during her pregnancy. In those circumstances, the Final Rule still appears to instruct health centers to provide only the list of comprehensive health services mentioned above, and again only if the woman has already decided to have an abortion.

86. By forcing providers to advocate for prenatal services even when medically contraindicated or not desired by the patient, the Final Rule compels providers to express, as their own, speech with which they do not in fact agree. In addition, by forcing providers to give patients a list that includes a majority of providers that do not perform abortion, even when the patient has requested an abortion referral and even when the provider determines that the patient should be informed of the abortion providers available, the Final Rule compels providers to express, as their own, speech with which they do not in fact agree.

87. By placing the burden on the patient to investigate and uncover which health service providers, if any, on the list described in § 59.14(c)(2) perform abortion, the Final Rule imposes an unreasonable barrier to patients' ability to access appropriate medical care, and impedes timely access to health care services.

88. The Final Rule's ban on referrals for abortion and its restriction on abortion options counseling additionally interferes with communications between the patient and the medical provider regarding the full range of treatment options available to the patient, and restricts the ability of medical providers to fully disclose all relevant information to pregnant patients making decisions about their health care. These provisions thus violate the principle of informed consent and prevents health care professionals from fulfilling their ethical obligation to provide all information necessary for patients to make informed choices about their medical care. *See* AMA Principles of Medical Ethics 2.1.3; American College of Obstetricians & Gynecologists, "The Limits of Conscientious Refusal in Reproductive Medicine," ACOG Committee Op. No. 385 (Nov. 2007).

89. In addition, the Final Rule contradicts the federal government's own QFP recommendations. As explained above, the QFP recommendations emphasize that nondirective

options counseling is a core part of family planning services, that providers should 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. By prohibiting providers from giving referrals for abortion, and by restricting the information that may be provided to pregnant patients regarding their options for terminating the pregnancy, the Final Rule is irreconcilable with the Department's own recommendations.

2. Physical and Financial Separation Requirements

90. In addition to its interference with the provider-patient relationship, the Final Rule also imposes onerous physical and financial separation requirements on Title X recipients (including both grantees and sub-recipients).

91. Under the Final Rule, "[a] Title X project must be organized so that it is physically and financially separate . . . from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16"—*i.e.*, abortion referral and any activities that promote abortion or seek to make it more available.[41] § 59.15. In a departure from decades of settled practice, the Final Rule declares that "[m]ere bookkeeping separation of Title X funds from other monies is not sufficient." § 59.15.

92. The Final Rule gives the Secretary unbounded discretion to determine whether a Title X project is sufficiently separate from "prohibited activities" based on "review of facts and circumstances." *Id.* The relevant factors the Secretary may consider in making this determination include, but are not limited to:

i) The existence of separate, accurate accounting records;

[41] Section 59.16 of the Final Rule prohibits Title X-funded entities (including grantees and sub-recipients) from taking actions that "assist women to obtain abortions," "increase the availability or accessibility of abortion," or "encourage, promote or advocate abortion as a method of family planning," including by: (1) "[l]obbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning"; (2) "[p]roviding speakers or educators who promote the use of abortion as a method of family planning"; (3) "[a]ttending events or conferences during which the grantee or sub-recipient engages in lobbying"; (4) "[p]aying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes"; (5) "[u]sing legal action to make abortion available in any way as a method of family planning"; and (6) "[d]eveloping or disseminating in any way materials . . . advocating abortion as a method of family planning."

ii) The degree of separation from facilities (e.g., treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, education services, and website) in which prohibited activities occur and the extent of such prohibited activities;

iii) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

iv) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

93. Although the Final Rule lists these factors, it does not specify what weight each factor carries, nor does it specify how many factors a Title X site must satisfy in order to be considered compliant. It also does not prohibit the Secretary from considering other, unidentified "facts and circumstances." Moreover, the Final Rule provides no examples to guide Title X recipients.

94. Because of this vagueness and uncertainty, Title X recipients must take the most cautious approach possible by attempting to satisfy each of the factors listed above in order to be confident that the Secretary will not deem a Title X project insufficiently "separate" from "prohibited activities." Thus, the Final Rule effectively requires Title X funding recipients to provide Title X services in facilities totally separate from the "prohibited activities."

95. The Final Rule imposes this physical and financial separation requirement on Title X sub-recipients as well as grantees like Plaintiff Essential Access that engage in provider training, advocacy, or public education activities outside of the Title X program. If a Title X-funded entity deems it necessary to provide a patient with information on abortion, or refer the patient to an abortion provider, that entity cannot be confident that the Secretary will deem it compliant with the separation requirement unless the abortion counseling or referral is provided in a totally separate facility. This requirement thus effectively prohibits providers from counseling the patient or providing a referral during her visit despite determining that such counseling or referral is medically indicated. Likewise, if a Title X grantee, like Plaintiff Essential Access, uses

non-Title X funds to engage in provider training, advocacy, or public-education efforts that may be deemed as "increas[ing] the availability or accessibility of abortion," or "encourag[ing], promot[ing] or advocat[ing] abortion as a method of family planning," the Title X grantee cannot be confident that the Secretary will deem it compliant unless those advocacy and public-education efforts are operated using offices and personnel that are physically separate from those it uses to administer the Title X program.

96. Because the Final Rule effectively requires Title X-funded health centers to provide abortion counseling, referrals, and care in physically separate facilities from the rest of their programs, patients will have to visit multiple sites to receive complete care. Thus, the Final Rule imposes an unreasonable barrier to patients' ability to access appropriate medical care, and impedes timely access to health care services.

3. Reporting Requirements

97. The Final Rule also imposes new, vague reporting requirements on Title X grantees and sub-recipients.

98. A Title X funding recipient must provide assurance "satisfactory to the Secretary" that it does not provide abortion and does not include abortion as a method of family planning. § 59.17. "Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements of §§ 59.14 through 59.16." *Id.* This compliance reporting requirement does not provide any further information on what the Secretary considers a "satisfactory" or adequate representation.

99. A Title X-funded health center must provide documentation "satisfactory to the Secretary" of its plans to comply with state laws regarding the reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking laws. § 59.17(b)(1). Such documentation must include the age of minor clients and, where required by state law, the age of minor clients' sexual partners. § 59.17(b)(2).

4. Dilution of Quality of Care

100. The Final Rule eliminates the requirement that family planning methods provided through Title X projects be "medically approved." *Compare* § 59.5(a)(1) *with* 42 C.F.R. § 59.5(a)(1) (2007). This will allow Title X grants to fund the provision of contraceptive methods that do not meet the FDA's or the Department's own standards for medical care. In particular, FDA-approved methods of contraception are considered more safe and effective than other methods of birth control. If Title X funds are provided to health centers that do not offer these medically approved and more effective contraceptives, the quality of care offered at Title X-funded health centers will be lowered, contrary to congressional intent and QFP recommendations, which specifically recommend that patients have access to the full range of FDA-approved contraceptive methods.

