No. 19-15974

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALEX AZAR, in his Official Capacity as Secretary of the U.S. Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellants,

v.

STATE OF CALIFORNIA, by and through Attorney General Xavier Becerra,

Plaintiff-Appellee.

On Appeal from the United States District Court
for the Northern District of California

No. 3:19-cv-01184-EMC
Hon. Edward M. Chen, District Judge

OPPOSITION TO MOTION FOR STAY PENDING APPEAL

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May 20, 2019

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INTRODUCTION

Title X of the Public Health Service Act is the nation's sole federal grant program devoted to supporting family planning services for low-income individuals. Defendants the United States Department of Health and Human Services and Secretary Alex M. Azar II issued a Final Rule aimed at excluding well-qualified reproductive healthcare providers from grants authorized by Title X. The district court preliminarily enjoined the Final Rule, finding that it will likely "decimate the network of Title X providers in California and drastically reduce patients' access to a wide range of vital services, including contraceptive resources and screenings for sexually transmitted infections, reproductive cancers, and HIV." Add.2. Not coincidentally, the Final Rule is also contrary to law. As the district court concluded, Plaintiff is likely to succeed on the merits of its claim that the rule contravenes two separate statutes enacted by Congress, and is arbitrary and capricious.

That conclusion was entirely correct, but the Court need not reach the merits at this stage. Defendants seek a stay of the preliminary injunction pending appeal.[1] In order to obtain such a stay, Defendants must show that they will be irreparably harmed if the preliminary injunction is not stayed. They cannot do so: No

[1] Briefing on the merits of Defendants' appeal of the preliminary injunction is currently scheduled to take place in June and July, 2019.

irreparable harm would flow from maintaining the status quo that prevailed for decades before Defendants issued the Final Rule. None of the other stay requirements are met, and the balance of harms tips sharply in favor of Plaintiff. Defendants' request to stay the district court's order pending the merits of the appeal should be denied.

BACKGROUND

Title X authorizes Defendants to make grants to support "voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services." 42 U.S.C. § 300(a). Section 1008 of Title X prohibits funding for "programs where abortion is a method of family planning." *Id*. § 300a-6. Well-established federal regulations and guidance have allowed grantees to provide neutral, unbiased counseling to pregnant women about their options, including appropriate referrals to programs that provide prenatal care, adoption, or abortion. Add.4-9; Cal.Suppl.Add.5-6, 98-101.

In 1988, HHS first issued regulations banning counseling, including referrals, for abortion (also known as the gag rule), as well as instituting strict physical and financial separation between Title X-funded projects and any activities related to abortion outside of the Title X program. 42 C.F.R. §§ 59.8(a)(1), 59.9 (1989). The Supreme Court considered a challenge to these regulations in *Rust v. Sullivan*, 500 U.S. 173 (1991). The Court determined that

Section 1008 was ambiguous with respect to the scope of Title X's prohibition on "abortion as a method of family planning," and thus that Congress had not spoken "directly to the issues of counseling, referral, advocacy, or program integrity." *Rust*, 500 U.S. at 184. In the absence of clear direction from Congress, the Court deferred to HHS's interpretation of Section 1008, concluding, "we are unable to say that the Secretary's construction of the prohibition in § 1008 to require a ban on counseling, referral, and advocacy within the Title X project is impermissible." *Id*. at 184. The Court also determined that the separation requirements were "not inconsistent with congressional intent." *Id*. at 188. The 1988 regulations were never fully implemented, however, and HHS suspended them entirely in 1993. *See* 58 Fed. Reg. 7462 (Feb. 5, 1993).

Starting in 1996, and for every year since, Congress addressed the ambiguity identified by the Supreme Court in *Rust* by passing appropriations legislation (known as a "rider") for Title X funds requiring that "all pregnancy counseling shall be nondirective." Dep't of Def. and Labor, Health and Human Servs., and Educ. Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., Tit. II, 132 Stat. 2981, 3070-71 (2018); 84 Fed. Reg. 7714, 7725 (Mar. 4, 2019) (acknowledging that the nondirective counseling requirement "has been regularly included in HHS's appropriations through fiscal year 2019"). In 2010, Congress passed another law affecting HHS's regulatory authority,

directing in Section 1554 of the Affordable Care Act (ACA) that the agency "shall not promulgate any regulation" that "creates any unreasonable barriers to the ability of individuals to obtain medical care," "impedes timely access to health care services," "restricts the ability of health care providers to provide full disclosure of all relevant information," "violates the principles of informed consent and the ethical standards of health care professionals," or "interferes with communications regarding a full range of treatment options between the patient and the provider." 42 U.S.C. § 18114.

In 2000, HHS issued new regulations harmonizing Section 1008's prohibition on projects that promote or encourage abortion with Congress' nondirective counseling mandate. 65 Fed. Reg. 41281 (July 3, 2000). The 2000 regulations do this by requiring Title X projects to provide pregnant women with only "neutral, factual information and nondirective counseling on each of [her] options, and referral on 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*. The 2000 regulations remained in place for almost two decades, throughout multiple changes of administration.

During this time, HHS developed additional evidence-based guidance for Title X projects. Most notably, HHS required grantees to adhere to federal Quality Family Planning guidelines issued by HHS's Office of Population Affairs and the

Centers for Disease Control and Prevention (CDC)—developed in collaboration with expert medical bodies, such as the American College of Obstetricians and Gynecologists (ACOG)—which set forth standards for high-quality, ethical clinical practice in the provision of family planning care. Cal.Suppl.Add.5, 36, 47-48. According to these guidelines, and consistent with Congress' nondirective mandate and the 2000 regulations, Title X patients should be presented with pregnancy test results "followed by a discussion of options and appropriate referrals," which "should be made at the request of the client, as needed." *Id*. at 48; 42 C.F.R. § 59.5(a)(5)(ii) (2000).

Defendants' March 4, 2019 Final Rule sharply departed from this established practice and substantially returned to the 1988 rule, despite no intervening change in the law, no change in the evidentiary bases supporting nondirective counseling, and no evidence that Title X providers are failing to comply with program rules. Some aspects of the Final Rule are similar to the 1988 regulations, including the physical and financial separation requirements. The 2019 Final Rule forbids referrals for abortion, but it allows presentation of abortion as an option. 42 C.F.R. § 59.5(a)(5) (2019). In addition, the Final Rule mandates referrals to prenatal care for all pregnant patients, even if they have decided not to continue their pregnancy. 42 C.F.R. § 59.14(b)(1) (2019).

On April 26, 2019, the district court issued a preliminary injunction blocking implementation of the Final Rule in California. Among other consequences of the Final Rule, the district court found, after reviewing numerous expert and provider declarations, that the Final Rule would drive "large numbers of providers out of the program," including reproductive health clinics, federally qualified health centers, and other providers currently serving more than three quarters of California Title X patients, leading to a substantial reduction in availability of and access to vital health services. Add.15-16. As a result, the district court concluded that "irreparable injury, balance of hardships, and public interest factors tip sharply in Plaintiffs' favor." Add.14 (citing *All. for the Wild Rockies v. Pena*, 865 F.3d 1211, 1217 (9th Cir. 2017)).

The district court also concluded that Plaintiffs had shown a likelihood of success on their core APA claims. The court closely examined Congress' post-*Rust* enactments, specifically the nondirective counseling mandate and Section 1554 of the ACA, and concluded that significant aspects of the Final Rule, including the gag rule, violate both of these provisions. Add.35, 46.

The district court further determined that other aspects of the Final Rule likely violate the APA's prohibition on arbitrary and capricious agency action. Add.46-73. These aspects include the separation requirements, restrictions on counseling, including referrals, a limitation on clinicians who may provide options

counseling to only doctors or nurses with graduate degrees, removal of a requirement that Title X projects offer "medically approved" family planning methods, and HHS's cost-benefit analysis. *Id.* The district court considered *Rust*'s rejection of an arbitrary and capricious claim, but determined that the 1988 rule, in contrast to the 2019 Final Rule, was based on a "reasoned analysis" including "critical reports of the General Accounting Office (GAO) and the Office of the Inspector General (OIG)." Add.47-48 (citing *Rust*, 500 U.S. at 187). Two other district courts in the Ninth Circuit have come to the same conclusion, reasoning that *Rust* is insufficient to sustain the Final Rule in light of significant changes in federal law and the agency's inadequate analysis of the record before it today. *See Oregon v. Azar*, No. 6:19-CV-00317-MC, 2019 WL 1897475, at *7-8 (D. Or. Apr. 29, 2019) (in light of subsequent legal developments, "HHS must do more than merely dust off the 30-year old regulations and point to *Rust*"); *Washington v. Azar*, No. 1:19-CV-03040-SAB, 2019 WL 1868362, at *7-8 (E.D. Wash. Apr. 25, 2019) ("[I]t seems the Department has relied on the record made 30 years ago, but not the record made in 2018-19").

On May 8, 2019, the district court denied Defendants' request for a stay of the preliminary injunction pending appeal, finding that they had not met their burden of showing circumstances that would justify a stay. Add.85. The district court found that the declaration of David Johnson, Operations and Management

Officer for HHS's Office of Population Affairs, showed no imminent harm. *Id*. at 86. At Defendants' request, the district court refined its injunction to exclude two provisions of the Final Rule that Plaintiffs did not challenge, relating to reporting requirements for grant applicants. *Id*. at 86-87.

ARGUMENT

A "stay is an 'intrusion into the ordinary processes of administration and judicial review,' and accordingly 'is not a matter of right.'" *Nken v. Holder*, 556 U.S. 418, 427 (2009) (citations and quotations omitted). Defendants bear the heavy burden of "showing that the circumstances justify an exercise of [the Court's] discretion." *Id*. at 433-434. In determining whether a stay should issue, the Court considers "four factors: '(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.'" *Id*. at 434 (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)).

Here, Defendants seek a "stay pending appeal of a preliminary injunction." *Lopez v. Heckler*, 713 F.2d 1432, 1436 (9th Cir. 1983). Thus, "in order to determine whether [they have] raised serious legal questions or […] show a probability of success on the merits," this Court "must evaluate [their] arguments

for overturning the district court's preliminary injunction on appeal." *Id.* The Court "'review[s] the district court decision to grant … a preliminary injunction for abuse of discretion.'" *BOKF, NA v. Estes*, __ F.3d __, No. 18-15369, 2019 WL 1941931, at *3 (9th Cir. May 2, 2019) (citing *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 918 (9th Cir. 2003) (en banc), and the district court's factual findings are reviewed for clear error, *adidas Am., Inc. v. Skechers USA, Inc.*, 890 F.3d 747, 753 (9th Cir. 2018).

Defendants cannot meet the heavy burden required for a stay. The district court correctly concluded that Plaintiff is likely to succeed in showing that the Final Rule is contrary to Congress' intent as expressed in the nondirective counseling mandate and Section 1554 of the ACA, and that the equities tip sharply in Plaintiff's favor. The scope of the injunction is likewise proper. Defendants' request for a stay should be denied.

I. DEFENDANTS HAVE FAILED TO DEMONSTRATE IMMINENT, IRREPARABLE HARM

Defendants have not demonstrated that they would suffer imminent, irreparable injury without a stay. The preliminary injunction merely "preserves the status quo" that has prevailed in the provision of Title X federal family planning care for more than two decades. *See Feldman v. Ariz. Sec'y of State's Office*, 843 F.3d 366, 369 (9th Cir. 2016) (en banc). The federal government generally does not suffer irreparable harm from an injunction that keeps "long standing …

procedures" in place pending judicial review. *Id.*; *see also, e.g.*, *E. Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1255 (9th Cir. 2018) (holding that the United States had "fail[ed] to show irreparable harm" needed to obtain a stay pending appeal of district court TRO that "temporarily restored the law to what it had been for many years prior to" the challenged rule).

Defendants claim that in the absence of a stay, HHS will suffer administrative burdens and the Title X program and its grantees will be harmed by "uncertainty." Mot. at 19. Mere uncertainty does not support issuance of a stay; as the district court noted, "the uncertainty that is created when a preliminary injunction is appealed is inevitable regardless of whether a stay is granted." Add.86. Furthermore, the district court found that the administrative tasks described in the Johnson Declaration (which Defendants failed to submit with their initial opposition to the motion for a preliminary injunction) are not imminent because the agency disbursed grants prior to the Final Rule's effective date, and the agency "does not intend to 'offer guidance' to grantees regarding future grants until October 2019." *Id*. And any future harm that might exist is caused only by Defendants' self-imposed March 4, 2020 deadline for compliance with the Final Rule, which could be mitigated if Defendants so choose. *See* 42 U.S.C. § 300a-4 (a) (Defendants have the authority to promulgate regulations governing the execution of Title X grants and contracts).

Lacking any genuine imperative for a stay, Defendants fall back on harm supposedly inflicted "whenever [the federal government] 'is enjoined by a court from effectuating statutes […].'" Mot. at 18 (quoting *Maryland v. King*, 567 U.S. 1301 (2012) (Roberts, C.J., in chambers)). Here the district court did *not* enjoin a statute itself, but an agency regulation that it found "is not in accordance with law and exceeds statutory authority." Add.25. Defendants' rationale would amount to a blanket rule that no federal agency regulation could ever be preliminarily enjoined, even if contrary to statute. This Court has rejected such arguments. *See, e.g.*, *E. Bay Sanctuary Covenant*, 909 F.3d at 1254 (concluding that this circumstance "do[es] not alone amount to an injury that is 'irreparable'"); *Washington v. Trump*, 847 F.3d 1151, 1168 (9th Cir. 2017) (same). Defendants do not argue (nor provide any evidence in the record) that the Final Rule is necessary to prevent any specific misuse of funds, apart from their differing view regarding the underlying merits of their new interpretation of Section 1008.

II. A STAY WILL SUBSTANTIALLY INJURE CALIFORNIA AND OTHER PARTIES

In contrast, a stay will immediately harm the State of California and the public, which has a strong "interest in access to contraceptive care." *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018). The district court found, on the basis of substantial, unrebutted evidence, that implementation of the Final Rule would reduce the quality and availability of Title X services to individual women and

other California residents who depend upon that network for necessary contraceptive care and other health services. Add.14-18. Medical reproductive health experts and numerous healthcare providers of Title X services submitted sworn declarations that implementation of the Final Rule will cause an exodus from the Title X program. *Id*. at 15-17.[2] For providers who remain in the program, the gag rule will "directly compromise providers' ability to deliver effective care and force them to obstruct and delay patients with pressing medical needs." *Id*. at 15.

Moreover, the district court made a number of well-supported findings regarding the serious public harms that will follow as a result of reductions in the quality of and access to Title X care. Title X patients will find it harder to access more effective methods of birth control, including long-acting reversible contraceptives. Add.17-18. This will cause an increase in unintended pregnancies, leading to increased rates of premature birth, low-birth, and other negative child and maternal health outcomes. *Id*. at 18. Reduced access to Title X-funded

[2] In contrast, Defendants never provided the district court with any evidence to support their assertion that new Title X providers will "fill [any] gaps," Mot. at 20, in the availability and quality of Title X providers. The district court correctly did not defer to Defendants' conclusory predictions in the Final Rule that its action would not have a negative effect on access to or quality of family planning services. Add.68-69 ("HHS provides no evidence to indicate that there are new grantees waiting in the wings to join Title X, much less enough new grantees to fill the vacuum left by the impending exodus.").

screening will likely increase sexually transmitted diseases and other preventable illnesses. *Id*. While the State of California is not a direct grantee of the Title X program, the district court found that California will likely be harmed through a clear, direct causal chain linking decreases in access to Title X services with harm to public health and the public fisc. *Id*. at 18-19; *see also California*, 911 F.3d at 582 (affirming preliminary injunction in light of "potentially dire public health and fiscal consequences" faced by states as a result of new federal rules limiting coverage of contraception).

III. DEFENDANTS ARE NOT LIKELY TO PREVAIL ON THE MERITS

A. The Final Rule is Contrary to Law

Defendants' argument that Plaintiff is unlikely to succeed hinges on the assumption that *Rust v. Sullivan* precludes Plaintiff's claims. But Defendants read *Rust* too broadly and fail to account for federal laws that Congress passed in the years after *Rust*. In two different statutes—the nondirective mandate appropriations rider attached to legislation funding Title X and Section 1554 of the ACA—Congress has removed Defendants' authority to issue a Final Rule that adopts the same interpretation at issue in *Rust*.

The Supreme Court in *Rust* held only that the agency's 1988 prohibition on abortion referrals and strict separation requirement was one "permissible construction" of Section 1008. 500 U.S. at 187. It never held that this was the

only permissible interpretation, or even that this interpretation was superior to the agency's longstanding policy and practice of allowing such referrals. Accordingly, determining whether HHS's current interpretation, as reflected in the Final Rule, remains a viable interpretation of Section 1008 requires an analysis of the *current* legal landscape, including statutory changes postdating *Rust*.

The district court rejected Defendants' characterization of Plaintiff's claims as the "implied repeal" of either Section 1008 or *Rust*.[3] Instead the district court appropriately harmonized Section 1008 with the Title X appropriations rider and Section 1554 of the ACA. Add.27-28 (citing *Radzanower v. Touche Ross & Co*., 426 U.S 148, 154-55 (1976) (courts consider repeals by implication only "where provisions in the two acts are in irreconcilable conflict")). As noted above, beginning in 1996 and renewed in appropriations legislation ever since, Congress has clarified that pregnancy counseling within the Title X program must be nondirective. Congress also specified in Section 1554 that HHS has no authority to issue regulations that create barriers to access to healthcare, interfere with provider's ability to discuss a full range of treatment options, or that violate medical ethics. In light of these statutory changes, the agency interpretation of

[3] At oral argument, Defendants disclaimed any argument regarding "silent repeal." Cal.Suppl.Add.175 (defense counsel stating "I don't think it's a repeal at all. I think what the Court has to do is read Section 1008 and the appropriations rider together.").