101. HHS ignored substantial evidence that removing requirements for comprehensive, evidence-based reproductive healthcare would merely encourage the entry of lower-quality providers into the Title X program and impede women's access to reproductive health services. For example:

> The federal government promoting any single family planning method within Title X would actively undermine the program's mandate to ensure patients' choices are wholly voluntary and free from coercion. Furthermore, actively directing Title X funds toward natural family planning is unnecessary: It has always been provided for under the statute, and 93% of Title X–funded sites specifically report offering "natural family planning instruction or supplies."[Guttmacher Institute].
>
> "[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 -funded health centers to provide a larger range of effective family planning methods onsite and to offer services associated with high quality care. This study found that health centers that receive Title X funds were nearly twice as likely to offer onsite dispensing of oral contraceptives (78 percent versus 41 percent) and more than 1.5 times more likely to offer LARCs, including the contraceptive implant and intrauterine devices (IUDs). In fact, the availability of onsite oral contraceptive pills has significantly decreased among clinics that do not receive Title X funding, from 53 percent in 2011 to 41 percent in 2017. While the Proposed Rule suggests the proposed changes would improve access to and quality of care provided at Title X-funded sites, evidence indicates that Title X-funded sites are more likely than non-Title X-funded sites to follow recommendations of the U.S. Preventive Services Task Force and QFP recommendations, such as screening sexually active women age 25 or younger for chlamydia that can result in infertility if untreated. [American College of Obstetricians and Gynecologists Comment]

5. Limits on Care for Adolescents

102. Separate and apart from the barriers to care the Final Rule imposes on all patients, it imposes additional barriers to care for adolescents specifically.

103. First, the Rule requires that a minor may be found to be financially eligible for subsidized Title X services only if the provider has documented in the minor's medical records "specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services." § 59.2.

104. The Title X provider need not encourage the minor to involve his or her family only if the provider "has documented in the medical record: (1) That it suspects the minor to be the victim of child abuse or incest; and (2) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities." *Id.*

105. The Final Rule also requires a Title X project to provide assurance "satisfactory to the Secretary" that it has committed to "conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD)" or "pregnancy" in order to "rule out victimization of a minor." § 59.17(b)(1)(iv). Such screenings are required regardless of whether there is any indication of abuse.

106. The administrative record shows that providers who specialize in the treatment of adolescents overwhelmingly believe that these new requirements will create barriers to access to care for adolescents in need of reproductive health services.

6. Dates of Implementation

107. Pursuant to § 59.19 of the Final Rule, the physical separation requirement of § 59.15 takes effect one year after publication of the Final Rule, or March 4, 2020, and the financial separation requirement, found in the same subsection, takes effect 120 days after publication.

108. Section 59.5(a)(5)'s requirement that a provider "[s]hall [n]ot [p]rovide, [p]romote, [r]efer [f]or, or [s]upport [a]bortion as a [m]ethod of [f]amily planning" takes effect 60 days after publication. § 59.19. However, confusingly, recipients of Title X funding have until 120 days after publication to comply with the revisions to § 59.14, which contains the Final Rule's

prohibition on abortion counseling and referral, and its mandate regarding referrals to prenatal services.

109. All other requirements in the Final Rule, take effect 60 days after final publication, or May 3, 2019. § 59.19.

110. Notwithstanding these technical deadlines for compliance, the Final Rule's onerous referral, separation, and reporting requirements will force Essential Access to immediately begin training its sub-recipients on the Final Rule and how to implement it. Essential Access sub-recipients will need to conduct training on the new Title X regulations, create and implement new policies and workflows to respond to the Final Rule, update their medical records systems and financial records, potentially undertake extensive renovations, and hire new staff and personnel.

111. Recipients of Title X funding will therefore face a Hobson's Choice long before the Final Rule takes effect: attempt to comply with the Final Rule to continue receiving Title X funds, or forfeit Title X funds because accepting the money will require health centers to contravene clinical treatment standards, deceive their patients, and/or undertake costly measures to physically and financially separate their operations.

G. Defendants' Purported Justifications for the New Regulations

112. Defendants assert several purported justifications for the Final Rule, but fail to identify any evidence to support their assertions.

113. To justify the removal of the previous requirement that Title X-funded projects provide neutral, factual information and nondirective counseling on abortion when requested, 42 U.S.C. § 59.5(a)(5) (2007), Defendants argue that the provision conflicts with the conscience protections of the Church, Coats-Snowe, and Weldon Amendments. 84 Fed. Reg. 7714, 7746-47; *see also* 83 Fed. Reg. 25502, 25506. According to Defendants, these Amendments "protect[ ] conscience in health care," allowing "institutional entities who object" to providing abortions or referrals for abortions to opt out of doing so. 84 Fed. Reg. 7714, 7716.

114. But those Amendments do not justify Defendants' removal of the nondirective counseling requirement. Under Defendants' reading of those Amendments, with which Plaintiffs do not necessarily agree, entities with a moral or religious objection to providing abortion

services are ***already*** excused from providing counseling regarding abortion. Defendants cannot claim that the removal of the counseling requirement is necessary to protect the rights of those with moral or religious objections to providing information about abortion, while at the same time claiming that those people are already protected by the Church, Coats-Snowe, and Weldon Amendments in refusing such counseling.

115. To justify the restriction on options counseling and the ban on referral for abortion in the new § 59.14, the proposed rule's preamble claimed that the Department's previous interpretation of Section 1008—which prohibited direct funding or facilitation of abortions, but allowed nondirective counseling and referral for abortion—"creat[ed] confusion about which activities are proscribed by [Section 1008]." 83 Fed. Reg. 25502, 25506. But Defendants cited no evidence of actual confusion about which activities were proscribed and which were allowed under the prior rule. The Final Rule's preamble provides no additional justifications for § 59.14.

116. To justify the physical separation requirements of the new § 59.15, the proposed rule's preamble claimed that the previous regulations—which allowed Title X projects to share physical facilities with abortion-related activities so long as Title X funds were financially segregated—"create[d] a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities," and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics. 83 Fed. Reg. 25502, 25507. But the proposed rule cited no evidence of misuse of Title X funds or confusion about whether Title X grants are used to fund abortions. The Final Rule simply repeats the same concerns about potential misuse of funds or confusion about what Title X funds are being used for. 84 Fed. Reg. 7714, 7764-65.

117. Defendants claim that the "concern" about misuse or co-mingling of Title X funds is "particularly acute in light of" a study showing that so-called "nonspecialized clinics," such as doctors' offices, accounted for a higher percentage of abortions in 2014 than in prior years. 84 Fed. Reg. 7714, 7765; *see also* 83 Fed. Reg. 25502, 25507. According to Defendants, "[t]he performance of abortions at nonspecialized clinics that also may provide Title X services

increases the risk and potential both for confusion and for the co-mingling or misuse of Title X funds." 84 Fed. Reg. 7714, 7765. But Defendants cite no evidence that any of the nonspecialized clinics mentioned in the study ever received Title X funds, much less any evidence that those clinics misused Title X funds or that anyone was confused about whether Title X was funding their abortion activities.

118. Defendants also attempt to justify the physical separation requirements of § 59.15—and the related § 59.18 prohibition on the use of Title X funds to build infrastructure for "prohibited activities"—partly based on their concern that Title X funds are currently being used to "build infrastructure for abortion services." 84 Fed. Reg. 7714, 7773; *see also* 83 Fed. Reg. 25502, 25508. But Defendants cite no evidence that Title X funds have been used in this manner. Defendants cite to studies explaining how family-planning providers use Title X funds in conjunction with other funds—such as Medicaid reimbursement[42]—by, for example, conducting outreach, hiring and training staff, and purchasing supplies. 84 Fed. Reg. 7714, 7773-74; *see also* 83 Fed. Reg. 25502, 25508. None of the cited studies, however, suggests that any Title X recipients use Title X funds to build infrastructure for abortion-related services.

119. To justify the Final Rule's new reporting and monitoring requirements, the proposed rule's preamble identified isolated instances where Title X-funded health centers overbilled Medicaid. 83 Fed. Reg. 25502, 25508. But Medicaid overbilling is not evidence of misuse of Title X funds for abortion-related services. The Final Rule acknowledges as much, agreeing that "demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused." 84 Fed. Reg. 7714, 7725. But the Final Rule nevertheless applies the same faulty logic, asserting that "examples of abuse in other Federal programs" indicate a need for the rule's new requirements, even though other federal programs like Medicaid (in which providers bill for services) operate in an entirely different manner from Title X (in which projects receive grants).

[42] Under the prior rule, Title X grants could be awarded only to projects that had other funding sources in addition to Title X. 42 C.F.R. § 59.7(c) (2007) ("No grant may be made for an amount equal to 100 percent for the project's estimated costs."). Often, the additional source of funding is reimbursement from Medicaid for services.

120. To justify the Final Rule's restriction on lobbying or advocacy activity, and its concomitant requirement that Title X recipients provide documentary assurance that they understand the statutory prohibitions on using Title X funds for lobbying and political activity, Defendants similarly point to a theoretical risk of misuse of funds. Again, Defendants cite no evidence that Title X funds have been misused.

121. While pointing to the theoretical risk of misuse of Title X funds as a justification for the Final Rule's onerous reporting and separation requirements, Defendants fail to even mention the safeguards already in place to ensure that Title X funds are used only for approved services and kept separate from abortion services. As described below, multiple safeguards ensure that Title X recipients comply with all applicable statutes and regulations. Defendants fail to explain why these safeguards are inadequate and why the additional requirements of the Final Rule are necessary.

122. OPA provides strict oversight of health centers that receive Title X grants to ensure that federal funds are used appropriately and that funds are not used for any prohibited activities, such as abortion services. OPA maintains several layers of accountability, including: (1) careful review of grant applications to ensure that the applicant understands the requirements and has the capacity to comply with all requirements; (2) independent financial audits to examine whether there is a system to account for program-funded activities and non-allowable program activities; (3) yearly comprehensive reviews of the grantees' financial status and budget report; and (4) periodic and comprehensive program reviews and site visits by OPA regional offices.

123. The first layer of accountability is OPA's direct oversight of Title X grantees and sub-recipients, which includes two main enforcement tools: the "Comprehensive Program Review," and annual data gathering for the Family Planning Annual Report ("FPAR").

124. OPA's Title X Regional Offices conduct a Comprehensive Program Review of each Title X grantee every three years. The goals of the three-year review are, among other things, to ensure compliance with Title X statutes and regulations, assess the grantee's progress in carrying out the plan laid out in its Title X grant application, verify expenditure of funds, verify the services offered, and ensure proper use of funds. As part of the comprehensive review, personnel

and/or consultants from the Regional Offices conduct on-site visits of Title X grantees and one to three 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. For any area in which a Title X grantee is found noncompliant, the reviewers and the grantee create a Corrective Action Plan ("CAP"), and engage in continuing follow-up discussions to ensure the grantee reaches compliance.

125. OPA also receives detailed data from Title X grantees for compilation in the FPAR. The data OPA receives from Title X grantees includes data on users, providers, services offered, and providers' sources of revenue. This data is used by OPA to, among other things, monitor compliance with statutory and regulatory performance requirements, assess the impact of Title X grants, and guide planning and resource allocation in the future.

126. In addition to OPA's direct oversight of Title X grantees, Title X grantees in turn oversee their sub-recipients. Essential Access has a three-pronged oversight process modeled on the process OPA uses.

127. First, 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 uses a tool similar to OPA's Program Review Tool to evaluate sub-recipients' compliance with Title X statutes, regulations, and program priorities. The on-site 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.

128. 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.

129. Other Title X grantees exercise similar oversight over their sub-recipients. Nevertheless, Defendants fail to mention any of the steps that OPA and Title X grantees take to ensure compliance with Title X statutory and regulatory requirements, or why any of these steps are inadequate.

130. During the comment period on the proposed rule, several commenters noted the lack of evidentiary support for Defendants' purported justifications for the rule's onerous new requirements. Nevertheless, Defendants fail to provide any supporting evidence with their publication of the Final Rule.

H. The Final Rule's Harmful Impact on Plaintiffs and Title X Patients

131. The Final Rule will have negative, far-reaching effects in California and nationwide at every level of the family-planning health-care system.

1. The Final Rule Interferes with the Provider-Patient Relationship.

132. The Final Rule will impede medical providers from carrying out their professional obligations to their patients.

133. Patients trust and rely on doctors and other medical providers to provide comprehensive, accurate, and unbiased information about all available treatment options. Medical providers, in turn, have ethical, legal, and moral obligations to provide patients with comprehensive, accurate, and unbiased information about all available treatment options.