Section 1008 that was upheld in *Rust* (including a blanket prohibition on presenting factual referral information about abortion), can no longer be reconciled with Congress' directives. HHS itself similarly harmonized Section 1008 and the nondirective counseling mandate in its 2000 regulations. 65 Fed. Reg. 41270, 41272-74 (July 3, 2000).

Counseling that mandates referrals for one primary option a pregnant woman might choose (prenatal care), while omitting any referral for another primary option (abortion), is not "nondirective." Nor are the provisions in the Final Rule that limit any list offered to a patient in need of a referral to only "comprehensive primary health care providers" (excluding specialty women's clinics that may provide abortion services, but not "comprehensive primary" care); that forbid providers from explicitly identifying convenient, affordable, and high quality providers who do offer abortion; and that allow Title X clinics to deliberately exclude *all* abortion providers from the list, without any patient notification. 84 Fed. Reg. at 7716; 42 C.F.R. § 59.14(b)(1)(ii), (c)(2); Add.33-34. Moreover, these limitations are contrary to medical ethics and interfere with providers' ability to care for their patients. Add.44-46 (noting "medical professionals overwhelmingly agree that the Final Rule's counseling and referral restrictions violate principles of medical ethics and informed consent").

As the district court concluded, Defendants' argument that Congress' annual nondirective rider should be ignored because the act of "counseling" is separate from "referrals" is contrary to Congress' use of those terms in the Public Health Services Act, the agency's own use of those terms in other parts of the Final Rule, agency guidance, and accepted usage of those terms within the medical community. Add.28-31; 42 U.S.C. § 254c-6(a)(1); 84 Fed. Reg. at 7730, 7733-34; Cal.Suppl.Add.99-101. Defendants contend that it would amount to "hid[ing] an elephant[] in [a] mousehole[]" for Congress to foreclose the agency construction of Section 1008 at issue in *Rust* in an appropriations rider. Mot. at 11. That argument is meritless. An appropriations bill funding HHS is exactly where one would expect to find congressional mandates guiding that agency's regulatory authority. And the phrase Congress has used in every such bill since 1996—"all pregnancy counseling shall be nondirective"—speaks succinctly but clearly to the exact issue presented here, namely the type of counseling Title X grant recipients should provide to pregnant women.

Congress' 2010 adoption of Section 1554 of the ACA also places significant and clear new limits on Defendants' authority to construe Section 1008 as they do in the 2019 version of the Final Rule. As the district court found, "[t]here is no question" that the Final Rule violates Section 1554's substantive requirements. Add.43-46. Defendants complain that Plaintiff waived this legal claim because

public comments did not specifically raise this ACA provision. Mot. at 13, n.2. But the district court, after reviewing supplemental briefing from the parties on this question, found "commenters raised issues pertaining to Section 1554 with sufficient clarity to provide notice to HHS," complemented by "numerous comments using identical or substantially identical language to section 1554 to describe how the Final Rule would impede access to care." Add.37.

B. THE DISTRICT COURT CORRECTLY DETERMINED THAT THE SEPARATION RULE IS LIKELY ARBITRARY AND CAPRICIOUS

The district court correctly held that the separation rule is arbitrary and capricious, and that the Supreme Court's holding that the 1988 regulations did meet the APA's criteria for reasoned decision-making does not apply to the 2019 Final Rule.

Defendants argue that the district court should have deferred to their conclusions asserted in the 2019 rulemaking that, even in the absence of any evidence of improper use of taxpayer funds, the "risk and perception that taxpayer funds will be used to fund abortion," is a sufficient basis to upend established Title X regulations. Mot. at 15. This is not what the Court held in *Rust*, and it is not the law today. As the district court noted, *Rust* found that the 1988 regulations were justified by critical GAO and OIG reports published in the 1980s. Add.47-48; *Rust*, 500 U.S. at 187. The Final Rule provides no recent such evidence, and no

evidence of improper use of funds was brought before the district court apart from Defendants' new interpretation of Section 1008. Cal.Suppl.Add.226:12-231:5.

Likewise, Defendants maintain that their contention that physical co-location will "impermissibly subsidize abortion" sufficiently explains their change in policy, despite a lack of concrete evidence that Title X funds "subsidize" non-program funds, and despite the significant reliance interests at stake. Mot. at 15-17. But the cases Defendants cite, in which courts have upheld agency decision-making, involve more careful, fact-based analysis. In *International Rehabilitative Sciences, Inc., v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012), the Ninth Circuit upheld HHS's decision to exclude Medicare coverage for certain medical equipment because the agency had examined and weighed scientific studies that ran counter to the agency's decision, and found them to come from biased sources or to contain other methodological deficiencies.

HHS failed to undertake a comparable analysis here. Defendants' decision-making process in this case is premised on an outright rejection of years of agency experience, available and expansive public health and medical expert evidence, and a reliance on "speculative fears of theoretical abuse" in order to justify a drastic shift in public policy. Add.49. For example, Defendants ignore studies examining policy experiments similar to the Final Rule and finding that exclusion of specialty providers like Planned Parenthood results in significant costs to patient

health, including decreased access to contraceptives, and increased rates of unintended pregnancies. Add.69-73.

Defendants ask the Court to defer to their prediction that the exit of existing Title X providers from the program will cause no reduction in access to services or other harm. Mot. at 16. But when asked at oral argument to identify the agency's evidence that new Title X providers would emerge to replace exiting current providers, defense counsel explained only, "it's just intuitive […] the medical marketplace is as fluid as any other marketplace." Cal.Suppl.Add.154:15-21; Add.22 ("Intuition is no rebuttal to Plaintiffs' evidence of threatened irreparable harm."). This is consistent with the Final Rule's lack of substantiation for this prognostication. It states, without explanation or evidence addressing the likely exit of current providers, that HHS does not "anticipate that there will be a decrease in the overall number of facilities offering services." 84 Fed. Reg. at 7782. This is not the type of "predictive judgment" to which courts appropriately defer. *Cf. Trout Unlimited v. Lohn*, 559 F.3d 946, 958 (9th Cir. 2009) (deferring to federal agency expertise after court was "convinced" that the agency's decisions were "based upon the best scientific evidence available," including using criteria identified by experts and relying upon numerous expert reports). Here, the agency ignored evidence from experts in the field of reproductive health, and failed to identify any expert reports regarding availability or quality of alternative Title X

providers. Add.20-22. The district court correctly found that Defendants failed to meet the minimum requirements set forth by the Administrative Procedure Act for reasoned decision-making.

C. THE DISTRICT COURT CORRECTLY DETERMINED THAT OTHER ASPECTS OF THE FINAL RULE ARE LIKELY ARBITRARY AND CAPRICIOUS

The district court likewise did not abuse its discretion in determining that other aspects of the Final Rule were likely arbitrary and capricious.

The new rule that only doctors and "advanced practice practitioners" (APPs) with graduate degrees can provide options counseling for pregnant patients was adopted without adequate support or justification. The district court reviewed public comments (corroborated by evidence introduced to show the harm that this provision would cause) and found that a large majority of current Title X clinics rely on non-APPs to counsel patients, that this ban runs contrary to medical practice and needs, and that it would negatively impact a Title X clinic's ability to maintain patient volumes, impeding delivery of services. Add.64. Defendants cited no evidence and offered no argument to the contrary. The sole explanation in the Final Rule for this requirement—HHS's assertion that it "drew the line at APPs, [because they] have 'advanced medical degrees, licensing, and certification requirements''— offers no actual details. *Id*. Where significant reliance interests have developed, the Administrative Procedure Act requires a better explanation.

See F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). As the district court found, Title X clinics have made substantial investments in staff on the assumption that any well-trained clinician can provide pregnancy options counseling, regardless of whether they possess an advanced degree. Add.64-65.

Likewise, the district court reviewed the available evidence and correctly concluded that Defendants failed to offer an adequately reasoned basis for the removal of the requirement that Title X projects offer a broad range of methods of contraception that are "medically approved." Expert comments as well as HHS's own CDC Family Planning Guidelines all supported retention of this requirement. Add.66. Defendants' assertion that this requirement has caused confusion, without any concrete evidence and in the face of the medical community's contrary consensus, led the district court to conclude correctly that this portion of the Final Rule runs counter to the evidence before the agency. *Id*. (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)).

IV. THE SCOPE OF THE PRELIMINARY INJUNCTION IS NOT OVERBROAD

Defendants ask the Court in the alternative to stay the injunction with respect to provisions of the Final Rule that the district court "did not find were likely invalid." Mot. at 20. However, Defendants do not specifically identify any such provisions. The district court considered Defendants' overbreadth argument

in its May 8, 2019 order, and narrowed the injunction accordingly. Add.86-87. No further tailoring is needed.

CONCLUSION

For the foregoing reasons, Defendants' motion for a stay pending appeal of the preliminary injunction should be denied.

Dated: May 20, 2019

Respectfully submitted,

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19-15974

IN THE UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

State of California, by and through Attorney General Xavier Becerra,

Plaintiff-Appellee,

v.

ALEX M. AZAR II, in his Official Capacity as Secretary of the U.S. Department of Health and Human Services; U.S. Department of Health and Human Services,

Defendants-Appellants.

STATEMENT OF RELATED CASES

The following related cases are pending before this Court: *State of Oregon v. Azar* and *American Medical Association v. Azar* (No. 19-35386); *Essential Access Health, Inc., v. Azar* (No. 19-15979).

Plaintiff the State of California is not aware of any other related cases, as defined by Ninth Circuit Rule 28-2., that are currently pending in this Court.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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9th Cir. Case Number(s) 19-15974

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- ○ is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature /s/Anna Rich **Date** May 20, 2019

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Dated: May 20, 2019 */s Anna Rich*

STATE OF CALIFORNIA SUPPLEMENTAL ADDENDUM

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

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

Plaintiff,

v.

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

Defendants.

DECLARATION OF CLAIRE BRINDIS IN SUPPORT OF A MOTION FOR A PRELIMINARY INJUNCTION

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

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

1. I am a Professor in the Departments of Pediatrics and Obstetrics and Gynecology and Reproductive Sciences at the University of California, San Francisco, where I have held positions as a researcher and faculty member since 1983.

2. I am a Founding Director of the Philip R. Lee Institute for Health Policy Studies. This Institute is an interdisciplinary health policy research unit that collaborates with universities, the private sector, government, and community-based organizations to address issues concerning health care delivery, access and quality of care, and health services outcomes. I have been associated with Center since its initiation and have served as one of its co-Directors since 2004, now Founding Director beginning in 2008.

3. I am a Director of the Bixby Center for Global Reproductive Health. This Center leads research and training programs around the world to improve reproductive health policies, treatment, and care guidelines around the world. I have been associated with this Center since its initiation and have served as one of its co-Directors since 2004.

4. I received a Master's Degree in Public Health in Maternal and Child Health, International Health, and Family Planning from the University of California at Los Angeles and a Doctoral Degree in Public Health (with a specialty in Behavioral Sciences) from the University of California at Berkeley.

5. A copy of my curriculum vitae is attached as Exhibit A.

6. My area of academic expertise is child, adolescent, and women's health policy. I have conducted research regarding reproductive health services for men and women, pregnancy and pregnancy prevention, and health care reform, among other topics. Of particular relevance, I served on the 2011 Institute of Medicine Women's Committee on Preventive Services for Women, which produced a report of recommendations for women's health, including an annual preventive health visit, counseling on sexually transmitted infections (STIs), and access to all Food and Drug Administration (FDA)-approved contraceptive services without copayment. I also served for nearly 20 years as the co-Principal Investigator for California's Family Planning,

Access, Care, and Treatment (PACT) Program, the state's Medicaid waiver program that provides family planning services to low-income men and women and one of the largest publicly funded therefore untreated sexually transmitted infections. I currently serve as the Principal Investigator for a National Institutes of Health-funded program, Building Interdisciplinary Research Careers in Women's Heath, which supports junior faculty conducting research aimed at improving women's health.

7. I have served as a research grantee, advisor, and/or consultant to a variety of federal government projects and agencies since 1983, including: member of the advisory panel for the U.S. Congress Office of Technology Assessment on Adolescent Health (1991); advisor to the Centers for Disease Control and Prevention (CDC) regarding adolescent pregnancy prevention efforts (1995-2000); member of the Adolescent Health Work Group, Maternal and Child Health Bureau, U.S. Department of Health and Human Services (DHHS) (1995-1996); member of the Steering Committee, Women's Health Panel, Bright Futures for Women's Health and Well-Being: National Guidelines Project, Maternal and Child Health Bureau, DHHS (2001-2002); member of the Technical Experts Advisory Committee for the Office of Population Affairs, Office of Family Planning, and CDC in connection with revision of the Title X Family Planning Program Guidelines, Adolescent Panel (2011). I have also served on several National Academy of Medicine Expert Committees on adolescents, young adult health, children and young adults with disabilities, women's health, and Title X.[1]

8. I have not been paid a fee for my work in connection with this case. I will be reimbursed for all reasonable and necessary out-of-pocket expenses incurred in connection with this engagement, such as travel expenses. This reimbursement is not contingent on the nature of my findings or conclusions, or on the outcome on this litigation.

9. On July 31, 2018, I submitted a comment letter in strong opposition to the proposed rule titled *Compliance with Statutory Program Integrity Requirements*, 83 Fed. Reg.

[1] *See* Inst. of Med., *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results* (2009), http://nationalacademies.org/hmd/reports/2009/a-review-of-the-hhs-family-planning-program-mission-management-and-measurement-of-results.aspx.

25,502 (proposed June 1, 2018), expressing my serious concerns from a public-health perspective in particular. That letter is attached as Exhibit B.

10. I have been asked to provide my opinion about the final rule "Compliance with Statutory Program Integrity Requirements," 84 Fed. Reg. 7714 (Mar. 4, 2019) (to be codified at 42 C.F.R. 59), (hereinafter "the Final Rule") published in the Federal Register on March 4, 2019, as it relates to this case, focusing on its public health consequences as well as impact on California and its Title X program.

11. In summary, my prior comments on the proposed rule apply with the same force to the final Rule. I have incorporated those prior comments here in my expert declaration on the Rule, updated with more recent data as appropriate. My conclusion is the same as before—and just as dire: The Final Rule would significantly and detrimentally alter Title X and put at risk the vital reproductive and other essential health care it has provided to millions of low-income individuals across the country for many decades.

I. The Final Rule

12. I am familiar with the Final Rule.

13. Among other things, I understand that the Final Rule imposes a gag on the medical profession that would have practitioners in the Title X program direct pregnant women toward continuing a pregnancy to term—regardless of what a patient actually prefers and needs. Among other things, this requirement would ban referrals for abortion while requiring referrals for prenatal care. It would further authorize biased and incomplete pregnancy counseling, and would compel speech from medical professionals when counseling on abortion. It would even limit *who* could counsel on abortion—imposing a speaker based prohibition on anyone but doctors or "advanced practice providers" ("APPs") from providing "nondirective pregnancy counseling," whether on abortion or otherwise.

14. I understand that the Final Rule also imposes "physical and financial" separation requirements on Title X providers that engage in so-called "prohibited activities"—essentially,

anything having to do with abortion—including speaking about or providing abortions with non-Title X funds.

II. The Final Rule Would Undermine Title X's Goal of Providing Comprehensive Family-Planning Services to Those Unable to Pay for Them

15. Over the course of its nearly 50-year history, the federal Title X program has proven successful in providing access to many important aspects of health care for low-income individuals. In 2017, Title X clinics[2] served 4 million patients nationwide, through a network of over 1,000 providers at 3,858 locations, with more than one million patients in California alone.[3] Most obviously, Title X programs have successfully provided a broad range of family planning services, including and especially contraceptives, to low-income women who would otherwise not have access to that care.

16. The standards that Title X programs have, prior to issuance of the Final Rule, been required to adhere to mandate delivery of non-judgmental, non-coercive family planning services and promotion of informed, voluntary decision-making. These include broadly accepted, evidence-based standards published by the U.S. Department of Health and Human Services and the CDC, "Providing Quality Family Planning Services," attached as Exhibit C.[4]

17. These Quality Family Planning recommendations are considered by the public health community to be the standard of care for all family planning practitioners. The American College of Obstetricians and Gynecologists, the American College of Physicians, and the American Academy of Family Physicians all endorse non-directive options counseling as the most clinically appropriate role for family planning providers. This builds upon extensive research in the field of family planning counseling that supports that women want to be supported

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[2] Throughout this declaration, I use the term "Title X clinics" or "Title X providers" to refer to entities that have qualified for and received Title X funding according to the U.S. Department of Health and Human Services' evidence-based grant criteria in effect prior to the Rule.

[3] Christina I. Fowler et al., *Title X Family Planning Annual Report: 2017 National Summary* B-2 (2018), https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.

[4] CDC, *Providing Quality Family Planning Services*, 63:4 Morbidity & Mortality Wkly. Rep., Apr. 25, 2014, available at https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.

by family planning staff, but that they have the opportunity to make their own decision based upon information provided by their providers.[5]

18. The Quality Family Planning recommendations further recommend that providers offer a full range of FDA-approved contraceptive methods.

19. Access to a wide range of contraceptive methods is crucial for women's reproductive health, given their life course, ranging from primary prevention through inter-conceptual contraceptive needs and post-family formation, if in fact, they choose or are unable to bear children. Women often use multiple contraceptive methods in their lifetimes: 86% of women have used three or more methods by their early 40s.[6] Women rely on a variety of contraceptive methods and sometimes employ multiple methods simultaneously.[7]

20. Research shows that Title X-funding, when allocated according to program rules and criteria in effect before the Final Rule, succeeds in offering patients a wide range of contraceptive choices. Title X clinics are more likely than non-Title X family planning clinics to provide a full range of FDA-approved contraceptive methods: 72% of Title X providers offer the full range, compared with 49% of non-Title X clinics.[8] Title X clinics offer a choice among an average of 12 contraceptive methods on average, and 85% of Title X clinics offer at least one long-acting reversible contraceptive (LARC) method.[9]

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[5] *See* Edith Fox et al., *Client Preferences for Contraceptive Counseling: A Systematic Review*, 55 Am. J. Preventive Med. 691 (2018); Karen Pazol et al. *Impact of Contraceptive Education on Knowledge and Decision Making: An Updated Systematic Review*, 55 Am. J. Preventive Med. 703 (2018).

[6] Kimberly Daniels et al., *Contraceptive Methods Women Have Ever Used: United States, 1982-2010*, 62 Nat'l Health Statistics Rep., February 14, 2013, https://www.cdc.gov/nchs/data/nhsr/nhsr062.pdf.

[7] Megan L. Kavanaugh and Jenna Jerman, *Contraceptive Method Use in the United States: Trends and Characteristics Between 2008, 2012 and 2014*, 97 Contraception 14 (2017), https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.

[8] Mia R. Zolna & Jennifer J. Frost, Guttmacher Inst., *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols* 12 (2016), http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[9] *Id.* at 11.

21. LARC methods are widely recognized as the most medically effective and cost-effective forms of contraception.[10] LARC methods are highly effective, but come with high up-front costs for patients (over $1,000 per insertion) if unsubsidized.[11] Oral contraceptives could cost patients at least $50 per month ($600 per year) out-of-pocket.[12] Title X clinics' offerings of free or low-cost support enables very low-income women (up to 250% of poverty)[13] to make the contraceptive choice that is best for them, without facing the burden of making choices based upon their financial resources.

22. In California, Title X is complemented by the Family Planning, Access, Care, and Treatment (Family PACT) program, the state's Medicaid family planning expansion. Not all clinics that participate in Family PACT are Title X providers, but all Title X clinics in California are also Family PACT providers. Title X providers serve a disproportionate percentage of all Family PACT clients; in FY 2008-2009, Title X clinics represented only 13 percent of the clinics in the Family PACT network, but served half of all Family PACT clients.[14]

23. My research shows that, within Family PACT, Title X funding, as administered by California's long-time Title X grantee, Essential Access Health, results in family planning

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[10] Am. Coll. Obstetricians & Gynecologists ("ACOG"), *Committee Opinion No. 642, Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy* 2 (2015) (reaffirmed 2018), *available at* https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co642.pdf?dmc=1&ts=20170629T1443175185 (characterizing implants and IUDs as among the most effective methods of contraception); James Trussell et al., *Cost Effectiveness of Contraceptives in the United States*, 79 Contraception 5, 13 (2009); Paul D. Blumenthal et al., *Strategies to Prevent Unintended Pregnancy: Increasing Use of Long-Acting Reversible Contraception*, 17 Hum. Reprod. Update 121, 131 (2011).

[11] David Eisenberg et al., *Cost as a Barrier to Long-acting Reversible Contraceptive (LARC) Use in Adolescents*, 52 J. Adolescent Health S59, S60 (2013), http://www.jahonline.org/article/S1054-139X(13)00054-2/fulltext.

[12] Planned Parenthood, How Do I Get Birth Control Pills?, https://www.plannedparenthood.org/learn/birth-control/birth-control-pill/how-do-i-get-birth-control-pills.

[13] The 2019 HHS poverty guidelines state $25,750 as the poverty level for a family of four. Office of the Assistant Sec'y for Planning and Evaluation, U.S. Dep't of Health & Hum. Svcs., *2019 Poverty Guidelines*, https://aspe.hhs.gov/2019-poverty-guidelines.

[14] Bixby Ctr. for Global Reprod. Health, *The Impact of Title X on Publicly Funded Family Planning Services in California: Access and Quality* 6 (2014), https://bixbycenter.ucsf.edu/sites/bixbycenter.ucsf.edu/files/OPAreportRev_April2014.pdf.

providers that are more likely to participate in clinical training opportunities that help clinicians offer higher quality, evidence-based services and are more likely to use advanced technologies.[15]

24. Furthermore, my research shows that, within Family PACT, Title X funding leads to better access for clients to family planning services. A greater proportion of Title X providers than non-Title X public and private providers offered onsite services for the following birth control methods: intrauterine contraceptives (90% Title X, 51% public non-Title X, 38% private); contraceptive implants (58% Title X, 19% public non-Title X, 7% private); vasectomy (8% Title X, 4% public non-Title X, 1% private); and fertility-awareness methods (69% Title X, 55% public non-Title X, 49% private).[16]

25. Title X clinics in California's Family PACT program are significantly more likely to provide LARC methods, such as contraceptive impacts and intrauterine contraceptives, than non-Title X providers: the odds of a clinic providing LARC services are 35% less at public non-Title X clinics and 61% less at private clinics, compared to Title X clinics.[17]

26. Title X clinics are more likely to offer the option of insertion of a LARC in a single visit, without requiring the patient to make an appointment to return. Same-day insertion of LARC devices is an essential component of effective family planning because it eliminates the time and cost associated with follow-up visits and the risk that patients will be unable to return at a later time, or become pregnant in the interim.[18]

27. Title X clinics are more likely to provide contraceptives on site, helping women avoid a separate trip to a pharmacy or a repeat appointment: 72% of Title X clinics provide the pill on site, compared with 40% of non-Title X clinics.[19] The "quick-start" protocol for oral

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[15] *Id*. at 15.

[16] Heike Thiel de Bocanegra et al., *Onsite Provision of Specialized Services: Does Title X Funding Enhance Access?*, 23 J. Women's Health 428 (2014), https://www.liebertpub.com/doi/abs/10.1089/jwh.2013.4511. *See also* Bixby Ctr. for Global Reprod. Health, *supra* note 14 at 12.

[17] Bixby Ctr. for Global Reprod. Health, *supra* note 14 at 14.

[18] See ACOG, *Committee Opinion No. 615, Access to Contraception* 4 (2015) (reaffirmed 2017), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co615.pdf?dmc=1.

[19] Zolna & Frost, *supra* note 8, at 15, 19, 31.

contraceptives, wherein women start taking pill immediately rather than waiting until a specific point on their menstrual cycle (widely accepted by professional associations and experts), is more likely to be offered at a Title X clinic (87%) than at a non-Title X clinic (66%).[20] Title X clinics are also more likely than non-Title X clinics to supply contraceptives without requiring a pelvic exam: 88% of Title X clinics do not require a pelvic exam, compared with 76% of non-Title X clinics.[21] This practice follows clinical guidelines established by the World Health Organization and the American College of Obstetricians and Gynecologists.[22]

28. Title X funding helps clinicians receive training and spend time with patients to offer detailed contraceptive options counseling.[23] Title X clinicians spend more time on patients' initial visits for contraceptive care than clinicians at non-Title X clinics, particularly with patients who are younger, have limited English proficiency, or have other specific medical or personal needs.[24]

29. California's Title X providers are more likely than other publicly funded family planning providers to provide outreach services, and to offer extended clinic hours.[25] They are also more likely than other publicly funded family planning providers to provide sexual and reproductive health education to their communities.[26] Health education helps connect individuals to healthcare and information needed to support their reproductive health goals.

30. These data are all important because a patient's choice of a method of

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[20] *Id.* at 15, 17, 31.

[21] *Id.* at 17, 21, 31.

[22] World Health Org., *Selected Practice Recommendations for Contraceptive Use* (3rd. ed. 2016), https://www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/; ACOG, *Committee Opinion No. 754, The Utility of and Indications for Routine Pelvic Examinations*, 132 Obstetrics & Gynecology e174 (2018), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co754.pdf.

[23] Adam Sonfield et al., Guttmacher Inst., *Moving Forward: Family Planning in the Era of Health Reform* 15 (2014), https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

[24] Jennifer J. Frost et al., Guttmacher Inst., *Variation in Service Delivery Practices Among Clinics Providing Publicly Funded Family Planning Services in 2010* 15, (2012), https://www.guttmacher.org/sites/default/files/report_pdf/clinic-survey-2010.pdf.

[25] Bixby Ctr. for Global Reprod. Health, *supra* note 14 at 15.

[26] *See* Bixby Ctr. for Global Reprod. Health, *supra* note 14.

contraceptive may be influenced by ease of access and on-site availability. Some patients are reasonably hesitant to choose a contraceptive method if it requires them to go to another site, and therefore will choose a less effective or perhaps, feel compelled to accept a more invasive method that is available on-site rather than facing barriers to accessing care elsewhere, such as transportation, scheduling challenges, lack of trust. Moreover, delayed access to care puts patients at greater risk of unintended pregnancy and sexually transmitted infections ("STIs"), including the complications that develop from belated detection. Thus, when providers do not provide all FDA-recommended methods or when they do so with delays, gaps in coverage may occur or a client may use a contraceptive method that is not her preferred choice or not the one that is most medically appropriate for her.[27] Title X providers have been very effective at preventing such gaps in coverage.[28]

31. Providing a range of contraceptive options helps Title X providers offer their clients more satisfactory methods of family planning, which in turn increases the effectiveness of contraception. Women who use a contraceptive method with which they are satisfied are more likely to use contraception correctly and consistently.[29] For instance, a study showed that only 35% of women who were satisfied with their use of oral contraceptives had skipped a dose in the previous three months, as compared to 48% of women who were unsatisfied.[30]

32. Current Title X provider practices reflect advances in contraceptive technology that have occurred in recent decades. Currently available LARC methods are now considered

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[27] Women may prefer specific methods not only because of their efficacy in preventing pregnancy, but also due to side effects, interactions with other medications, risk of sexually transmitted infections, and other considerations. Lauren N. Lessard et al., *Contraceptive Features Preferred by Women at High Risk of Unintended Pregnancy*, 44 Persp. on Sexual and Reprod. Health 194 (2012), https://www.guttmacher.org/journals/psrh/2012/09/contraceptive-features-preferred-women-high-risk-unintended-pregnancy.

[28] Adam Sonfield, *Why Family Planning Policy and Practice Must Guarantee a True Choice of Contraceptive Methods*, 20 Guttmacher Pol'y Rev. 103 (2017), https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods.

[29] Jennifer J. Frost & Jacqueline E. Darroch., *Factors Associated with Contraceptive Choice and Inconsistent Method Use, United States, 2004*, 40 Persp. on Sexual and Reprod. Health 94 (2008), https://www.ncbi.nlm.nih.gov/pubmed/18577142.

[30] *Id.*

easy to use, safe, long-lasting, quickly reversible, and highly effective in preventing pregnancy; they are also highly cost-effective over the long run, despite their up front cost.[31] Updated medical practice guidelines recommend their use for a majority of women of all ages.[32] Provider education and training makes a difference in the uptake of this highly effective form of birth control.[33]

33. The Final Rule puts all of this at risk. It would undoubtedly force clinics that currently provide the full range of contraceptive options out of the program—either because they would refuse to comply with the interference in the provider-patient relationship the Final Rule commands, or because they could not logistically and economically comply with the Final Rule's separation requirements, or both. Indeed, as Planned Parenthood itself made clear in comments on the proposed rule, *all* of its member affiliates and numerous States would be forced to withdraw from the Title X program if the Gag Requirement goes into effect. It would accordingly also eliminate a valuable resource to women who count upon their reproductive health provider as the entry point for any number of other medical services unrelated to reproductive health. And it would seemingly impose all of these hardships in service of emphasizing family-planning methods—such as natural family planning—that are universally regarded as ineffective.[34]

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[31] Donna Shoupe, *LARC methods: Entering a New Age of Contraception and Reproductive Health*, 1 Contraception & Reprod Med., Feb. 23, 2016.

[32] *See, e.*g., ACOG, *Committee Opinion No. 450: Increasing Use of Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy*, 114 Obstetrics Gynecology 1434 (2009); Am. Acad. of Pediatrics, *Policy Statement: Contraception for Adolescents*, 134 Pediatrics e1244, e1251 (2014).

[33] Tess L. Weber et al., *Exploring the Uptake of Long-Acting Reversible Contraception in South Dakota Women and the Importance of Provider Education*, 70 J. S. D. Med. Ass'n 493 (2017).

[34] *See* CDC, *Effectiveness of Family Planning Methods*, https://www.cdc.gov/reproductivehealth/contraception/unintendedpregnancy/pdf/Contraceptive_methods_508.pdf; *see also* Robert A. Hatcher, *Contraceptive Technology* 844-845 (21st Ed., 2018), available at http://www.contraceptivetechnology.org/wp-content/uploads/2013/09/Contraceptive-Failure-Rates.pdf; American Sexual Health Association, *Birth Control Method Comparison Chart* (2013), http://www.ashasexualhealth.org/pdfs/ContraceptiveOptions.pdf.

34. As I explained in my comment letter, when considering whether to finalize the proposed rule, the Department should have considered how the changes in Title X would undermine not only access to reproductive health care, but also to important primary health care screenings and referrals that many women depend upon, as well as the extent to which this impact would increase costs to the health care system.

35. As the Final Rule shows, HHS plainly failed to do so—largely ignoring or simply disregarding these serious health care consequences.

36. In my opinion, based on nearly four decades of work in this area, these public-health care consequences of the Final Rule will be numerous and severe. I focus on these in the sections below.

III. California Title X Clinics Are Diverse, and Include Clinics Specializing in Women's Health

37. California's diverse Title X provider network includes federally qualified health centers (FQHCs), community health centers, city and county health departments, hospitals, school-based health clinics, stand-alone family planning clinics, and Planned Parenthood affiliates. Each provider type plays an important role in enabling access to family planning services.

38. The Final Rule is clearly designed to make it impossible for reproductive health-focused providers, like Planned Parenthood health centers, to continue to serve people through the program. This is a grave public health mistake, one with far-reaching consequences.

39. High-quality, specialized women's health clinics, including Planned Parenthood affiliates and other specialty women's reproductive health clinics, are a valuable part of the Title X network. As the Guttmacher Institute has detailed, in 2015, Planned Parenthood facilities made up just 6% of publicly funded clinics providing contraceptive services, yet 32% of all female contraceptive clients who visited a publicly funded clinic visited a Planned Parenthood facility.[35]

[35] Jennifer J. Frost et al., Guttmacher Inst., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* 1, 9(2017), https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf. "Publicly funded clinic" is defined as "a site [that serves at least 10 contraceptive clients per year] that offers contraceptive services to the

40. A majority of women (6 in 10) who receive contraceptive services at a clinic focused on reproductive healthcare choose the specialist provider explicitly; for the remaining 4 in 10 women, the specialist reproductive healthcare clinic was their only healthcare provider in the past year, despite the presence of other healthcare providers in their communities.[36] Women explain their preferences for reproductive healthcare clinics by saying that "The staff here treat me respectfully" (84%), "Services here are confidential" (82%), and "The staff here know about women's health" (80%).[37]

41. Title X providers' focus on family planning and women's health issues serve an important function in the family planning network as models for evidence-based practice of reproductive healthcare.[38] The Final Rule will have the perverse effect of driving out some of the most effective health care providers from the Title X program, Planned Parenthood especially.

IV. The Final Rule Radically Underestimates the Costs That It Will Impose

42. Research has shown that consistent and correct use of contraception helps women avoid unintended pregnancies. Among women who are sexually active, but who do not want to become pregnant, only 5% of unintended pregnancies occur among women who consistently and correctly use contraception.[39]

43. Title X clinics help women achieve their desired timing and spacing of pregnancies. In 2015, Title X providers helped women avoid an estimated 822,000 unintended

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general public and uses public funds (e.g., federal, state or local funding through programs such as Title X, Medicaid or the federally qualified health center program) to provide free or reduced-fee services to at least some clients." "Female contraceptive client" is defined as "a woman who made at least one initial or subsequent visit for contraceptive services during the 12-month reporting period … includ[ing] all women who received a medical examination related to the provision of a contraceptive method, made supply-related return visits, received contraceptive counseling and a method prescription but deferred the medical examination, or chose nonmedical contraceptive methods."

[36] Jennifer J. Frost et al., *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*, 22 Women's Health Issues e519 (2012), https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/j.whi.2012.09.002.pdf.

[37] *Id.*

[38] Bixby Ctr. for Global Reprod. Health, *supra* note 14, at 15.