134. The AMA code of ethics states that "withholding information without the patient's knowledge or consent is ethically unacceptable." AMA Principles of Medical Ethics 2.1.3. The AMA advises that "[t]ruthful and open communication between physician and patient" is "essential[.]" *Id.* The American College of Obstetricians and Gynecologists ("ACOG") underscores this standard, providing that health care professionals "must provide [the patient] with accurate and unbiased information so that patients can make informed decisions about their health care." American College of Obstetricians and Gynecologists, "The Limits of Conscientious Refusal in Reproductive Medicine," ACOG Committee Opinion No. 385 (Nov. 2007). Even where a health care professional personally objects to the provision of standard reproductive health care, including abortions, they must "refer patients in a timely manner to other providers." *Id.*

135. The Final Rule's effective restriction on nondirective pregnancy options counseling and its ban on referrals for abortion force medical providers to violate medical ethics and standards of care by withholding relevant information from patients and withholding referrals to appropriate providers. No other safe and medically-approved medical procedure is subject to such government interference.

136. 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 violating their medical and ethical duties by accepting the Rule's interference with candid, transparent provider-patient communication. For example, if the Final Rule were implemented and CommuniCare continued to receive Title X funding, Dr. Marshall likely could not provide family planning services in an ethical manner. As a clinician, she has an obligation to provide unbiased options counseling, and she must honor and support her patients' autonomy. As a doctor, she provides factual information to her patients, and she has a legal, ethical, and moral obligation to do so. Abiding by the Final Rule would fundamentally alter her relationship with her patients and interfere with their provider-patient dialogue.

137. Furthermore, this interference with Dr. Marshall's relationship with her patients would have far-reaching and devastating effects. As set forth above, many of Dr. Marshall's patients have had negative interactions with the healthcare system in the past. Most of her patients also face one or more challenges—low income levels, linguistic barriers, behavioral health issues, substance use—and many have experienced trauma. To care effectively for these patients, Dr. Marshall must build trust and ensure that her patients are comfortable sharing their concerns with her. If there were any indication that Dr. Marshall were judging or misleading her patients, it would harm her patient relationships. The Final Rule—under which Dr. Marshall would have to remain silent or misrepresent options to patients—would thus have adverse health consequences for her patients. Ultimately, the Final Rule would discourage Title X patients from visiting Dr. Marshall's health center and getting treatment in general, thereby compounding health disparities.

138. The majority of Essential Access's Title X sub-recipients 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 health care providers to work in Title X programs because of the Final Rule's interference with the provider-patient relationship.

139. In addition to interfering with the doctor-patient relationship, the Final Rule would 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 Provider staff 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.

140. In enacting the Final Rule, Defendants ignored substantial evidence that the proposed rule, which is substantially similar to the Final Rule, would interfere with the relationships between medical providers and their patients, and impede women's access to reproductive health services. For example:

- This rule conflicts with a fundamental principle that guides health care providers every day: patients' needs are paramount and providers have an ethical obligation to put the needs of patients first. The prohibition on abortion referrals contravenes medical ethics and leaves providers in the position of not providing the best level of medical care or no longer participating in the Title X program. […] The gag rule has been associated with an increase in abortions, an increase in maternal deaths and encouraging unsafe abortions. [Comment of the American Public Health Association]

- CMA 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. […] 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. [Comment of California Medical Association]

- Forcing clinicians to sabotage the rapport and trust they have built with patients stands in sharp conflict with patients' right to self-determination. It may also cause patients to retreat, possibly from seeking health care for other needs; this may be particularly true for women of color, low-income women and others who have historically experienced coercive treatment in the context of reproductive health care. [Guttmacher Institute]

141. By inhibiting open and truthful communications between medical professionals and their patients, the Final Rule, if implemented, will impede the ability of providers like Dr. Marshall to provide quality sexual and reproductive health care to their patients.

2. The Final Rule Imposes Significant Costs to Comply and Will Reduce Access to Care.

142. Essential Access's sub-recipients include federally qualified health centers, city and county health departments, hospitals, stand-alone family planning and women's health centers, and an Urban Indian Health Center. In order to receive Title X funding, Essential Access and its sub-recipients must demonstrate that they are in compliance with the Title X statute, regulations, legislative mandates, and program priorities. But numerous Essential Access sub-recipients report that implementing the Final Rule would force them to incur major financial burdens.

143. As explained above, the Final Rule's physical and financial separation requirements will effectively force Title X funding recipients who provide abortions, abortion options counseling, unrestricted abortion referrals, or educational materials about abortion to obtain separate office and clinic space, hire separate personnel, create separate financial systems, create separate health records systems, and create separate advertising materials for their Title X-funded programs. Building this separate infrastructure will be too expensive for the majority of Essential Access's Title X sub-recipients. For example, creating separate health records systems alone would cost an average of $130,000 per site.

144. These requirements undermine the original intent and purpose of the Title X program, which was to provide low-income individuals with access to comprehensive, quality family planning services. By effectively forcing Title X funding recipients to divide their services between separate facilities, the Final Rule creates barriers to the best practice of providing patients with integrated care.

145. The cost of complying with the separation requirements will in most cases be impossible for Essential Access's sub-recipients to afford, leaving them with no choice but to forego Title X funds. Health centers vital to their communities will be forced to reduce access to services, reduce staff positions and close satellite sites at community colleges and school based health centers absent this critical funding source. 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.

146. The Final Rule would also require Essential Access to expend resources to separate its *non*-Title X-funded training, advocacy, and public-education activities that discuss abortion. Essential Access estimates that the cost of separating its non-Title X-funded training, advocacy, and public education activities would be about $325,000 for the first year, and $212,500 every year after. 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. Many of the Learning Exchange's training participants from across the state and country are Title X providers. Through the Learning Exchange, Essential Access offers training on quality pregnancy options, including how to provide patients with medically accurate, unbiased, non-judgmental information about abortion, adoption, and parenting. The Final Rule would effectively require Essential Access to either abandon such educational efforts entirely, or open a "mirror" office to continue to participate in the Title X program. Maintaining full separation between its Title X programs and "prohibited activities" would be too costly for Essential Access to comply.

147. The Final Rule further requires grantees and sub-recipients to document their compliance and conduct additional monitoring, enforcement, training, and reporting. These requirements place additional, unnecessary, and costly financial and administrative burdens on Essential Access and its sub-recipients. Additional training, and the closure of health centers during that training, would cost Essential Access's sub-recipients an average of over $40,000 per site. The creation and implementation of new policies, procedures, workflows, and electronic health records fields and templates would cost, on average, an additional $45,000 per site. Additional documentation and reporting of referral and collaborative relationships would cost, on

average, over $30,000 per site. Overall, Title X-funded health centers will be required to expend on average $119,487 per site to comply with the Final Rule.