[39] Sonfield et al., supra note 23, at 8-9.

pregnancies, which would have resulted in approximately 387,000 births and 278,000 abortions.[40] The U.S. rate of unintended pregnancy would have been 31% higher, and the rate of teen unintended pregnancy would have been 44% higher, without the services provided by these Title X clinics.[41]

44. In 2017, Title X clinics served 3.1 million women at risk of unintended pregnancy, and 70% (2.2 million women) left their last appointment with either a most-effective contraceptive method (such as sterilization, implant or IUD) or a moderately-effective contraceptive method (such as the shot, the ring, the patch, or the pill).[42] These methods are far more effective at preventing pregnancy than the low-cost options that are available over the counter in a drugstore (such as make condoms and spermicide).[43]

45. Women who are able to time and space their pregnancies are able to focus on accomplishing their educational and professional goals. Title X clinics therefore support women's economic stability and advancement.[44] A survey conducted at Title X clinics in 2011 found that contraception helped 63% of women to take better care of themselves or their families, 56% to support themselves financially, 51% to complete their education, and 50% to obtain or keep a job.[45] The same survey found that 65% of women were seeking contraceptive care because they were unable to care for a baby or another baby, 63% were not ready to have children, 60% felt that contraception gave them control over their lives, and 60% wanted to wait to have a child until their lives were more stable.[46]

46. Access to contraception is associated with economic benefits and reduced incidence of adverse mental health conditions. Women's ability to use oral contraceptives is

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[40] Frost et al., *supra* note 35, at 1, 10.
[41] *Id.* at 1.
[42] Fowler et al., *supra* note 3, at ES-2, 30.
[43] Hatcher et al., *supra* n.34.
[44] Urban Inst., *'Birth Control is Transformative': Women Share Their Experiences with Contraceptive Access* (2019), https://www.urban.org/sites/default/files/publication/99912/birth_control_is_transformative_1.pdf
[45] Jennifer J. Frost & Laura Lindberg, *Reasons for Using Contraception: Perspectives of U.S. Women Seeking care at Specialized Family Planning Clinics*, 87 Contraception 465 (2013), https://www.ncbi.nlm.nih.gov/pubmed/23021011.
[46] *Id.*

correlated with their ability to obtain higher levels of education, participate more fully in the workforce, and receive more pay—a combination that has helped reduce the gender pay gap.[47] Indeed, one study shows that proximity to Planned Parenthood was associated with higher rates of high school completion among adolescent girls, one of the major drivers in preventing poverty.[48]

47. And since contraception assists women to decide whether and when to have children, it may help individuals avoid the increased instances of depression and anxiety and the decreased sense of happiness that accompany births from unintended pregnancies.[49]

48. Conversely, unintended pregnancies carry increased risks. There are several risks to infants and mothers that occur more frequently with unintended pregnancies than with planned pregnancies. In some instances, preexisting health conditions, such as having recently given birth, obesity, or diabetes, make it important for women to be able to delay becoming pregnant.[50] If women with these conditions become pregnant before the conditions are properly managed, they risk pregnancy loss, stillbirths, pre-term births, fetal growth that is either too small or too large relative to gestational age, birth defects, and increased risk of hypoglycemia (low blood

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[47] Martha J. Bailey & Jason M. Lindo, Nat'l Bureau of Econ. Research, *Access and Use of Contraception and Its Effects on Women's Outcomes in the U.S.: NBER Working Paper 23465*, (2017); Adam Sonfield et al., Guttmacher Inst., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children* 7-17 (2013), https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.

[48] R. Alta Charo, *The Trump Administration and the Abandonment of Teen Pregnancy Prevention Programs*, 177 JAMA Internal Med. 1557 (2017).

[49] Jessica D. Gipson et al., *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature*, 39 Studies in Family Planning 18 (2008), https://www.ncbi.nlm.nih.gov/pubmed/18540521.

[50] ACOG, *Committee Opinion No. 654, Reproductive Life Planning to Reduce Unintended Pregnancy* 127 Obstetrics & Gynecology 415 (2016), https://www.ncbi.nlm.nih.gov/pubmed/26942389 ,; ACOG, *Frequently Asked Questions No. 182, Obesity and Pregnancy* (2016), https://www.acog.org/-/media/For-Patients/faq182.pdf?dmc=1&ts=20170630T0349076575; ACOG, *Frequently Asked Questions No. 142, Diabetes and Women* (2016), https://www.acog.org/-/media/For-Patients/faq142.pdf?dmc=1&ts=20170630T0346285947.

Planned Parenthood discusses such conditions with patients to help inform physicians' and patients' discussions regarding timing and planning for a safe pregnancy. Planned Parenthood, *Pre-Pregnancy Health*, https://www.plannedparenthood.org/learn/pregnancy/pre-pregnancy-health; *see also* Office of Disease Prevention and Health Promotion, 2020 Topics & Objectives, Family Planning, Overview, https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning (regarding importance of pre-conception care).

sugar) or respiratory distress for the baby.[51] In addition, pregnant women who are obese may be at increased risk for a variety of adverse health outcomes, including increased instances of gestational diabetes and sleep apnea, and an increased risk for cesarean delivery.[52]

49. The effects of unintended pregnancies on infants after birth may persist into childhood and even adulthood. For example, children from unintended pregnancies are more likely to experience poor mental and physical health during childhood, and they have lower educational attainment and more behavioral issues in their teen years.[53] Infants who are born to mothers who are overweight or obese (whether those pregnancies were intended or unintended) may have higher body mass indexes into adulthood, and infants who are born to mothers with diabetes may experience long-term risks of obesity, cardiovascular disease, and renal disease.[54]

50. In addition, because women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, they are more likely to receive prenatal care only later in their pregnancies—or not at all.[55] They are also more likely during their pregnancies to smoke and consume alcohol, experience depression, and be victims of domestic violence.[56]

51. The Final Rule will undermine these benefits of access to contraception and family planning services. Meanwhile, the Final Rule radically underestimates the costs it will impose on

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[51] *See* ACOG sources cited *supra* note 50.

[52] ACOG, Frequently Asked Questions No. 142, *supra* note 50.

[53] Office of Disease Prevention and Health Promotion, *supra* note 50.

[54] Liliana Garcia-Vargas et al., *Gestational Diabetes and the Offspring: Implications in the Development of the Cardiorenal Metabolic Syndrome in Offspring*, 2 CardioRenal Med. 134, 136-38 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3376343/pdf/crm-0002-0134.pdf.

[55] Diana Cheng et al., *Unintended Pregnancy and Associated Maternal Preconception, Prenatal and Postpartum Behaviors*, 79 Contraception 194, 196 (2009).

[56] *Id.*; *see also* ACOG, Committee Opinion No. 654, *supra* note 50; Mary K. Ethen et al., *Alcohol Consumption by Women Before and During Pregnancy*, 13 Maternal Child Health J., 274, 278-79, 281 (2009), https://www.ncbi.nlm.nih.gov/pubmed/18317893; Christie A. Lancaster et al., *Risk Factors for Depressive Symptoms During Pregnancy: A Systematic Review*, 202 Am. J. Obstetrics & Gynecology 5, 11 (2010), https://www.ajog.org/article/S0002-9378(09)01014-X/pdf; Lois James et al., *Risk Factors for Domestic Violence During Pregnancy: A Meta-Analytic Review*, 28 Violence & Victims 359, 368-69 (2013), https://www.researchgate.net/publication/249995549_Risk_Factors_for_Domestic_Violence_During_Pregnancy_A_Meta-Analytic_Review.

patients, providers, and society, given the increase an unplanned and mistimed pregnancies it will likely cause.

52. That increase is a near certainty under the Final Rule—and indeed it is practically the Final Rule's goal, given in my view its solicitude for low-efficacy family planning methods like "natural family planning or other fertility awareness-based methods." 84 Fed. Reg. at 7,787 (to be codified at 42 C.F.R. § 59.2). Patients who lose access to contraceptive services at current Title X clinics are likely to use less effective forms of birth control. For example, in a study encompassing a variety of clinic types participating in California's publicly funded family planning program ("Family PACT"), individuals were asked what they would do if they had to pay for their family planning services.[57] Responses indicated that, on the whole, patients would use less effective means of contraception. Specifically, patients reported that their use of low-efficacy methods, such as condoms, would nearly double (from 25% to 46%).[58] Patients' projected use of medium-efficacy methods, such as contraceptive injections, oral contraceptives ("OCs"), and the contraceptive patch and ring, would decrease from 63% to 44%.[59] Patients' use of high-efficacy methods, such as IUDs, contraceptive implants, and sterilization, would decrease from 11% to 7%.[60] And use of no method of birth control at all would increase from 2% to 3%.[61]

53. It is no surprise that this decrease in the use of high-efficacy contraception methods and increase in use of low-efficacy methods will result in more unintended pregnancies. High-efficacy methods have failure rates of less than 1%, meaning that fewer than 1% of women using these methods will experience an unintended pregnancy within the first year of use.[62] Medium-efficacy methods have failure rates of 6-12%, because some women miss or delay

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[57] M. Antonia Biggs et al., Bixby Ctr. for Global Reprod. Health, *Findings from the 2012 Family PACT Client Exit Interviews* 53 (2014), http://www.familypact.org/Research/reports/10-24-2015CEI-Report.pdf.

[58] *Id.* at 53. Low-efficacy methods include condoms, diaphragms, and other barrier methods; natural family planning; abstention; and emergency contraception. *Id.*at 34.

[59] *Id.* at 34, 53.

[60] *Id.*

[61] *Id.* at 54.

[62] CDC, *supra* note 34; ACOG, Committee Opinion No. 642, *supra* note 10, at 2.

injection or ingestion of the pill.[63] Low-efficacy methods, including male condoms, have failure rates of 18% or higher.[64] Using no method of contraception has a failure rate of 85%.[65] These failure rates explain why the Guttmacher Institute estimated that in 2015, Planned Parenthood's provision of contraceptive services averted approximately 430,000 unintended pregnancies.[66]

54. This projected increase in unintended pregnancies is not speculative. It is rooted in experience. For example, after the State of Texas severely restricted public funding for family planning and excluded Planned Parenthood from its publicly funded family planning programs, a study in the New England Journal of Medicine reported a 35% decline in women using the most effective methods of family planning and a 27% increase in births among women who had been using an injectable contraceptive methods prior to Texas's restrictions.[67] The same study showed that the number of claims submitted for LARC contraceptives in counties where Planned Parenthood affiliates were located decreased sharply.[68] Researchers concluded that their

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[63] CDC, *supra* note 34; ACOG, Committee Opinion No. 642, *supra* note 10, at 1-2.

[64] CDC, *supra* note 34; ACOG, Committee Opinion No. 642, *supra* note 1010, at 2.

[65] James Trussell, *Contraceptive Failure in the United States*, 83 Contraception 397, 398 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/pdf/nihms458000.pdf.

[66] Guttmacher Inst., *Unintended Pregnancies and Abortions Averted by Planned Parenthood*, https://www.guttmacher.org/infographic/2017/unintended-pregnancies-and-abortions-averted-planned-parenthood-2015; s*ee also* M. Antonia Biggs et al., Bixby Ctr. for Global Reprod. Health, *Cost-Benefit Analysis of the California Family PACT Program for Calendar Year 2007*, at 16, 17 (2010), https://www.ansirh.org/sites/default/files/publications/files/familypactcost-benefitanalysis2007_2010apr_featured.pdf (in California, across all publicly funded contraceptive providers—including Planned Parenthood—it was estimated that, for every seven women who received publicly funded contraceptive services, two pregnancies were averted. There, in one year, it was estimated that provision of contraceptive services to 998,084 clients averted 286,700 unintended pregnancies).

[67] Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women's Health Program*, 374 New Eng. J. Med. 853, 858 (2016), https://www.nejm.org/doi/pdf/10.1056/NEJMsa1511902. *See also* Kari White et al., *The Impact of Reproductive Health Legislation on Family Planning Clinic Services in Texas*, 105 Am. J. Pub. Health 851, 851 (2015). White and colleagues describe how, in 2011, prior to Planned Parenthood's outright exclusion from Texas's publicly funded family planning program, Texas substantially cut public funding for family planning providers and imposed a priority system of reimbursement for services that placed certain providers, including Planned Parenthood, at the bottom of the hierarchy. In the year following those cuts, 54% fewer clients received publicly funded family planning services. *Id.* at 855. Providers suspected that clients stopped seeking reproductive health care. *Id.* at 856.

[68] Stevenson, *supra* note 67, at 856-58.

"analyses suggest that the exclusion of Planned Parenthood affiliates from the Texas Women's Health Program had an adverse effect on low-income women in Texas by reducing the provision of highly effective methods of contraception, interrupting contraceptive continuation, and increasing the rate of childbirth covered by Medicaid."[69]

55. Iowa enacted similar restrictions in 2017. In April through June 2018, the state's family planning program covered only 970 family planning services like contraception, a 73% drop from the 3,637 services provided in the same period of the previous year, when Planned Parenthood and other similar providers were included in the program.[70] Additionally, the total number of patients enrolled in the program dropped 51% year-over-year, to 4,177 in June 2018 from 8,570 in June 2017.[71]

56. The fiscal costs of these additional unintended pregnancies are immense. In 2010, approximately $2.2 billion in public funds were spent on family planning and related sexual and reproductive health services (such as STI testing).[72] Those services were estimated to have averted approximately 2.2 million unintended pregnancies, among other adverse health outcomes.[73] The estimated public costs associated with those unintended pregnancies and outcomes—*i.e.*, maternity care, birth, child health care through 5 years of age, miscarriages or abortions, and treating the effects of undetected STIs—would have been $15.8 billion, $15.2 billion of which is attributable to publicly covered maternity and child health care.[74] Accordingly, publicly funded family planning and related care saved $13.6 billion in public

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[69] *Id.* at 858-59.

[70] Tony Leys & Barbara Rodriguez, *State Family Planning Services Decline 73 Percent in Fiscal Year as $2.5M Goes Unspent*, Des Moines Register, Oct. 18, 2018, https://www.desmoinesregister.com/story/news/health/2018/10/18/iowa-health-care-family-planning-contraception-services-planned-parenthood-abortion-medicaid/1660873002/.

[71] *Id.*

[72] Jennifer J. Frost et al., Guttmacher Inst., *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, 92 Milbank Q. 667, 696 (2014), http://www.ncbi.nlm.nih.gov/pubmed/25314928.

[73] *Id.* at 692.

[74] Id. at 668, 696. The average public cost per birth, from prenatal care through infant care through 12 months of age, is $12,770. *Id.* at 712.

costs.[75] In other words, for every public dollar spent on contraceptive care, the public saved $7.09 in costs associated with unintended pregnancies and other reproductive health issues (through age 5).[76] To give another example, in 2007 California's Family PACT averted 286,700 unintended pregnancies that saved the state over $4 billion from conception to age 5 in the form of public-sector health care and social services.[77] For every public dollar spent on contraceptive care in California that year, the public saved $9.25 in costs associated with unintended pregnancies (through age 5).[78]

57. The Final Rule will not only raise the rate of unintended pregnancy, it will likely cause more abortions. It will do so by encouraging low-efficacy methods of family planning and decreasing access to contraceptives and, therefore, increasing unintended pregnancies. Studies show that, as the rate of contraceptive use by unmarried women increased in the U.S. between 1982 and 2001, rates of abortion for unmarried women also declined.[79] A study regarding California's Family PACT program estimated that the provision of contraception to approximately one million women and 100,000 men through that program in 2007 prevented approximately 122,200 abortions.[80] Similarly, when Iowa increased access to contraceptive services over the course of 2006 to 2008, studies found lower abortion rates.[81] It is likely that a decrease in contraceptive use will not only raise the rate of unintended pregnancy, then, but also raise the rate and number of abortions.

58. According to HHS, the Final Rule is justified in part because it would increase the availability of family planning methods such as "sexual risk avoidance" and "natural family planning." However, these family planning methods are universally regarded as ineffective and

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[75] *Id.* at 696.
[76] *Id.* at 668, 696.
[77] Biggs et al., *supra* note 66, at 23.
[78] *Id.* at 20.
[79] Heather D. Boonstra et al., Guttmacher Inst., *Abortion in Women's Lives* 18 (2006), https://www.guttmacher.org/sites/default/files/pdfs/pubs/2006/05/04/AiWL.pdf.
[80] Biggs et al., *supra* note 66, at 6, 16.
[81] M. Antonia Biggs et al., *Did Increasing Use of Highly Effective Contraception Contribute to Declining Abortions in Iowa?*, 91 Contraception 167, 169 (2015), https://cloudfront.escholarship.org/dist/prd/content/qt9md7v7sn/qt9md7v7sn.pdf (study included 78 service sites, 24 of which were affiliated with Planned Parenthood).

inferior to the wide range of medically-approved alternatives, and would not promote public health.

59. The Final Rule would impose costs associated with loss of Title X health centers' access to testing, counseling, and treatment for sexually transmitted infections (STls) and reproductive cancers.

60. In 2017, Title X providers tested 61% of all female patients under age 25 (939,900 individuals) for chlamydia and performed 2.4 million gonorrhea tests, 1.2 million HIV tests, and 700,000 syphilis tests.[82] Of the HIV tests that were performed, 2,200 were shown to be positive.[83]

61. According to estimates from Guttmacher Institute, these STI services alone averted approximately[84] 90 to 400 cases of HIV[85] and 47,740 to 56,670 other STls—and, in turn, many pelvic inflammatory disease (PID) cases, ectopic pregnancies, and infertility cases.[86]

62. Reduced STI testing means that STIs will go undiagnosed or will be diagnosed much later. This will put STI-positive patients and their partners at greater health risk. In general, women who contract STIs suffer adverse reproductive health outcomes.[87] STIs in women are often asymptomatic[88] but can result in PID—a major cause of infertility—ectopic

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[82] Fowler et al., *supra* note 3, at 44-47.

[83] *Id.* at 44.

[84] The tool provided by Guttmacher requires inputting a state where the service is provided. California data was used as a case study (as it represents one of the largest states by population and numbers of Planned Parenthoods) for calculating the potential outcomes among all of the following examples.

[85] A range is provided because the estimated health outcomes depend on whether HIV tests were provided to male or female clients, which was not specified in Planned Parenthood's report. The result of 90 cases of HIV assumes all tests were administered to women; the result of 400 cases assumes all tests were administered to men.

[86] Guttmacher Inst., *Data Center, Health Benefits and Cost Savings of Publicly Funded Family Planning*, https://data.guttmacher.org/calculator. The tool provided by Guttmacher is limited in the type of STI tests that can be entered and the type of STls it indicates were averted. This range assumes that all STI tests provided by Planned Parenthood were for chlamydia, and reflects the number of chlamydia cases likely averted were that assumption true. The low end of the range assumes all tests were provided to women; the high end assumes all tests were provided to men.

[87] *See* David Friedel & Suzanne Lavoie, *Epidemiology and Trends in Sexually Transmitted Infections*, in *Public Health & Preventive Medicine* 155, 159 (Robert B. Wallace et al. eds., 2008).

[88] CDC, *Sexually Transmitted Disease Surveillance 2017* 3, 31, 37, 38, 40, 41 (2018),

pregnancy, and chronic pelvic pain.[89] Chlamydia infections also facilitate the transmission of HIV infections.[90] In some cases, pregnant women infected with chlamydia can pass the infection to their infants during delivery, potentially resulting in ophthalmia neonatorum, which can lead to blindness and pneumonia.[91] Untreated syphilis infections in pregnant women can cause significant complications, including fetal death in up to 40% of pregnant women or preterm birth.[92] It can lead to infection of the fetus in 80% of cases, which can result in both physical and mental developmental disabilities.[93] Additionally, an undiagnosed or belatedly diagnosed STI means more opportunity for the infection to be spread to others.

63. Title X clinics provide services to screen for women's reproductive cancers, specifically Pap tests, HPV screening, and HPV vaccinations, all of which seek to detect and prevent cervical cancer. Pap tests, which are often performed alongside HPV tests, aim to detect any abnormal or precancerous cells and enable early treatment of cervical cancer.[94] HPV vaccinations protect patients from the strains of the virus that cause cervical cancer, as well as those that can lead to cancer of the vulva, vagina, anus, rectum, and oropharynx.[95]

64. In 2017, Title X clinics provided Pap tests to 18% of all female patients (649,300 individuals); 14% of these tests returned abnormal results that would call for further investigation

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https://www.cdc.gov/std/stats17/2017-STD-Surveillance-Report_CDC-clearance-9.10.18.pdf.

[89] Kristen Kreisel et al., *Prevalence of Pelvic Inflammatory Disease in Sexually Experienced Women of Reproductive Age—United States 2013-2014*, 66 Morbidity & Mortality Wkly Rpt. 80, 80 (2017); CDC, *Pelvic Inflammatory Disease (PID) – CDC Fact Sheet* (2017), https://www.cdc.gov/std/pid/PID-FS-July-10-2017.pdf. Approximately 10-20% of women with chlamydia or gonorrhea may develop PID without adequate treatment. CDC, *supra* note 88, at 37.

[90] CDC, *supra* note 88, at 3, 11, 23.

[91] *Id.* at 3.

[92] *Id.* at 23.

[93] *Id.* at 23, 38.

[94] Adam Sonfield, *Beyond Preventing Unplanned Pregnancy: The Broader Benefits of Publicly Funded Family Planning Services*, 17 Guttmacher Pol'y Rev. 2, 3 (2014), https://www.guttmacher.org/gpr/2014/12/beyond-preventing-unplanned-pregnancy-broader-benefits-publicly-funded-family-planning.

[95] CDC, *Human Papillomavirus: Why is HPV Vaccine Important* (2017), https://www.cdc.gov/hpv/hcp/hpv-important.html.

or possible treatment.[96] In 2010, it is estimated that Title X clinics helped to prevent 2,000 cases of cervical cancer.[97]

65. A 2010 analysis found that the publicly funded clinics' role in screening, testing, and preventing STIs during family planning visits saved an estimated $123 million taxpayer dollars that year, in the form of costs to treat PID or other results of untreated chlamydia or gonorrhea, HIV infections, and HPV sequelae.[98] Early detection of HIV can reduce transmission of the virus due to changes in individuals' sexual behavior following a positive diagnosis, as well as the effects of treatment on levels of the virus that could be transmitted.[99] Even a relatively small number of averted HIV/AIDS cases results in substantial savings.

66. HHS plainly failed to recognize, evaluate, and justify these additional consequences and costs that would likely occur if a large number of agencies—about 650 hundred Planned Parenthood centers alone—would no longer be part of the network of family planning agencies providing Title X services. These impose an unnecessary burden on the Title X program and the country.

V. The Final Rule Would Exacerbate Existing Health Care Disparities

67. The Final Rule would exacerbate the disparities in health care that are already pervasive across the country. The adverse consequences discussed above are likely to be felt most intensely by historically underserved populations, including populations living in rural America. As studies have shown, people of color in the United States are disproportionately unable to gain access to and benefit from high-quality health care.[100]

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[96] Fowler et al., *supra* note 3, at 41.

[97] Frost et al., *supra* note 72, at 693.

[98] *Id.* at 696.

[99] Gary Marks et al., *Meta-analysis of High-risk Sexual Behavior in Persons Aware and Unaware They Are Infected with HIV in the United States: Implications for HIV Prevention Programs*, 39 J. Acquired Immune Deficiency Syndromes 446 (2005), https://www.ncbi.nlm.nih.gov/pubmed/16010168.

[100] *See generally* Sec'y's Advisory Comm. on Nat'l Health Promotion and Disease Prevention Objectives for 2020, *Healthy People 2020: An Opportunity to Address Societal Determinants of Health in the U.S.* (2010), https://www.healthypeople.gov/sites/default/files/SocietalDeterminantsHealth.pdf; Shiriki K. Kumanyika & C. Morrissink, *Bridging Domains in Efforts to Reduce Disparities in Health and Health Care*, 33 Health Educ. Behav. 440 (2006).

68. Specifically, although unintended pregnancies occur across all income levels, races, and ages, the rates of unintended pregnancies are higher among certain groups.[101] For example, 82% of pregnancies to mothers ages 15 to 19 are unintended.[102] Women whose income is below the federal poverty level and black women and Latinas also have higher rates of unintended pregnancies than other demographic groups.[103]

69. The increased incidence of STIs is also likely to disproportionately affect low-income patients and patients of color. For example, prevalence of gonorrhea, syphilis, and chlamydia is highly dependent on the geographic area in which women live and sociodemographic factors, with increased rates occurring among Hispanic and African-American populations and among lower-income individuals.[104]

70. Current Title X providers strive to address and minimize these disparities. They offer low- or no-cost services, without requiring insurance and who are eligible for services; they have convenient clinic locations and hours; and they offer cultural- and youth-sensitive services.[105] In California specifically, among all clinics that participate in the Family PACT program, Title X-funded clinics are more likely to reduce barriers to care through extended hours, multilingual services, and community outreach efforts.[106] These Title X-funded clinics have greater proportions of bilingual staff and are more likely to provide outreach to vulnerable or hard-to-reach populations, such as adolescents; males; lesbian, gay and transgender individuals; persons experiencing homelessness, those with limited English proficiency; migrant workers;

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[101] *See, e.g.*, Blumenthal et al., *supra* note 10, at 123.

[102] Office of Disease Prevention and Health Promotion, *supra* note 50.

[103] *Id.*; Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 New Eng. J. Med. 843, 846-47 (2016); Frost et al., *supra* note 72, at 668.

[104] *Id.* at 698.

[105] *See, e.g.*, Susan A. Cohen, *Abortion and Women of Color: The Bigger Picture*, 11 Guttmacher Pol'y Rev. 2, 4-5 (2008), https://www.guttmacher.org/sites/default/files/article_files/gpr110302.pdf; Katherine H. Mead et al., *The Role of Federally Qualified Health Centers in Delivering Family Planning Services to Adolescents*, 57 J. Adolescent Health 87 (2015).

[106] Bixby Ctr. for Global Reprod. Health, *supra* note 14 at 15.

individuals coping with alcohol and substance abuse; refugees and immigrants; and persons with disabilities.[107]

71. A 2010 survey showed that a greater number of Title X clinics report being open at least two weekday nights and on weekends: 41% Title X, 23% public, non-Title X, 14% private. Title X clinics are also more likely to employ Spanish-speaking licensed clinical staff (84% Title X, 81% public non-Title X, 78% private) and unlicensed clinical staff (89% Title X, 71% public non-Title X, 58% private), as well as to post Spanish-language signage (95% Title X, 85% public non-Title X, 82% private).[108]

72. Title X providers' cultural competence is particularly important for traditionally underrepresented groups. For example, in a study of Latino adolescents, participants largely agreed with the guidelines from the National Council of La Raza, a Hispanic advocacy organization, which states that optimal pregnancy-prevention programs for Latino youth should include the following: having culturally sensitive and nonjudgmental staff, being responsive to Latino subgroup differences, emphasizing education, and recognizing cultural values regarding gender roles.[109]

73. Forcing high-quality current Title X providers out of the already limited network of providers available to these women and families will disproportionately harm already medically underserved populations. Other safety-net clinics that are not ethically forced to drop-out of the Title X program will likely not be able to pick up the additional demands for services and to provide care to a substantial proportion of the 1.6 million women, men, and adolescents who today receive vital family planning services from Planned Parenthood. Planned Parenthood clinics serve 41% of women who visit Title X clinics to receive contraception.[110] The Guttmacher

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[107] *Id.*; Heike Thiel de Bocanegra et al., *Enhancing Service Delivery Through Title X Funding: Findings from California*, 44 Persp. on Sexual and Reprod. Health 262, 265 (2012), https://onlinelibrary.wiley.com/doi/10.1363/4426212.

[108] Thiel de Bocanegra et al., *supra* note 107, at 265.

[109] Anne K. Driscoll et al., *In Their Own Words: Pregnancy Prevention Needs of Latino Teen Mothers*, 1 Cal. J. Health Promotion 118, 120 (2003), http://cjhp.fullerton.edu/Volume1_2003/Issue2-TEXTONLY/118-129-driscoll.pdf.

[110] Jennifer J. Frost et al., *supra* note 35, at 9 (data cited as of 2015).

Institute has estimated that other Title X providers (should they remain in the program) would have to increase their patient caseload by 70% to serve the women who currently receive care at Title X-funded Planned Parenthood sites.[111] In 13 states, these other providers would have to more than double their caseloads.[112]

VI. Title X Clinics Act as A Gateway to Other Healthcare Services

74. In addition to the delivery of family planning care, Title X providers play an essential and important role in connecting low-income individuals to a number of other vital health services. A survey of Title X clinics in 2016 showed that Title X clinics are the only source of medical care for 60% of their patients.[113] The confidentiality, low cost, and high quality of care that Title X clinics provide encourage many individuals to visit Title X clinics when they would otherwise refuse to visit a medical provider.[114]

75. Medical services provided by Title X-funded clinics include screenings for cervical cancer, diabetes, high blood pressure, and sexually transmitted infections (STls), among a range of other services aimed at primary prevention and referral. A study of California Family PACT providers indicated that most new clients received an initial health assessment; 83% of adults received a blood pressure test; more than 70% were screened for alcohol, tobacco and drug use; more than 60% were asked whether they had high blood pressure or diabetes; about half

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[111] Memorandum from Jennifer J. Frost and Mia R. Zolna to Senator Patty Murray, Response to Inquiry Concerning the Impact on Other Safety-Net Family Planning Providers of "Defunding" Planned Parenthood 2 (June 14, 2017), https://www.guttmacher.org/sites/default/files/article_files/guttmacher-murray-memo-2017_1.pdf.

[112] *Id.* at 6.

[113] Megan L. Kavanaugh et al., *Use of Health Insurance Among Clients Seeking Contraceptive Services at Title X-Funded Facilities in 2016*, 50 Persp. on Sexual and Reprod. Health 101, 105 (2018), https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

[114] Rachel Benson Gold, *The Role of Family Planning Centers as Gateways to Health Coverage and Care*, 14 Guttmacher Pol'y Rev. 15, 18 (2011), https://www.guttmacher.org/gpr/2011/06/role-family-planning-centers-gateways-health-coverage-and-care.

were asked whether they had gained, lost, or been maintaining their weight; and more than half were asked about interpersonal violence in the past 12 months.[115]

76. For many low-income individuals, especially women, access to this set of services represents the most trusted entry point to all medical care. Many patients are not aware of other services that may be offered in the community, and the Title X program serves as a gateway to other needed health care.

77. Title X clinics have relationships with other healthcare and social service agencies and are able to refer their patients when appropriate. For instance, 99% of Title X clinics have referral relationships with other medical providers, 97% refer to public providers, such as FQHCs or community clinics, 90% refer to private practices, 62% refer to social services agencies, and 47% refer to home visiting programs.[116]

78. The Final Rule's forced exit of existing, high-quality providers, combined with the removal of requirements, such that programs provide non-directive pregnancy options counseling, that methods of family planning contraceptives provided be medically and FDA approved, and/or that programs offer a wide range of contraceptive options, will encourage the introduction of lower-quality providers into the Title X program. Indeed, under the Final Rule, in California, a Title X provider could qualify for the funding without meeting the minimum requirements to become a Family PACT provider. The Final Rule will therefore make it harder for California Title X patients to connect with other needed healthcare services.

VII. The Final Rule Will Cause Harm Nationwide

79. The Final Rule will immediately shift Title X in a direction that will be harmful for women and costly for state and local governments.

80. The Final Rule's new limits on clinicians' ability to respond fully and accurately to patients' questions or requests concerning abortions; its removal of the requirement to offer nondirective options counseling to pregnant patients; the requirement that pregnant women to undergo coercive prenatal counseling and to receive advice on protecting the "unborn child"; and

[115] M. Antonia Biggs et al., *supra* note 57, at 85-88.
[116] Zolna & Frost, *supra* note 8, at 42.

the prohibition on referrals that identify abortion providers as such, all seek to limit the information patients receive and thus, to impede or coerce patients' informed decision-making. Without fully informed decision-making, women will be delayed from obtaining the care they desire or need, and may not receive it at all.

81. In addition, the Final Rule's requirement to involve or notify parents that their adolescent is receiving confidential healthcare reduces the likelihood that an adolescent will seek and obtain treatment from a Title X clinics. A survey of adolescent females seeking sexual health care showed that only 1% would stop having sex if a parental notification requirement were implemented, but 59% would stop using all sexual healthcare services.[117]

82. The Final Rule also limits the range and availability of contraceptive methods by encouraging non-traditional family planning providers that may offer only a single method of contraception, often natural family planning, at the expense of experienced providers that offer a range of FDA-approved contraceptive methods.

83. In addition to harms directed to women and patient care, the Final Rule will upend the existing Title X provider network by forcing Title X clinics to make an impossible choice: will they agree to provide care that violates medical and ethical guidelines in order to continue to provide some care to some patients, or will they forgo Title X funding in order to continue providing high quality care, but on a more limited scale?

84. If providers attempt to remain in the Title X program, they will have to obtain new office space, staff members, medical equipment, and office and records materials. The expense would be considerable, and would leave the clinics in a weak financial position from which to continue providing reproductive health services, especially as Title X funding levels have not increased in the previous four fiscal years.[118]

[117] Diane M. Reddy et al., *Effects of Mandatory Parental Notification on Adolescents' Use of Sexual Health Care Services*, 288 JAMA 710, 713 (2002), https://www.ncbi.nlm.nih.gov/pubmed/12169074.

[118] U.S. Dep't of Health & Hum. Servs., Office of Population Affairs, *Funding History* (August 2, 2018), https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html.

85. Other Title X clinics that do not offer abortion services may be forced out of Title X because of the Final Rule's restrictions on abortion counseling and on "activities that encourage, promote or advocate for abortion," which include developing materials, attending conferences, paying membership dues, and providing education.

86. All Planned Parenthood grantees or sub-grantees have stated that they will be forced out of the Title X program if the Final Rule goes into effect. At least four states—Washington, New York, Hawaii, and Oregon—have given similar indications.

87. A survey in 2016 found that 26% of patients at Title X-funded clinics stated that it was the only place they could go for the care they need.[119]

88. Geographic realities would also impede FQHCs' ability to absorb Title X patients: there is no FQHC that provides contraceptive services in 33% of counties that currently have at least one Title X clinics. [120] In 47% of counties with a Title X clinic, contraceptive-offering FQHCs would have to at least double their capacity to provide care for contraceptive patients, and in 24% of counties with a Title X clinic, contraceptive-offering FQHCs would have to increase their capacity by at least six times.[121] 2.8 million contraceptive patients who receive care at Title X clinics that are not FQHCs live in the 1,625 counties where either FQHCs would have to double their caseloads or there is no FQHC providing contraception.[122]

89. This analysis of FQHCs is significant because these clinics are often focused on primary care and the Final Rule's imposes a requirement that Title X providers "offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site." This requirement is unnecessary, given the work Title X clinics already do as healthcare gatekeepers, as described above.

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[119] Kavanaugh et al., *supra* note 113, at 104.

[120] Memorandum from Jennifer J. Frost and Mia R. Zolna to Senator Patty Murray, Response to Inquiry Concerning the Availability of Publicly Funded Contraceptive Care to U.S. Women 7 (May 3, 2017), https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017.

[121] *Id.*

[122] *Id.*

90. When clinics of all kinds leave Title X, the loss will not be evenly felt across the country. Rural areas or regions with few options for publicly funded family planning will be more affected if their Title X clinic leaves the program. Correspondingly, low-income individuals in those regions will suffer a greater burden to access affordable, high-quality family planning services, as well as other related services, such as STI screening and treatment.

91. Therefore, delays and gaps in care will result from the Final Rule's disruption of the Title X network. Patients will be shunted to clinics that are unable to handle the additional caseloads, and will be unable to see clinicians with whom they have an existing patient-provider relationship and who are likely to offer a broad range of contraceptive services.