148. The Final Rule would further place significant and unnecessary administrative burdens on Essential Access to demonstrate compliance. Those burdens, and demonstrating compliance more broadly, will require Essential Access to divert significant time and resources from other activities critical to achieving its mission. In order to comply with the Final Rule, Essential Access would be required to, among other things: develop new materials and trainings for subrecipients, program staff, and administrative, clinical, and fiscal consultants; increase sub-recipient technical assistance regarding new requirements that will dramatically change clinic practices and processes; and expand sub-recipient monitoring tools and processes regarding administrative, clinical, and financial requirements. The additional administrative work will require Essential Access to hire at least two additional staff and demand increased clinical consultant time. The Final Rule will also require Essential Access to provide its sub-recipients additional follow-up and technical assistance for program reviews and Corrective Action Plans.

3. The Final Rule Puts Patients at Risk

149. As discussed above, if implemented, the Final Rule would significantly reduce the number of providers participating in California's Title X program, impeding access to care and disproportionately harming individuals with limited resources. This will have a significant and adverse impact on patient care by increasing wait times, decreasing the number of patients that a facility can see, and increasing the duration between patient appointments. A majority of sub-recipients in Essential Access's Title X network confirm that implementation of the Final Rule will result in significant increases in patient wait times and would substantially increase the duration between patient appointments. A majority of Essential Access's sub-recipients also confirmed that implementation of the Final Rule would dramatically impact the total number of patients seen, and would result in diminished access to care.

150. 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. This patient population will no longer have access to extended clinic hours, outreach and education, bilingual or interpreter

services, technology improvements, and enhanced training opportunities for clinicians. For example, without Title X funding, CommuniCare would not be able to operate its teen outreach clinic, and Dr. Marshall would see fewer Title X patients each week. Many young women, especially, would be deprived of the contraceptive method that is best for them.

151. Without Title X funds, many Essential Access sub-recipients would also be forced to reduce staff positions, reduce staff hours, and reduce the amount of training and continuing education received by their staff. Many Essential Access sub-recipients would reduce outreach and education activities that connect community members to their family planning services. In some cases, these outreach activities for family planning services lead to patients accessing primary care services as well. Patients would miss out on the opportunity to access much needed health care.

152. This disruption of services will have profound short- and long-term consequences for these women, 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.

153. The Final Rule's effects will result in reduced access to LARCs and other effective methods of contraception, which may result in a greater number of unintended pregnancies. LARCs are highly effective because they obviate the need for daily administration or use at the time of intercourse. 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.

154. Contraceptive use also benefits women's health overall. Contraceptive use can prevent preexisting health conditions from worsening and new health problems from occurring, because pregnancy can exacerbate existing health conditions such as diabetes, hypertension, and heart disease. Contraception is sometimes used to treat menstrual disorders and pelvic pain. Long-

term use of oral contraceptives has been shown to reduce women's risk of endometrial cancer, pelvic inflammatory disease, and some breast diseases.

155. Health centers that are no longer able to accept Title X funding because of the Final Rules draconian conditions will be forced to cut back or entirely stop offering these medically-accepted and effective forms of contraception. The patient population that relies on Title X funded centers for family planning services will be left with a much lower quality of care than the general population.

156. The Final Rule also jeopardizes adolescents' access to care by putting unnecessary pressure on providers to involve parents or guardians in virtually all cases. While most adolescents seek medical care with their parents' knowledge, studies show that many teens are much less likely to seek contraceptive care when their parents are involved. Furthermore, it requires providers to screen for abuse all teens who become pregnant or test positive for STIs, regardless of whether there is any indication of abuse.

157. If obligated to implement the Final Rule's family involvement requirements that extend beyond current statutory requirements, the majority of Essential Access's sub-recipients would leave or consider leaving the Title X program altogether. The majority of sub-recipients confirm that, if these requirements were to become effective, fewer adolescent patients would 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.

158. The Final Rule would further harm patients by impeding access to time-sensitive family planning and reproductive health services. Under the Final Rule, 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. Studies of mandatory waiting periods for abortion confirm that imposing delays on access to abortion burdens patients and results in later-term abortions. In addition, diverting resources from entities that offer a wide range of medically

accepted family-planning methods to entities that provide only one type of family planning method (such as natural family planning methods or abstinence) will delay patient access to the time-sensitive contraceptive care that meets their unique health needs and reproductive goals.

159. 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. Indeed, 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.

160. The Final Rule further harms patients by failing to explicitly allow for abortion referrals when abortion is medically necessary. In addition, other medical conditions may make pregnancy a threat to a woman's health, including by exacerbating existing medical conditions such as heart disease, hypertension, diabetes, sickle cell anemia, cancer, and AIDS. The Final Rule's lack of an explicit exception for abortion referrals in medically necessary or other threatening situations threatens to chill provider speech and impede patient access to the full range of information they need to make informed decisions about their health.

161. In conjunction with other California providers, Essential Access and its network has invested significant time and resources in a "no wrong door" approach to reproductive healthcare. Under this approach, the goal is to ensure that regardless of which provider a patient initially contacts for treatment, 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 ability to make referrals to all needed reproductive services and related care. By limiting providers' ability to

make referrals, the Final Rule impedes California providers' efforts to offer seamless reproductive healthcare.

162. In addition to the prohibitive costs outlined above, the Final Rule's physical separation requirement also compromises quality of care and puts patients at risk. To the extent that some health centers can afford the cost of complying with the Final Rule's physical and financial separation requirements, separating workspace, staff, and financial systems will impede patient's timely access to care, contrary to best practices and the QFP recommendations. In addition, 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 cause 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.

163. Finally, because Title X patients are overwhelmingly members of underserved communities such as low-income individuals and people of color, the Final Rule's negative impact on patients' access to timely care would exacerbate existing health disparities by reducing access to care for these communities.

4. The Final Rule Frustrates Essential Access's Mission.

164. Essential Access's mission is to champion and promote quality sexual and reproductive health care for all. Essential Access achieves its mission by supporting the effective delivery of family planning and related health services through its diverse network of sub-recipient health care organizations. Essential Access also furthers its mission through an umbrella of programs and services such as training and education for health care professionals, clinic support initiatives, advocacy, public awareness campaigns, and advanced clinical research. Finally, Essential Access furthers its mission to provide comprehensive and high-quality health care for all through the distribution of Title X funds to its network of sub-recipients.