92. And even if new, qualified clinics are eventually able to join Title X, the gap in time between the departure of existing grantees (perhaps in the middle of their grant periods) and the enrollment of new providers could cause serious harm due to delays in implementation. Patients may lack care for a period of months, a long time when viewed in the context of making decisions about pregnancy prevention and STIs.

VIII. Conclusion

93. Overall, the changes in the Final Rule will reorient Title X in a harmful direction that offers lower quality care to fewer patients. The benefits to individual and public health achieved by the Title X program over decades will be undone; as funding is redirected to inexperienced and unqualified entities that provide services at odds with widely accepted clinical standards of care for family planning providers.

94. Forcing Planned Parenthood and other current, high-quality Title X providers from the already limited network of providers available to women and families will undermine the effectiveness of the vital reproductive health services Title X has provided over the past decades to millions of low-income individuals in California and across the country. It will gravely harm low-income women and families who are already medically underserved, and exacerbate existing public health challenges and health disparities.

95. As high-quality clinics are pushed out of Title X, access to their services will be reduced, and fewer highly effective contraceptive methods will be prescribed and used. The results among the Title X population will be increased risk of unintended pregnancy, undetected and untreated STIs, and a general lowering of the standard of reproductive healthcare received by low-income individuals. These health effects will be felt at the individual level and as negative impacts on public health at large. Additional costs associated with unintended pregnancy will be borne by the state, and in turn, the nation.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on March 21, 2019 in San Francisco, California.

Claire Brindis, DrPH
Director, Philip R. Lee Institute for Health Policy Studies
University of California San Francisco

SA2018101519

EXHIBIT C

Claire Brindis
Centers for Disease Control and Prevention (CDC)
Quality Family Planning Guidelines

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
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Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Providing Quality Family Planning Services

Recommendations of CDC and the U.S. Office of Population Affairs

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Summary

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The recommendations outline how to provide quality family planning services, which include contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, and sexually transmitted disease services. The primary audience for this report is all current or potential providers of family planning services, including those working in service sites that are dedicated to family planning service delivery as well as private and public providers of more comprehensive primary care.

The United States continues to face substantial challenges to improving the reproductive health of the U.S. population. Nearly one half of all pregnancies are unintended, with more than 700,000 adolescents aged 15–19 years becoming pregnant each year and more than 300,000 giving birth. One of eight pregnancies in the United States results in preterm birth, and infant mortality rates remain high compared with those of other developed countries.

This report can assist primary care providers in offering family planning services that will help women, men, and couples achieve their desired number and spacing of children and increase the likelihood that those children are born healthy. The report provides recommendations for how to help prevent and achieve pregnancy, emphasizes offering a full range of contraceptive methods for persons seeking to prevent pregnancy, highlights the special needs of adolescent clients, and encourages the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine and adopted by HHS.

Introduction

The United States continues to face challenges to improving the reproductive health of the U.S. population. Nearly half (49%) of all pregnancies are unintended (*1*). Although adolescent birth rates declined by more than 61% during 1991–2012, the United States has one of the highest adolescent pregnancy rates in the developed world, with >700,000 adolescents aged 15–19 years becoming pregnant each year and >300,000 giving birth (*2,3*). Approximately one of eight pregnancies in the United States results in a preterm birth, and infant mortality rates remain high compared with other developed countries (*3,4*). Moreover, all of these outcomes affect racial and ethnic minority populations disproportionately (*1–4*).

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Family planning services can help address these and other public health challenges by providing education, counseling, and medical services (*5*). Family planning services include the following:

- providing contraception to help women and men plan and space births, prevent unintended pregnancies, and reduce the number of abortions;
- offering pregnancy testing and counseling;
- helping clients who want to conceive;
- providing basic infertility services;
- providing preconception health services to improve infant and maternal outcomes and improve women's and men's health; and
- providing sexually transmitted disease (STD) screening and treatment services to prevent tubal infertility and improve the health of women, men, and infants.

This report provides recommendations developed collaboratively by CDC and the Office of Population Affairs (OPA) of the U.S. Department of Health and Human Services (HHS). The recommendations outline how to provide family planning services by:

- defining a core set of family planning services for women and men,
- describing how to provide contraceptive and other clinical services, serve adolescents, and perform quality improvements, and
- encouraging the use of the family planning visit to provide selected preventive health services for women, in accordance with the recommendations for women issued by the Institute of Medicine (IOM) and adopted by HHS (*6*).

The collaboration between CDC and OPA drew on the strengths of both agencies. CDC has a long-standing history of developing evidence-based recommendations for clinical care, and OPA's Title X Family Planning Program (*7*) has served as the national leader in direct family planning service delivery since the Title X program was established in 1970.

This report provides recommendations for providing care to clients of reproductive age who are in need of family planning services. These recommendations are intended for all current or potential providers of family planning services, including those funded by the Title X program.

Current Context of Family Planning Services

Women of reproductive age often report that their family planning provider is also their usual source of health care (*8*). As the U.S. health-care system evolves in response to increased efforts to expand health insurance coverage, contain costs, and emphasize preventive care (*9*), providers of family planning services will face new challenges and opportunities in care delivery. For example, they will have increased opportunities to serve new clients and to serve as gateways for their clients to other essential health-care services. In addition, primary care and other providers who provide a range of health-care services will be expected to integrate family planning services for all persons of reproductive age, including those whose primary reason for their health-care visit might not be family planning. Strengthened, multidirectional care coordination also will be needed to improve health outcomes. For example, this type of care coordination will be needed with clients referred to specialist care after initial screening at a family planning visit, as well as with specialists referring clients with family planning needs to family planning providers.

Defining Quality in Family Planning Service Delivery

The central premise underpinning these recommendations is that improving the quality of family planning services will lead to improved reproductive health outcomes (*10*–*12*). IOM defines health-care quality as the extent to which health-care services improve health outcomes in a manner that is consistent with current professional knowledge (*10*,*13*). According to IOM, quality health care has the following attributes:

- **Safety.** These recommendations integrate other CDC recommendations about which contraceptive methods can be provided safely to women with various medical conditions, and integrate CDC and U.S. Preventive Services Task Force (USPSTF) recommendations on STD, preconception, and related preventive health services.
- **Effectiveness.** These recommendations support offering a full range of Food and Drug Administration (FDA)–approved contraceptive methods as well as counseling that highlights the effectiveness of contraceptive methods overall and, in specific patient situations, draws attention to the effectiveness of specific clinical preventive health services and identifies clinical preventive health services for which the potential harms outweigh the benefits (i.e., USPSTF "D" recommendations).
- **Client-centered approach.** These recommendations encourage taking a client-centered approach by 1) highlighting that the client's primary purpose for visiting the service site must be respected, 2) noting the importance of confidential services and suggesting ways to provide them, 3) encouraging the availability of a broad range of contraceptive methods so that clients can make a selection based on their individual needs and preferences, and 4) reinforcing the need to deliver services in a culturally competent manner so as to meet the needs of all clients, including adolescents, those with limited English proficiency, those with disabilities, and those who are lesbian, gay, bisexual, transgender, or questioning their sexual identity (LGBTQ). Organizational policies, governance structures, and individual attitudes and practices all contribute to the cultural competence of a health-care entity and its staff. Cultural competency within a health-care setting refers to attitudes, practices, and policies that enable professionals to work effectively in cross-cultural situations (*14*–*16*).
- **Timeliness.** These recommendations highlight the importance of ensuring that services are provided to clients in a timely manner.
- **Efficiency.** These recommendations identify a core set of services that providers can focus on delivering, as well as ways to maximize the use of resources.
- **Accessibility.** These recommendations address how to remove barriers to contraceptive use, use the family planning visit to provide access to a broader range of primary care and behavioral health services, use the primary care visit to

provide access to contraceptive and other family planning services, and strengthen links to other sources of care.
- **Equity.** These recommendations highlight the need for providers of family planning services to deliver high-quality care to all clients, including adolescents, LGBTQ persons, racial and ethnic minorities, clients with limited English proficiency, and persons living with disabilities.
- **Value.** These recommendations highlight services (i.e., contraception and other clinical preventive services) that have been shown to be very cost-effective (*17–19*).

Methods

Recommendations Development Process

The recommendations were developed jointly under the auspices of CDC's Division of Reproductive Health and OPA, in consultation with a wide range of experts and key stakeholders. More information about the processes used to conduct systematic reviews, the role of technical experts in reviewing the evidence, and the process of using the evidence to develop recommendations is provided (Appendix A). A multistage process was used to develop the recommendations that drew on established procedures for developing clinical guidelines (*20*,*21*). First, an Expert Work Group* was formed comprising family planning clinical providers, program administrators, and representatives from relevant federal agencies and professional medical associations to help define the scope of the recommendations. Next, literature about three priority topics (i.e., counseling and education, serving adolescents, and quality improvement) was reviewed by using the USPSTF methodology for conducting systematic reviews (*22*). The results were presented to three technical panels† comprising subject matter experts (one panel for each priority topic) who considered the quality of the evidence and made suggestions for what recommendations might be supported on the basis of the evidence. In a separate process, existing clinical recommendations on women's and men's preventive services were compiled from more than 35 federal and professional medical associations, and these results were presented to two technical panels of subject matter experts, one that addressed women's clinical services and one that addressed men's clinical services. The panels provided individual feedback about which clinical preventive services should be offered in a family planning setting and which clinical recommendations should receive the highest consideration.

CDC and OPA used the input from the subject matter experts to develop a set of core recommendations and asked the Expert Work Group to review them. The members of the Expert Work Group were more familiar with the family planning service delivery context than the members of the Technical Panel and thus could better comment on the feasibility and appropriateness of the recommendations, as well as the supporting evidence. The Expert Work Group considered the core recommendations by using the following criteria: 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences, (e.g., the likelihood that implementation of the recommendation will have a substantial effect on health outcomes might be considered more than the logistical challenges of implementing it) (*20*). In certain cases, when the evidence from the literature reviews was inconclusive or incomplete, recommendations were made on the basis of expert opinion. Finally, CDC and OPA staff considered the individual feedback from Expert Work Group members when finalizing the core recommendations and writing the recommendations document. A description of how the recommendations link to the evidence is provided together with the rationale for the inclusion of each recommendation in this report (Appendix B).

The evidence used to prepare these recommendations will appear in background papers that will be published separately. Resources that will help providers implement the recommendations will be provided through a web-based tool kit that will be available at http://www.hhs.gov/opa.

Audience for the Recommendations

The primary audience for this report is all providers or potential providers of family planning services to clients of reproductive age, including providers working in clinics that are dedicated to family planning service delivery, as well as private and public providers of more comprehensive primary care. Providers of dedicated family planning services might be less familiar with the specific recommendations for the delivery of preconception services. Providers of more comprehensive primary care might be less familiar with the delivery of contraceptive services, pregnancy testing and counseling, and services to help clients achieve pregnancy.

This report can be used by medical directors to write clinical protocols that describe how care should be provided. Job aids and other resources for use in service sites are being developed and will be made available when ready through OPA's website (http://www.hhs.gov/opa).

*A list of the members of the Expert Work Group appears on page 52.
†A list of the members of the technical panels appears on pages 52 and 53.

In this report, the term "provider" refers to any staff member who is involved in providing family planning services to a client. This includes physicians, physician assistants, nurse practitioners, nurse-midwives, nursing staff, and health educators. The term "service site" represents the numerous settings in which family planning services are delivered, which include freestanding service sites, community health centers, private medical facilities, and hospitals. A list of special terms used in this report is provided (Box 1).

The recommendations are designed to guide general clinical practice; however, health-care providers always should consider the individual clinical circumstances of each person seeking family planning services. Similarly, these recommendations might need to be adapted to meet the needs of particular populations, such as clients who are HIV-positive or who are substance users.

Organization of the Recommendations

This report is divided into nine sections. An initial section provides an overview of steps to assess the needs of a client and decide what family planning services to offer. Subsequent sections describe how to provide each of the following services: contraceptive services, pregnancy testing and counseling, helping clients achieve pregnancy, basic infertility services, preconception health services, STD services and related preventive health services. A final section on quality improvement describes actions that all providers of family planning services should consider to ensure that services are of high quality. More detailed information about selected topics addressed in the recommendations is provided (Appendices A–F).

These recommendations focus on the direct delivery of care to individual clients. However, parallel steps might need to be taken to maintain the systems required to support the provision of quality services for all clients (e.g., record-keeping procedures that preserve client confidentiality, procedures that improve efficiency and reduce clients' wait time, staff training to ensure that all clients are treated with respect, and the establishment and maintenance of a strong system of care coordination and referrals).

Client Care

Family planning services are embedded within a broader framework of preventive health services (Figure 1). In this report, health services are divided into three main categories:

- **Family planning services.** These include contraceptive services for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and mental health). STD/HIV and other preconception health services are considered family planning services because they improve women's and men's health and can influence a person's ability to conceive or to have a healthy birth outcome.
- **Related preventive health services.** These include services that are considered to be beneficial to reproductive health,

BOX 1. Definitions of quality terms used in this report

Accessible. The timely use of personal health services to achieve the best possible health outcomes.*

Client-centered. Care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.†

Effective. Services are based on scientific knowledge and provided to all who could benefit and are not provided to those not likely to benefit.†

Efficient. Waste is avoided, including waste of equipment, supplies, ideas, and energy.†

Equitable. Care does not vary in quality because of the personal characteristics of clients (e.g., sex, race/ethnicity, geographic location, insurance status, or socioeconomic status).†

Evidence-based. The process of integrating science-based interventions with community preferences to improve the health of populations.§

Health-care quality. The degree to which health-care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.†

Process. Whether services are provided correctly and completely and how clients perceive the care they receive.¶

Safe. Avoids injuries to clients from the care that is intended to help them.†

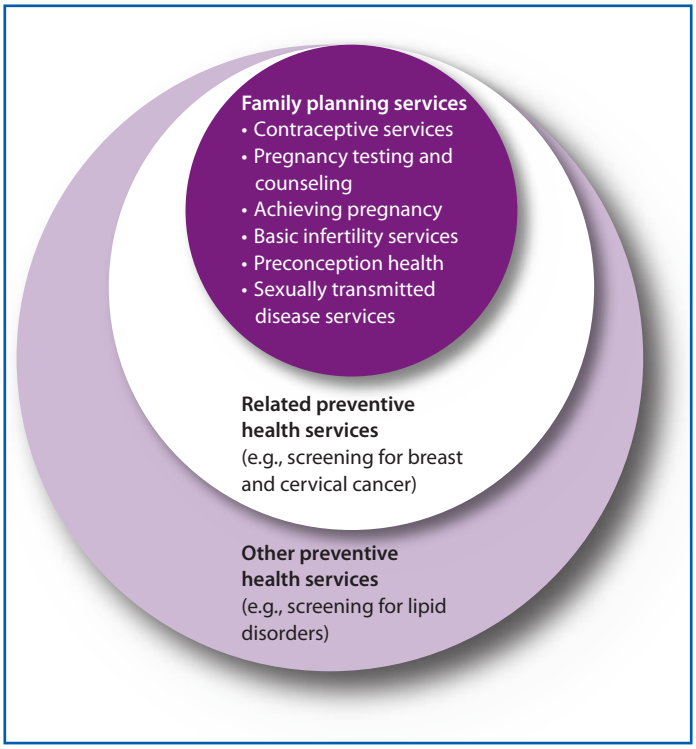
Structure. The characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure.¶

Timely. Waits and sometimes harmful delays for both those who receive and those who provide care are reduced.†

Value. The care provides good return relative to the costs involved, such as a return on investment or a reduction in the per capita cost of health care.*

* Source: Institute of Medicine. Future directions for the national healthcare quality and disparities reports. Ulmer C, Bruno M, Burke S, eds. Washington, DC: The National Academies Press; 2010.
† Source: Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Committee on Quality of Health Care in America, ed. Washington, DC: National Academies of Science; 2001.
§ Source: Kohatsu ND, Robinson JG, Torner JC. Evidence-based public health: an evolving concept. Am J Prev Med 2004;27:417–21.
¶ Source: Donabedian A. The quality of care. JAMA 1988;260:1743–8.

FIGURE 1. Family planning and related and other preventive health services



are closely linked to family planning services, and are appropriate to deliver in the context of a family planning visit but that do not contribute directly to achieving or preventing pregnancy (e.g., breast and cervical cancer screening).

- **Other preventive health services.** These include preventive health services for women that were not included above (*6*), as well as preventive services for men. Screening for lipid disorders, skin cancer, colorectal cancer, or osteoporosis are examples of this type of service. Although important in the context of primary care, these have no direct link to family planning services.

Providers of family planning services should be trained and equipped to offer all family planning and related preventive health services so that they can provide optimal care to clients, with referral for specialist care, as needed. Other preventive health services should be available either on-site or by referral, but these recommendations do not address this category of services. Information about preventive services that are beyond the scope of this report is available at http://www.uspreventiveservicestaskforce.org.

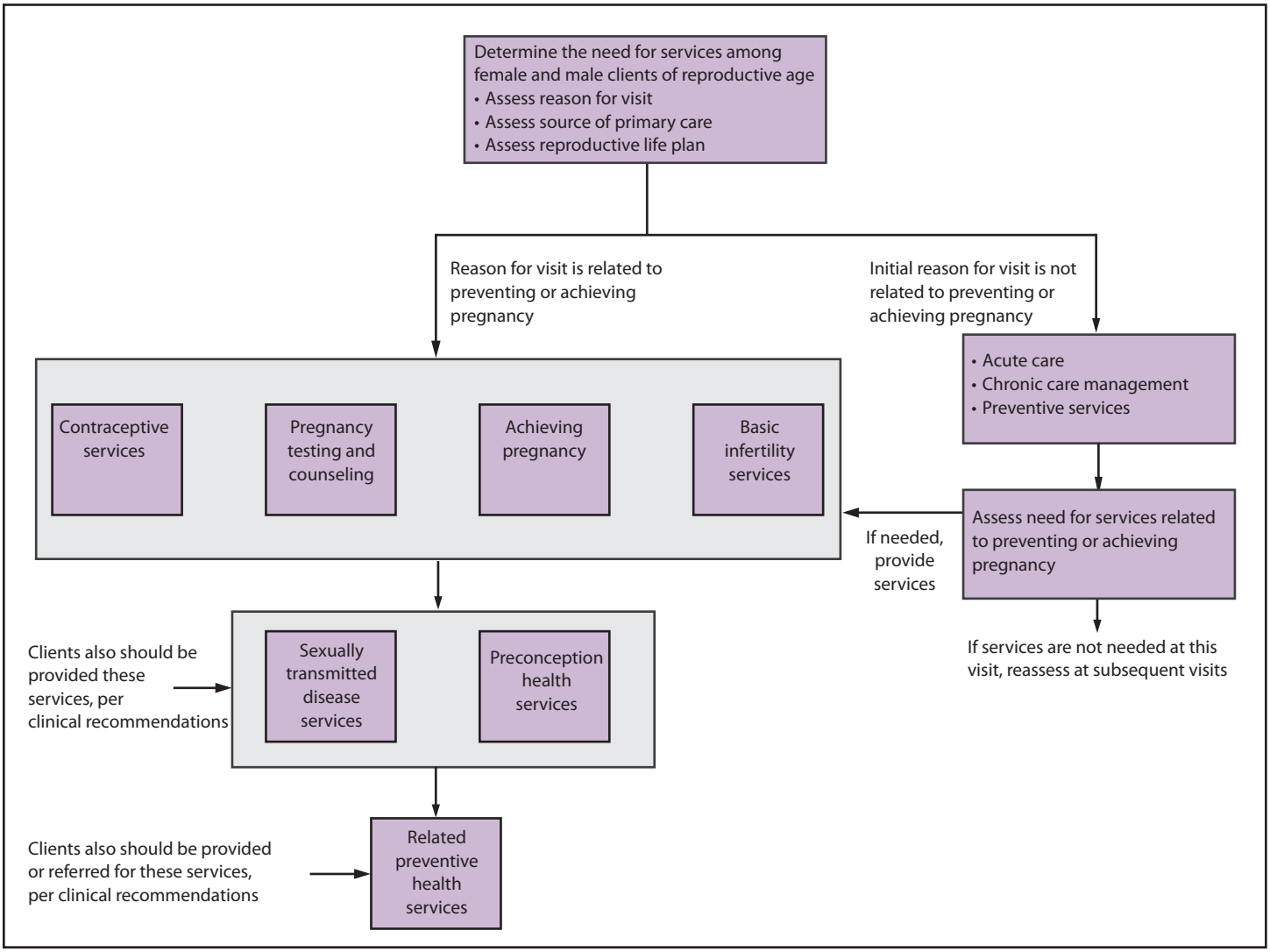
Determining the Client's Need for Services

These recommendations apply to two types of encounters with women and men of reproductive age. In the first type of encounter, the primary reason for a client's visit to a health-care provider is related to preventing or achieving pregnancy, (i.e., contraceptive services, pregnancy testing and counseling, or becoming pregnant). Other aspects of managing pregnancy (e.g., prenatal and delivery care) are not addressed in these recommendations. For clients seeking to prevent or achieve pregnancy, providers should assess whether the client needs other related services and offer them to the client. In the second type of encounter, the primary reason for a client's visit to a health-care provider is not related to preventing or achieving pregnancy. For example, the client might come in for acute care (e.g., a male client coming in for STD symptoms or as a contact of a person with an STD), for chronic care, or for another preventive service. In this situation, providers not only should address the client's primary reason for the visit but also assess the client's need for services related to preventing or achieving pregnancy.

A clinical pathway of family planning services for women and men of reproductive age is provided (Figure 2). The following questions can help providers determine what family planning services are most appropriate for a given visit.

- **What is the client's reason for the visit?** It is essential to understand the client's goals for the visit and address those needs to the extent possible.
- **Does the client have another source of primary health care?** Understanding whether a provider is the main source of primary care for a client will help identify what preventive services a provider should offer. If a provider is the client's main source of primary care, it will be important to assess the client's needs for the other services listed in this report. If the client receives ongoing primary care from another provider, the provider should confirm that the client's preventive health needs are met while avoiding the delivery of duplicative services.
- **What is the client's reproductive life plan?** An assessment should be made of the client's reproductive life plan, which outlines personal goals about becoming pregnant (*23–25*) (Box 2).The provider should avoid making assumptions about the client's needs based on his or her characteristics, such as sexual orientation or disabilities. For clients whose initial reason for coming to the service site was not related to preventing or achieving pregnancy, asking questions about his or her reproductive life plan might help identify unmet reproductive health-care needs. Identifying a need for contraceptive services might be particularly important given the high rate of unintended pregnancy in the United States.
  - If the client does not want a child at this time and is sexually active, then offer contraceptive services.
  - If the client desires pregnancy testing, then provide pregnancy testing and counseling.
  - If the client wants to have a child now, then provide services to help the client achieve pregnancy.

FIGURE 2. Clinical pathway of family planning services for women and men of reproductive age



– If the client wants to have a child and is experiencing difficulty conceiving, then provide basic infertility services.

- **Does the client need preconception health services?** Preconception health services (such as screening for obesity, smoking, and mental health) are a subset of all preventive services for women and men. Preconception health care is intended to promote the health of women and men of reproductive age before conception, with the goal of improving pregnancy-related outcomes (*24*). Preconception health services are also important because they improve the health of women and men, even if they choose not to become pregnant. The federal and professional medical recommendations cited in this report should be followed when determining which preconception health services a client might need.
- **Does the client need STD services?** The need for STD services, including HIV/AIDS testing, should be considered at every visit. Many clients requesting contraceptive services also might meet the criteria for being at risk of one or more STDs. Screening for chlamydia and gonorrhea is especially important in a family planning context because these STDs contribute to tubal infertility if left untreated. STD services are also necessary to maximize preconception health. The federal recommendations cited in this report should be followed when determining which STD services a client might need. Aspects of managing symptomatic STDs are not addressed in these recommendations.
- **What other related preventive health services does the client need?** Whether the client needs related preventive health services, such as breast and cervical cancer screening for female clients, should be assessed. The federal and professional medical recommendations cited in this report should be followed when determining which related preventive health services a client might need.

BOX 2. Recommended questions to ask when assessing a client's reproductive life plan

Providers should discuss a reproductive life plan with clients receiving contraceptive, pregnancy testing and counseling, basic infertility, sexually transmitted disease, and preconception health services in accordance with CDC's recommendation that all persons capable of having a child should have a reproductive life plan.*

Providers should assess the client's reproductive life plan by asking the client questions such as:

- Do you have any children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?

* Source: CDC. Recommendations to improve preconception health and health care—United States: a report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR 2006;55(No. RR-6).

The individual client's needs should be considered when determining what services to offer at a given visit. It might not be feasible to deliver all the needed services in a single visit, and they might need to be delivered over the course of several visits. Providers should tailor services to meet the specific needs of the population they serve. For example, clients who are trying to achieve pregnancy and those at high risk of unintended pregnancy should be given higher priority for preconception health services. In some cases, the provider will deliver the initial screening service but then refer to another provider for further diagnosis or follow-up care.

The delivery of preconception, STD, and related preventive health services should not become a barrier to a client's ability to receive services related to preventing or achieving pregnancy. For these clients, receiving services related to preventing or achieving pregnancy is the priority; if other family planning services cannot be delivered at the initial visit, then follow-up visits should be scheduled.

In addition, professional recommendations for how to address the needs of diverse clients, such as LGBTQ persons (*26*–*32*) or persons with disabilities (*33*), should be consulted and integrated into procedures, as appropriate. For example, as noted before, providers should avoid making assumptions about a client's gender identity, sexual orientation, race, or ethnicity; all requests for services should be treated without regard to these characteristics. Similarly, services for adolescents should be provided in a "youth-friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth, as recommended by the World Health Organization (*34*).

Contraceptive Services

Providers should offer contraceptive services to clients who wish to delay or prevent pregnancy. Contraceptive services should include consideration of a full range of FDA-approved contraceptive methods, a brief assessment to identify the contraceptive methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary. Contraceptive counseling is defined as a process that enables clients to make and follow through on decisions about their contraceptive use. Education is an integral component of the contraceptive counseling process that helps clients to make informed decisions and obtain the information they need to use contraceptive methods correctly.

Key steps in providing contraceptive services, including contraceptive counseling and education, have been outlined (Box 3). These key steps are in accordance with the five principles of quality counseling (Appendix C). To help a client who is initiating or switching to a new method of contraception, providers should follow these steps. These steps most likely will be implemented iteratively when working with a client and should help clients adopt, change, or maintain contraceptive use.

Step 1. Establish and maintain rapport with the client. Providers should strive to establish and maintain rapport. Strategies to achieve these goals include the following:

- using open-ended questions;
- demonstrating expertise, trustworthiness, and accessibility;
- ensuring privacy and confidentiality;
- explaining how personal information will be used;
- encouraging the client to ask questions and share information;
- listening to and observing the client; and
- being encouraging and demonstrating empathy and acceptance.

Step 2. Obtain clinical and social information from the client. Providers should ask clients about their medical history to identify methods that are safe. In addition, to learn more about factors that might influence a client's choice of a contraceptive method, providers should confirm the client's pregnancy intentions or reproductive life plan, ask about the client's contraceptive experiences and preferences, and conduct a sexual health assessment. When available, standardized tools should be used.

- **Medical history.** A medical history should be taken to ensure that methods of contraception being considered by a client are safe for that particular client. For a female client, the medical history should include menstrual history (including last menstrual period, menstrual frequency, length and amount of bleeding, and other

BOX 3. Steps in providing contraceptive services, including contraceptive counseling* and education

- Establish and maintain rapport with the client.
- Obtain clinical and social information from the client.
- Work with the client interactively to select the most effective and appropriate contraceptive method.
- Conduct a physical assessment related to contraceptive use, only when warranted.
- Provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow up, and confirm client understanding.

* Key principles of providing quality counseling including education have been outlined (Appendix C).

patterns of uterine/vaginal bleeding), gynecologic and obstetrical history, contraceptive use, allergies, recent intercourse, recent delivery, miscarriage, or termination, and any relevant infectious or chronic health condition and other characteristics and exposures (e.g., age, postpartum, and breastfeeding) that might affect the client's medical eligibility criteria for contraceptive methods (*35*). Clients considering combined hormonal contraception should be asked about smoking tobacco, in accordance with CDC guidelines on contraceptive use (*35*). Additional details about the methods of contraception that are safe to use for female clients with specific medical conditions and characteristics (e.g., hypertension) are addressed in previously published guidelines (*35*). For a male client, a medical history should include use of condoms, known allergies to condoms, partner use of contraception, recent intercourse, whether his partner is currently pregnant or has had a child, miscarriage, or termination, and the presence of any infectious or chronic health condition. However, the taking of a medical history should not be a barrier to making condoms available in the clinical setting (i.e., a formal visit should not be a prerequisite for a client to obtain condoms).

- **Pregnancy intention or reproductive life plan.** Each client should be encouraged to clarify decisions about her or his reproductive life plan (i.e., whether the client wants to have any or more children and, if so, the desired timing and spacing of those children) (*24*).
- **Contraceptive experiences and preferences.** Method-specific experiences and preferences should be assessed by asking questions such as, "What method(s) are you currently using, if any?"; "What methods have you used in the past?"; "Have you previously used emergency contraception?"; "Did you use contraception at last sex?"; "What difficulties did you experience with prior methods if any (e.g., side effects or noncompliance)?"; "Do you have a specific method in mind?"; and "Have you discussed method options with your partner, and does your partner have any preferences for which method you use?" Male clients should be asked if they are interested in vasectomy.
- **Sexual health assessment.** A sexual history and risk assessment that considers the client's sexual practices, partners, past STD history, and steps taken to prevent STDs (*36*) is recommended to help the client select the most appropriate method(s) of contraception. Correct and consistent condom use is recommended for those at risk for STDs. CDC recommendations for how to conduct a sexual health assessment have been summarized (Box 4).

Step 3. Work with the client interactively to select the most effective and appropriate contraceptive method. Providers should work with the client interactively to select an effective and appropriate contraceptive method. Specifically, providers should educate the client about contraceptive methods that the client can safely use, and help the client consider potential barriers to using the method(s) under consideration. Use of decision aids (e.g., computerized programs that help a client to identify a range of methods that might be appropriate for the client based on her physical characteristics such as health conditions or preferences about side effects) before or while waiting for the appointment can facilitate and maximize the utility of the time spent on this step.

Providers should inform clients about all contraceptive methods that can be used safely. Before the health-care visit, clients might have only limited information about all or specific methods of contraception (*37*). A broad range of methods, including long-acting reversible contraception (i.e., intrauterine devices [IUDs] and implants), should be discussed with all women and adolescents, if medically appropriate.

Providers are encouraged to present information on potential reversible methods of contraception by using a tiered approach (i.e., presenting information on the most effective methods first, before presenting information on less effective methods) (*38*,*39*). This information should include an explanation that long-acting reversible contraceptive methods are safe and effective for most women, including those who have never given birth and adolescents (*35*). Information should be tailored and presented to ensure a client-centered approach. It is not appropriate to omit presenting information on a method solely because the method is not available at the service site. If not all methods are available at the service site, it is important to have strong referral links in place to other providers to maximize opportunities for clients to obtain their preferred method that is medically appropriate.

BOX 4. Steps in conducting a sexual health assessment*

- **Practices:** Explore the types of sexual activity in which the patient engages (e.g., vaginal, anal, or oral sex).
- **Pregnancy prevention:** Discuss current and future contraceptive options. Ask about current and previous use of methods, use of contraception at last sex, difficulties with contraception, and whether the client has a particular method in mind.
- **Partners:** Ask questions to determine the number, gender (men, women, or both), and concurrency of the patient's sex partners (if partner had sex with another partner while still in a sexual relationship with the patient). It might be necessary to define the term "partner" to the patient or use other, relevant terminology.
- **Protection from sexually transmitted diseases (STDs):** Ask about condom use, with whom they do or do not use condoms, and situations that make it harder or easier to use condoms. Topics such as monogamy and abstinence also can be discussed.
- **Past STD history:** Ask about any history of STDs, including whether their partners have ever had an STD. Explain that the likelihood of an STD is higher with a past history of an STD.

* Source: CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59(No. RR-12).

For clients who have completed childbearing or do not plan to have children, permanent sterilization (female or male) is an option that may be discussed. Both female and male sterilization are safe, are highly effective, and can be performed in an office or outpatient surgery setting (*40*,*41*). Women and men should be counseled that these procedures are not intended to be reversible and that other highly effective, reversible methods of contraception (e.g., implants or IUDs) might be an alternative if they are unsure about future childbearing. Clients interested in sterilization should be referred to an appropriate source of care if the provider does not perform the procedure.