165. Family planning services at California's Title X-funded health centers helped to prevent 218,000 unintended pregnancies in 2015 alone. Public investment in family planning and related services provided at Title X-funded health centers in California saves $1.3 billion in

federal and state dollars annually. In 2017, Essential Access administered Title X funds that supported outreach and education activities connecting more than 500,000 individuals with information about family planning services and care in their local communities.

166. 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 will be forced to forfeit Title X funds, drastically reducing the number of family planning clinics participating in the Title X program. Many of Essential Access's sub-recipients would leave or consider leaving the Title X program if the Final Rule goes into effect. Thus, the Final Rule, if implemented, threatens to eliminate these benefits, frustrating Essential Access's mission to champion and promote quality sexual and reproductive health care for all.

167. 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 more than one million women, men, and teens that depend on them each year, and (2) increase the number of patients that receive 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. This mission is frustrated by the Final Rule because the number of clinics that are willing or able to accept Title X funds will shrink dramatically. Essential Access will be forced to expend additional funds and resources towards educating its sub-recipients about how to comply with the Final Rule and ensuring that sub-recipients serve low-income populations.

168. Reducing access to Title X-funded health centers would 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. The Final Rule's dilution of quality care in the Title X program frustrates Essential Access's mission to champion and promote quality sexual and reproductive health care for all.

169. The massive disruption the Final Rules 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, and towards compliance with the unethical, unlawful, and unnecessary Final Rule.

DECLARATORY AND INJUNCTIVE RELIEF ALLEGATIONS

170. An actual and substantial controversy exists between Plaintiffs and Defendants as to their respective legal rights and duties. Plaintiffs contend that, facially and as applied to them and others, the Final Rule is unlawful and unconstitutional.

171. If not enjoined by the Court, Defendants will implement the Final Rule in derogation of the rights of Plaintiffs and others. Such implementation will impose irreparable injury on the Plaintiffs and others.

172. Plaintiffs have no plain, speedy, and adequate remedy at law.

CLAIMS FOR RELIEF

COUNT ONE

ADMINISTRATIVE PROCEDURE ACT – CONTRARY TO LAW

(All Plaintiffs Against All Defendants)

173. Plaintiffs repeat and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

174. Defendant HHS is an "agency" under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551(1).

175. The Final Rule is an "agency action" under the APA, 5 U.S.C. § 551(13). The Final Rule is subject to judicial review because it constitutes "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

176. The APA requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . not in accordance with law." 5 U.S.C. § 706(2)(A).

177. The provisions of the Final Rule prohibiting Title X-funded providers from referring patients for abortion, and effectively restricting counseling concerning abortion, are contrary to law because they violate the Patient Protection and Affordable Care Act, which provides that "the

Secretary of Health and Human Services shall not promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs." Patient Protection and Affordable Care Act, Tit. 1, § 1554, 42 U.S.C. § 18114 (2010).

178. The provision of the Final Rule allowing only medical doctors and Advanced Practice Providers to provide pregnancy counseling is contrary to law because it (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services." *Id.*

179. The physical and financial separation requirements of the Final Rule are contrary to law because they "(1) create[] . . . unreasonable barriers to the ability of individuals to obtain appropriate medical care," and "(2) impede[] timely access to health care services." *Id.*

180. The provision of the Final Rule requiring documentation of Title X providers' efforts to involve family participation in the care of minor patients, and the provision of the Final Rule requiring that Title X providers screen minor patients for abuse if they present with an STD or pregnancy, regardless of any indication of abuse, are contrary to law because they "(1) create[] . . . unreasonable barriers to the ability of individuals to obtain appropriate medical care." *Id.*

181. The provisions of the Final Rule prohibiting Title X-funded health centers from referring patients for abortion and effectively restricting counseling concerning abortion, and the provisions of the Final Rule mandating that Title X-funded health centers refer pregnant patients to prenatal services, are contrary to law because they violate the Health and Human Services Appropriations Act, Pub. L. No. 115–245, Div. B, Tit. II, 132 Stat. 2981, 3070–71 (2019), which

provides that "all pregnancy counseling" in Title X family planning projects "shall be nondirective."

182. Presently, Plaintiffs have no adequate or available administrative remedy. In the alternative, it would be futile for Plaintiffs to seek an administrative remedy at this time.

183. Plaintiffs have no adequate remedy at law, outside of a claim under 5 U.S.C. § 706.

184. Because the Final Rule is contrary to law, it should be set aside under Section 706 of the APA.

COUNT TWO

ADMINISTRATIVE PROCEDURE ACT – EXCEEDS STATUTORY AUTHORITY

(All Plaintiffs Against All Defendants)

185. Plaintiffs repeat and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

186. Defendant HHS is an "agency" under the APA, 5 U.S.C. § 551(1).

187. The Final Rule is an "agency action" under the APA, 5 U.S.C. § 551(13). The Final Rule is subject to judicial review because it constitutes "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

188. The APA requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

189. The Final Rule exceeds the Secretary's statutory authority in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(C). Defendants' anticipated actions to enforce the new Title X regulations will also, unless enjoined, exceed Defendants' statutory authority in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(C).

190. With the Final Rule, Defendants exceed their statutory mandate and pervert congressional intent by, *inter alia*:

i) Effectively restricting Title X funding recipients from presenting abortion as an appropriate option for patients, contrary to congressional intent;

ii) Prohibiting Title X funding recipients from referring patients to abortion providers; and

iii) Effectively requiring Title X funding recipients to physically separate their Title X-funded activities from activities where they perform abortions, refer for abortions, counsel on abortion options, or provide educational material concerning abortions.

191. Presently, Plaintiffs have no adequate or available administrative remedy. In the alternative, it would be futile for Plaintiffs to seek an administrative remedy at this time.

192. Plaintiffs have no adequate remedy at law, outside of a claim under 5 U.S.C. § 706.

193. Because the Final Rule exceeds its statutory authority, it should be set aside under Section 706 of the APA.

COUNT THREE

ADMINISTRATIVE PROCEDURE ACT – ARBITRARY AND CAPRICIOUS ACTION

(All Plaintiffs Against All Defendants)

194. Plaintiffs repeat and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

195. Defendant HHS is an "agency" under the APA, 5 U.S.C. § 551(1).

196. The Final Rule is an "agency action" under the APA, 5 U.S.C. § 551(13). The Final Rule is subject to judicial review because it constitutes "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

197. The APA requires a reviewing court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

198. None of the purported justifications Defendants offer for the Final Rule is supported by evidence. Defendants claim that the prohibition on abortion referral, the physical separation requirement, the monitoring and reporting requirements, and the advocacy and lobbying restrictions are needed because of (1) the theoretical risk of public confusion concerning whether Title X recipients use Title X funds to pay for abortions or abortion-related activities, (2) the

theoretical risk of intentional or unintentional misuse of Title X funds to fund abortion-related services, (3) the theoretical risk of intentional or unintentional commingling of Title X funds with other funds, (4) the theoretical risk of Title X funds being used to pay for infrastructure for abortion-related services, and (5) the theoretical risk of Title X funds being used to advocate or lobby for expanded access to abortion. The Final Rule, however, cites no evidence that any of these theoretical risks have ever materialized, or that the Department's compliance monitoring and safeguards in place under the 2000 Regulations are inadequate. Defendants also point to the Church, Coats-Snowe, and Weldon Amendments, and claim that the Final Rule's removal of the nondirective options counseling requirement of the 2000 Regulations is needed in order to protect providers who object to abortion counseling or referral on religious or moral grounds. But even if the Church, Coats-Snowe, and Weldon Amendments applied to Title X, they would not justify removing the requirement of nondirective pregnancy options counseling and referral.

199. The Final Rule's removal of the requirement that Title X-funded health centers offer a broad range of "medically approved" family planning methods is contrary to the OPA's own recommendations to Title X health centers on what constitutes "effective" family planning methods. *See* Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 63 Recommendations and Reports No. 4 (Apr. 25, 2014) ("Effectiveness. These recommendations support offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods . . . ."). This contradiction is further evidence that the Final Rule is arbitrary and capricious.

200. The Final Rule's restriction on referrals to only "licensed, qualified, comprehensive primary health care providers" is not supported by any reasoning or justification, and unreasonably restricts a medical provider's judgment as to appropriate referrals. The restriction dramatically limits the providers to which a pregnant woman may be referred, and inserts the unnecessary and inappropriate requirement that a pregnant woman in all cases must be referred to a primary health care provider, rather than any other appropriate health care provider. This appears to be *in addition* to the requirement that all pregnant women be referred "to a health care provider for medically necessary prenatal health care." Defendants provided no justification for

this unnecessary and onerous requirement that—should a provider wish to provide a referral list—the referral list include primary health care providers (rather than prenatal health care providers).

201. The Final Rule's provision allowing only medical doctors and Advanced Practice Providers to provide pregnancy counseling is unsupported by any reasoning or evidence, and is therefore arbitrary and capricious.

202. Defendants released the Final Rule within weeks of posting the proposed regulations, while the process of review and approval normally takes more than a month. This is evidence that the Final Rule was not provided adequate consideration and is therefore arbitrary and capricious.

203. The Final Rule's failure to adequately assess the regulatory costs of the Final Rule, as required by Executive Orders 12866 and 13563 and the Department's own Regulatory Impact Analysis guidance,[43] is additional evidence that the rule is arbitrary and capricious. The Final Rule dramatically underestimates the costs of compliance, and therefore erroneously concludes that the rule does not meet the $100 million threshold for "economically significant" regulations. In particular:

i) Defendants underestimate the number of Title X recipients to which the physical separation requirement of the new § 59.15 applies. The Department assumes that the separation requirement will apply only to the approximately 20 percent of Title X recipients that offer abortion services at the same site as Title X projects. But by its own terms, the separation requirement applies to all entities that engage in so-called "prohibited activities," including abortion referral, abortion counseling, and lobbying and advocacy activities—which together constitute far more than 20 percent of Title X recipients, and include Essential Access and similar grantor organizations.

[43] Office of the Assistant Secretary for Planning and Evaluation, *Guidelines for Regulatory Impact Analysis* (2016), *available at* https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

ii) Defendants' estimate that the average Title X service site affected by the physical separation requirement would incur only $30,000 in costs to comply with the physical separation requirement is far too low and lacks any evidence. Indeed, the Department offers no basis for its apparently arbitrary choice of $30,000 as the average compliance cost. Given the wide discretion afforded to the Secretary in determining whether a Title X project is sufficiently separate from "prohibited activities," and the lack of specific guidance on how the Secretary will exercise that discretion, Title X entities will have to build entirely new facilities, or dramatically renovate existing facilities, in order to ensure that the Secretary does not find them out of compliance. The cost of renovating facilities will be orders of magnitude greater than Defendants' estimate.

iii) Defendants' regulatory impact analysis ignores the Final Rule's costs to the health of patient populations currently served by Title X recipients. Because the Final Rule's prohibition on nondirective abortion options counseling and referral is contrary to professional and ethical obligations of medical providers, many current Title X recipients will decline Title X funds under the new regulations, reducing low-income patients' access to quality, effective family planning services. Defendants fail to account for these costs, and instead assume that other, new entities will replace the Title X providers that are forced out of the program, such that, in Defendants' estimation, the impact on access to care will be "zero." 84 Fed. Reg. 7714, 7782. Defendants, however, offer no basis for their claim that Title X providers forced out of the program will be replaced by an equal number of new providers, or whether those new providers will offer the same standard and level of care.

iv) Defendants' regulatory impact analysis fails to consider whether and how the Final Rule will disproportionately affect certain groups of people, as required

by the Office of Management and Budget.[44] For example, Defendants fail to consider that the reduction in Title X services resulting from the Final Rule will disproportionately harm low-income individuals, women, young people, people of color, and LGBTQ individuals.

v) Defendants fail to explain how the Final Rule complies with Executive Order 13771, which requires the costs associated with the Rule "be offset by the elimination of existing costs associated with at least two prior regulations." *See* 84 Fed. Reg. 7714, 7784.

vi) Defendants identify few benefits of the Final Rule, and fail to meaningfully consider any regulatory alternatives.

204. The Final Rule fails to provide a statement of its impact on federalism, as required by Executive Order 13132. The Final Rule seeks to closely regulate the relationship between medical providers and patients, which is traditionally an area of state authority. Defendants are therefore incorrect to state that the rule "does not contain policies that have federalism implications." Defendants' failure to comply with Executive Order 13132 is further evidence that the Final Rule is arbitrary and capricious.

205. Presently, Plaintiffs have no adequate or available administrative remedy. In the alternative, it would be futile for Plaintiffs to seek an administrative remedy at this time.

206. Plaintiffs have no adequate remedy at law, outside of a claim under 5 U.S.C. § 706.

207. Because the Final Rule is arbitrary and capricious, it should be set aside under Section 706 of the APA.

[44] *See* Office of Management and Budget, *Circular A-4, Re: Regulatory Analysis* (Sept. 17, 2003), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

COUNT FOUR

ADMINISTRATIVE PROCEDURE ACT – ARBITRARY AND CAPRICIOUS ACTION

(All Plaintiffs Against All Defendants)

208. Plaintiffs repeat and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

209. Defendant HHS is an "agency" under the APA, 5 U.S.C. § 551(1).

210. The Final Rule is an "agency action" under the APA, 5 U.S.C. § 551(13). The Final Rule is subject to judicial review because it constitutes "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

211. The APA requires an agency to provide "[g]eneral notice of proposed rule making," including "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). The APA's notice requirement ensures, among other things, that interested parties have a sufficient opportunity to comment.

212. The APA requires a reviewing court to hold unlawful and set aside agency action, findings, and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "without observance of procedure required by law." 5 U.S.C. § 706(2).

213. Defendants promulgated the requirement that all referral lists must consist exclusively of "licensed, qualified, comprehensive primary health care providers (including providers of prenatal care." Final Rule § 59.14(b)(ii); §59.14(c)(2). The Proposed Rule proposed that any referral list would consist of "qualified, comprehensive health service providers." Defendants provided no notice whatsoever that it was considering limiting the referrals that a Title X provider could make to only "licensed . . . *primary health care providers*." Indeed, Defendants do not even acknowledge this dramatic change from the language of the proposed rule.

214. Defendants' restriction on referrals to only "licensed, qualified, comprehensive primary health care providers" is not a logical outgrowth of the Proposed Rule. The change in language dramatically limits the providers to which a pregnant woman may be referred, and

inserts the unnecessary and inappropriate requirement that a pregnant woman in all cases must be referred to a primary health care provider, rather than any other appropriate health care provider. This appears to be *in addition* to the requirement that all pregnant women be referred "to a health care provider for medically necessary prenatal health care." The agency provided no justification for, nor any notice of, the unnecessary and onerous requirement that—should a provider wish to provide a referral list—the referral list include primary health care providers (rather than prenatal health care providers).

215. Plaintiffs are prejudiced by the lack of notice and opportunity to comment on this drastic change to the Proposed Rule. The effect of this change is to dramatically limit the number of health care providers that could be listed for referral, thus reducing the breadth and availability of patient care. Plaintiffs could not and should not have known that Defendants contemplated such a drastic change to the Proposed Rule, and therefore did not submit comments that would have apprised Defendants of the significant negative effects of this change.

COUNT FIVE

VIOLATION OF THE FIRST AMENDMENT – FREE SPEECH

(Plaintiff Marshall Against All Defendants)

216. Plaintiff repeats and incorporates by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

217. Under the First Amendment to the United States Constitution, "Congress shall make no law . . . abridging the freedom of speech." The First Amendment applies equally to the actions and regulations of Executive agencies.

218. By mandating that Title X medical providers refer all pregnant patients to prenatal services regardless of the provider's professional judgment about the proper course of action for her patient, the Final Rule forces many providers to express an opinion which they do not hold or with which they do not agree, infringing the providers' First Amendment right to freedom of speech.

219. By requiring Title X providers to provide pregnant patients who have requested a referral for abortion with the names of comprehensive prenatal service providers who do not

provide abortion, regardless of whether the provider believes that prenatal services are an appropriate course of action for her patient, the Final Rule compels many Title X providers to express an opinion which they do not hold or with which they do not agree, infringing the providers' First Amendment right to freedom of speech.

220. By effectively prohibiting Title X providers from providing counseling on abortion, and by prohibiting Title X providers from referring patients for abortion, even upon request, the Final Rule infringes providers' First Amendment right to freedom of speech.

221. Because the receipt of Title X funds is conditioned on compliance with the above-described unconstitutional prohibitions and requirements, the Final Rule imposes an unconstitutional condition on the receipt of Title X funds.

222. Because the Final Rule violates the First Amendment rights of Plaintiff Dr. Marshall, it must be set aside.

COUNT SIX

FIFTH AMENDMENT – DUE PROCESS (VAGUENESS)

(All Plaintiffs Against All Defendants)

223. Plaintiffs repeat and incorporate by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

224. Under the Due Process Clause of the Fifth Amendment to the United States Constitution, a law is void for vagueness if it (1) fails to give a person of ordinary intelligence a reasonable opportunity to know what is prohibited, and (2) invites arbitrary and discriminatory enforcement.

225. Several provisions of the Final Rule are void for vagueness under the Due Process Clause of the Fifth Amendment. In particular:

i) The physical and financial separation requirement of § 59.15 provides the Secretary with excessive latitude to determine whether a Title X project has sufficiently separated its Title X-funded activities from so-called "prohibited activities." The Final Rule provides several factors to be considered—including, for example, the degree of separation of accounting records, examination and

waiting rooms, office entrances, phone numbers, website, personnel, and health records—but does not specify how separate the various facilities must be, or how heavily each factor is to be weighed. Section 59.15 also provides no examples. Section 59.15 therefore fails to give a person of ordinary intelligence a reasonable opportunity to know what degree of separation is required, and invites arbitrary and discriminatory enforcement by the Secretary.

ii) The Final Rule is ambiguous on whether Title X providers may refer patients for abortions in case of medical necessity.

iii) The Final Rule is ambiguous on what a Title X provider may discuss with respect to abortion if he or she provides a patient with "nondirective pregnancy counseling" under § 59.14(b)(1).

iv) Section 59.16's prohibition on actions that "assist women to obtain abortions," "increase the availability or accessibility of abortion," or "encourage, promote or advocate abortion as a method of family planning," is vague and invites arbitrary and discriminatory enforcement by the Secretary.

226. Because these provisions of the Final Rule are void for vagueness under the Due Process Clause of the Fifth Amendment, they should be set aside.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. Declare that the Final Rule is contrary to law;
2. Declare that the Final Rule exceeds Defendants' statutory authority;
3. Declare that the Final Rule is arbitrary, capricious, and an abuse of discretion, in violation of the Administrative Procedure Act;
4. Declare that the Final Rule violates the Free Speech Clause of the First Amendment to the U.S. Constitution;
5. Declare that the Final Rule is void for vagueness under the Fifth Amendment to the U.S. Constitution;
6. Postpone the effective date of the Final Rule, pending judicial review, pursuant to

5 U.S.C. § 705;

7. Hold unlawful and set aside the Final Rule, pursuant to 5 U.S.C. § 706(2);

8. Issue a preliminary injunction against implementation and enforcement of the Final Rule;

9. Issue a permanent injunction against implementation and enforcement of the Final Rule;

10. Award to Plaintiffs reasonable costs and attorneys' fees; and

11. Award such other relief as the Court deems fit and proper.

Dated: March 4, 2019

KEKER, VAN NEST & PETERS LLP

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