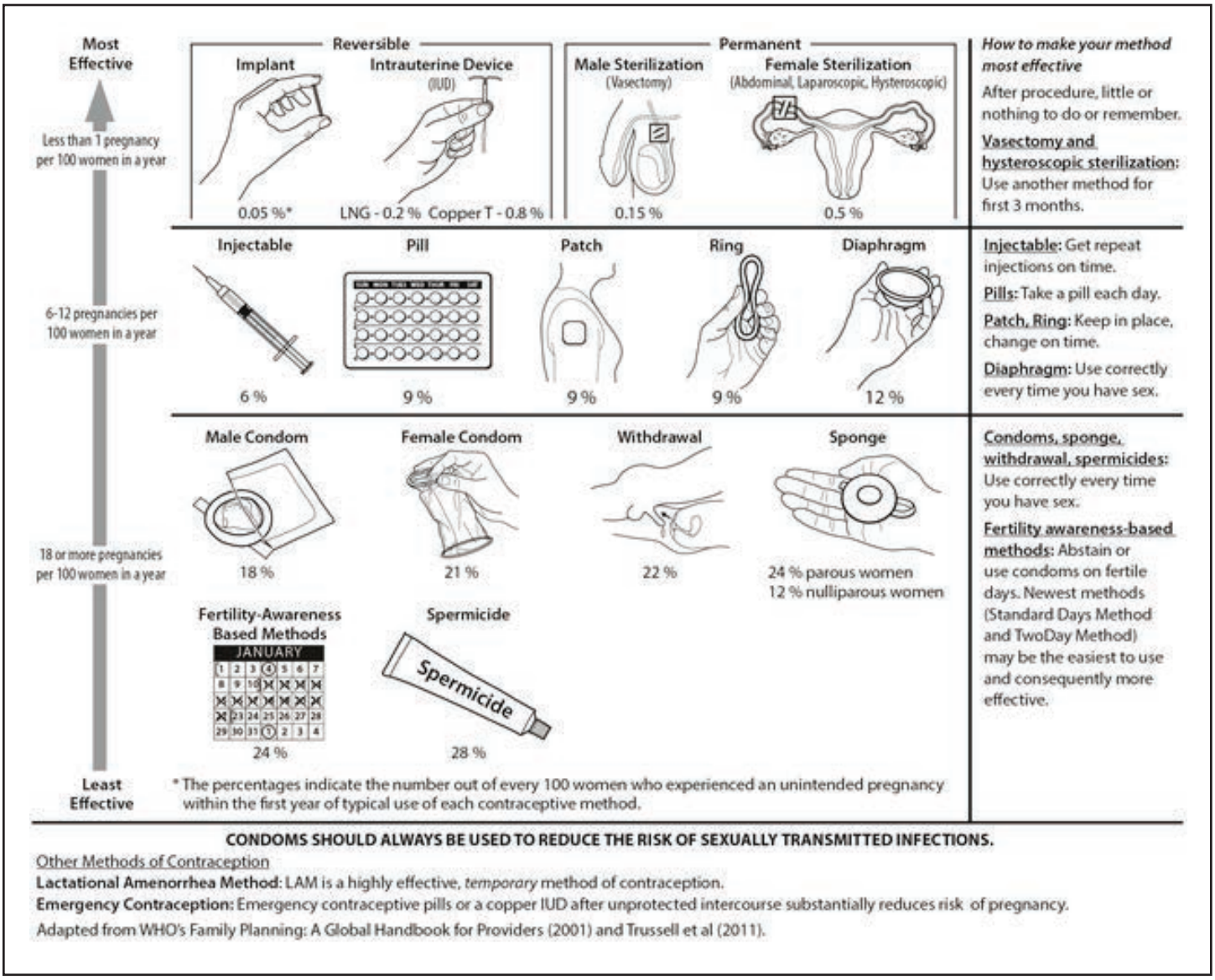
When educating clients about contraceptive methods that the clients can use safely, providers should ensure that clients understand the following:

- **Method effectiveness.** A contraceptive method's rate of typical effectiveness, or the percentage of women experiencing an unintended pregnancy during the first year of typical use, is an important consideration (Figure 3; Appendix D) (*38*,*42*).
- **Correct use of the method.** The mode of administration and understanding how to use the method correctly might be important considerations for the client when choosing a method. For example, receiving a contraceptive injection every 3 months might not be acceptable to a woman who fears injections. Similarly, oral contraceptives might not be acceptable to a woman who is concerned that she might not be able to remember to take a pill every day.
- **Noncontraceptive benefits.** Many contraceptives have noncontraceptive benefits, in addition to preventing pregnancy, such as reducing heavy menstrual bleeding. Although the noncontraceptive benefits are not generally the major determinant for selecting a method, awareness of these benefits can help clients decide between two or more suitable methods and might enhance the client's motivation to use the method correctly and consistently.
- **Side effects.** Providers should inform the client about risks and side effects of the method(s) under consideration, help the client understand that certain side effects of contraceptive methods might disappear over time, and encourage the client to weigh the experience of coping with side effects against the experience and consequences of an unintended pregnancy. The provider should be prepared to discuss and correct misperceptions about side effects. Clients also should be informed about warning signs for rare, but serious, adverse events with specific contraceptive methods, such as stroke and venous thromboembolism with use of combined hormonal methods.
- **Protection from STDs, including HIV.** Clients should be informed that contraceptive methods other than condoms offer no protection against STDs, including HIV. Condoms, when used correctly and consistently, help reduce the risk of STDs, including HIV, and provide protection against pregnancy. Dual protection (i.e., protection from both pregnancy and STDs) is important for clients at risk of contracting an STD, such as those with multiple or potentially infected partner(s). Dual protection can be achieved through correct and consistent use of condoms with every act of sexual intercourse, or correct and consistent use of a condom to prevent infection plus another form of contraception to prevent pregnancy. (For more information about preventing and treating STDs, see STD Services.)

When educating clients about the range of contraceptive methods, providers should ensure that clients have information that is medically accurate, balanced, and provided in a nonjudgmental manner. To assist clients in making informed decisions, providers should educate clients in a manner that can be readily understood and retained. The content, format, method, and medium for delivering education should be evidence-based (see Appendix E).

When working with male clients, when appropriate, providers should discuss information about female-controlled methods

FIGURE 3. The typical effectiveness of Food and Drug Administration–approved contraceptive methods



(including emergency contraception) encourage discussion of contraception with partners, and provide information about how partners can access contraceptive services. Male clients should also be reminded that condoms should be used correctly and consistently to reduce risk of STDs, including HIV.

When working with any client, encourage partner communication about contraception, as well as understanding partner barriers (e.g., misperceptions about side effects) and facilitators (e.g., general support) of contraceptive use (*43–46*).

The provider should help the client consider potential barriers to using the method(s) under consideration. This includes consideration of the following factors:

- **Social-behavioral factors.** Social-behavioral factors might influence the likelihood of correct and consistent use of contraception (*47*). Providers should help the client consider the advantages and disadvantages of the method(s) being considered, the client's feelings about using the method(s), how her or his partner is likely to respond, the client's peers' perceptions of the method(s), and the client's confidence in being able to use the method correctly and consistently (e.g., using a condom during every act of intercourse or remembering to take a pill every day) (*37*).
- **Intimate partner violence and sexual violence.** Current and past intimate partner sexual or domestic violence might impede the correct and consistent use of contraception, and might be a consideration when choosing a method (*47–49*). For example, an IUD might

be preferred because it does not require the partner's participation. The medical history might provide information on signs of current or past violence and, if not, providers should ask clients about relationship issues that might be potential barriers to contraceptive use. In addition, clients experiencing intimate partner violence or sexual violence should be referred for appropriate care.

- **Mental health and substance use behaviors.** Mental health (e.g., depression, anxiety disorders, and other mental disorders) and substance use behaviors (e.g., alcohol use, prescription abuse, and illicit drug use) might affect a client's ability to correctly and consistently use contraception (*47*,*50*). The medical history might provide information about the signs of such conditions or behaviors, and if not, providers should ask clients about substance use behaviors or mental health disorders, such as depression or anxiety, that might interfere with the motivation or ability to follow through with contraceptive use. If needed, clients with mental health disorders or risky substance use behaviors should be referred for appropriate care.

Step 4. Conduct a physical assessment related to contraceptive use, when warranted. Most women will need no or few examinations or laboratory tests before starting a method of contraception. Guidance on necessary examinations and tests related to initiation of contraception is available (*42*). A list of assessments that need to be conducted when providing reversible contraceptive services to a female client seeking to initiate or switch to a new method of reversible contraception is provided (Table 1) (*42*). Clinical evaluation of a client electing permanent sterilization should be guided by the clinician who performs the procedure. Recommendations for contraceptive use are available (*42*). Key points include the following:

- Blood pressure should be taken before initiating the use of combined hormonal contraception.
- Providers should assess the current pregnancy status of clients receiving contraception (*42*), which provides guidance on how to be reasonably certain that a woman is not pregnant at the time of contraception initiation. In most cases, a detailed history provides the most accurate assessment of pregnancy risk in a woman about to start using a contraceptive method. Routine pregnancy testing for every woman is not necessary.
- Weight measurement is not needed to determine medical eligibility for any method of contraception because all methods generally can be used among obese women. However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.
- Unnecessary medical procedures and tests might create logistical, emotional, or economic barriers to contraceptive access for some women, particularly adolescents and low-income women, who have high rates of unintended pregnancies (*1*,*51*,*52*). For both adolescent and adult female clients, the following examinations and tests are not needed routinely to provide contraception safely to a healthy client (although they might be needed to address other non-contraceptive health needs) (*42*):
  - pelvic examinations, unless inserting an intrauterine device (IUD) or fitting a diaphragm;
  - cervical cytology or other cancer screening, including clinical breast exam;
  - human immunodeficiency virus (HIV) screening; and
  - laboratory tests for lipid, glucose, liver enzyme, and hemoglobin levels or thrombogenic mutations.

For male clients, no physical examination needs to be performed before distributing condoms.

Step 5. Provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm client understanding.

- A broad range of FDA-approved contraceptive methods should be available onsite. Referrals for methods not available onsite should be provided for clients who indicate they prefer those methods. When providing contraception, providers should instruct the client about correct and consistent use and employ the following strategies to facilitate a client's use of contraception:
  - Provide onsite dispensing;
  - Begin contraception at the time of the visit rather than waiting for next menses (also known as "quick start") if the provider can reasonably be certain that the client is not pregnant (*42*). A provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria (*42*,*53*):
    - is ≤7 days after the start of normal menses,
    - has not had sexual intercourse since the start of last normal menses,
    - has been using a reliable method of contraception correctly and consistently,
    - is ≤7 days after spontaneous or induced abortion,
    - is within 4 weeks postpartum,
    - is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum;
  - Provide or prescribe multiple cycles (ideally a full year's supply) of oral contraceptive pills, the patch, or the ring

TABLE 1. Assessments to conduct when a female client is initiating a new method of reversible contraception

	Cu-IUD and LNG-IUD	Implant	Injectable	Combined hormonal contraception	Progestin-only pills	Condom	Diaphragm or cervical cap	Spermicide
Examination								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/height [m]^2)	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
Laboratory test								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

Source: CDC. U.S. selected practice recommendations for contraceptive use 2013. MMWR 2013;62(No. RR-5).
Abbreviations: A = Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method; B = Class B: contributes substantially to safe and effective use, but implementation might be considered within the public health and/or service context (the risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available); C = Class C: does not contribute substantially to safe and effective use of the contraceptive method; Cu-IUD = copper-containing intrauterine device; LNG-IUD = levonorgestrel releasing intrauterine device.
* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.
† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. Medical Eligibility Criteria 1) or generally can be used (U.S. Medical Eligibility Criteria 2) among obese women (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.
§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.
¶ Most women do not require additional STD screening at the time of IUD insertion, if they have already been screened according to CDC's STD treatment guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR. 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

to minimize the number of times a client has to return to the service site;
  - Make condoms easily and inexpensively available; and
  - If a client chooses a method that is not available on-site or the same day, provide the client another method to use until she or he can start the chosen method.

- Help the client develop a plan for using the selected method. Using a method incorrectly or inconsistently and having gaps in contraceptive protection because of method switching both increase the likelihood of an unintended pregnancy (*37*). After the method has been provided, or a plan put into place to obtain the chosen method, providers should help the client develop an action plan for using the selected method.

  Providers should encourage clients to anticipate reasons why they might not use their chosen method(s) correctly or consistently, and help them develop strategies to deal with these possibilities. For example, for a client selecting oral contraceptive pills who might forget to take a pill, the provider can work with the client to identify ways to routinize daily pill taking (e.g., use of reminder systems such as daily text messages or cell phone alarms). Providers also may inform clients about the availability of emergency contraceptive pills and may provide clients an advance supply of emergency contraceptive pills on-site or by prescription, if requested.

  Side effects (e.g., irregular vaginal bleeding) are a primary reason for method discontinuation (*54*), so providers should discuss ways the client might deal with potential side effects to increase satisfaction with the method and improve continuation (*42*).

- Develop a plan for follow-up. Providers should discuss an appropriate follow-up plan with the client to meet their individual needs, considering the client's risk for discontinuation. Follow-up provides an opportunity to inquire about any initial difficulties the client might be experiencing, and might reinforce the perceived accessibility of the provider and increase rapport. Alternative modes of follow-up other than visits to the service site, such as telephone, e-mail, or text messaging, should be considered (assuming confidentiality can be assured), as needed.

  As noted previously, if a client chooses a method that is not available on-site or during the visit, the provider

should schedule a follow-up visit with the client or provide a referral for her or him to receive the method. The client should be provided another method to use until she or he can start the chosen method.
- Confirm the client's understanding. Providers should assess whether the client understands the information that was presented. The client's understanding of the most important information about her or his chosen contraceptive method should be documented in the medical record (e.g., by a checkbox or written statement).

The teach-back method may be used to confirm the client's understanding by asking the client to repeat back messages about risks and benefits and appropriate method use and follow-up. If providers assess the client's understanding, then the check box or written statement can be used in place of a written method-specific informed consent form. Topics that providers may consider having the client repeat back include the following: typical method effectiveness; how to use the method correctly; protection from STDs; warning signs for rare, but serious, adverse events and what to do if they experience a warning sign; and when to return for follow-up.

Provide Counseling for Returning Clients

When serving contraceptive clients who return for ongoing care related to contraception, providers should ask if the client has any concerns with the method and assess its use. The provider should assess any changes in the client's medical history, including changes in risk factors and medications that might affect safe use of the contraceptive method. If the client is using the method correctly and consistently and there are no concerns about continued use, an appropriate follow-up plan should be discussed and more contraceptive supplies given (*42*). If the client or provider has concerns about the client's correct or consistent use of the method, the provider should ask if the client would be interested in considering a different method of contraception. If the client is interested, the steps described above should be followed.

Counseling Adolescent Clients

Providers should give comprehensive information to adolescent clients about how to prevent pregnancy (*55–57*). This information should clarify that avoiding sex (i.e., abstinence) is an effective way to prevent pregnancy and STDs. If the adolescent indicates that she or he will be sexually active, providers should give information about contraception and help her or him to choose a method that best meets her or his individual needs, including the use of condoms to reduce the risk of STDs. Long-acting reversible contraception is a safe and effective option for many adolescents, including those who have not been pregnant or given birth (*35*).

Providers of family planning services should offer confidential services to adolescents and observe all relevant state laws and any legal obligations, such as notification or reporting of child abuse, child molestation, sexual abuse, rape, or incest, as well as human trafficking (*58,59*). Confidentiality is critical for adolescents and can greatly influence their willingness to access and use services (*60–67*). As a result, multiple professional medical associations have emphasized the importance of providing confidential services to adolescents (*68–70*).

Providers should encourage and promote communication between the adolescent and his or her parent(s) or guardian(s) about sexual and reproductive health (*71–86*). Adolescents who come to the service site alone should be encouraged to talk to their parents or guardians. Educational materials and programs can be provided to parents or guardians that help them talk about sex and share their values with their child (*72,87*). When both parent or guardian and child have agreed, joint discussions can address family values and expectations about dating, relationships, and sexual behavior.

In a given year, approximately 20% of adolescent births represent repeat births (*88*), so in addition to providing postpartum contraception, providers should refer pregnant and parenting adolescents to home visiting and other programs that have been demonstrated to provide needed support and reduce rates of repeat teen pregnancy (*89–94*).

Services for adolescents should be provided in a "youth-friendly" manner, which means that they are accessible, equitable, acceptable, appropriate, comprehensive, effective, and efficient for youth as recommended by the World Health Organization (*34*).

Pregnancy Testing and Counseling

Providers of family planning services should offer pregnancy testing and counseling services as part of core family planning services, in accordance with recommendations of major professional medical organizations, such as the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) (*95–97*).

Pregnancy testing is a common reason for a client to visit a provider of family planning services. Approximately 65% of pregnancies result in live births, 18% in induced abortion, and 17% spontaneous fetal loss (*98*). Among live births, only 1% of infants are placed for adoption within their first month of life (*99*).

The visit should include a discussion about her reproductive life plan and a medical history that includes asking about any coexisting conditions (e.g., chronic medical illnesses, physical disability, psychiatric illness) (*95,96*). In most cases,

a qualitative urine pregnancy test will be sufficient; however, in certain cases, the provider may consider performing a quantitative serum pregnancy test, if exact hCG levels would be helpful for diagnosis and management. The test results should be presented to the client, followed by a discussion of options and appropriate referrals.

Options counseling should be provided in accordance with recommendations from professional medical associations, such as ACOG and AAP (*95*–*97*). A female client might wish to include her partner in the discussion; however, if a client chooses not to involve her partner, confidentiality must be assured.

Positive Pregnancy Test

If the pregnancy test is positive, the clinical visit should include an estimation of gestational age so that appropriate counseling can be provided. If a woman is uncertain about the date of her last normal menstrual period, a pelvic examination might be needed to help assess gestational age. In addition, clients should receive information about the normal signs and symptoms of early pregnancy, and should be instructed to report any concerns to a provider for further evaluation. If ectopic pregnancy or other pregnancy abnormalities or problems are suspected, the provider should either manage the condition or refer the client for immediate diagnosis and management.

Referral to appropriate providers of follow-up care should be made at the request of the client, as needed. Every effort should be made to expedite and follow through on all referrals. For example, providers might provide a resource listing or directory of providers to help the client identify options for care. Depending upon a client's needs, the provider may make an appointment for the client, or call the referral site to let them know the client was referred. Providers also should assess the client's social support and refer her to appropriate counseling or other supportive services, as needed.

For clients who are considering or choose to continue the pregnancy, initial prenatal counseling should be provided in accordance with the recommendations of professional medical associations, such as ACOG (*97*). The client should be informed that some medications might be contraindicated in pregnancy, and any current medications taken during pregnancy need to be reviewed by a prenatal care provider (e.g., an obstetrician or midwife). In addition, the client should be encouraged to take a daily prenatal vitamin that includes folic acid; to avoid smoking, alcohol, and other drugs; and not to eat fish that might have high levels of mercury (*97*). If there might be delays in obtaining prenatal care, the client should be provided or referred for any needed STD screening (including HIV) and vaccinations (*36*).

Negative Pregnancy Test

Women who are not pregnant and who do not want to become pregnant at this time should be offered contraceptive services, as described previously. The contraceptive counseling session should explore why the client thought that she was pregnant and sought pregnancy testing services, and whether she has difficulties using her current method of contraception. A negative pregnancy test also provides an opportunity to discuss the value of making a reproductive life plan. Ideally, these services will be offered in the same visit as the pregnancy test because clients might not return at a later time for contraceptive services.

Women who are not pregnant and who are trying to become pregnant should be offered services to help achieve pregnancy or basic infertility services, as appropriate (see "Clients Who Want to Become Pregnant" and "Basic Infertility Services"). They also should be offered preconception health and STD services (see "Preconception Health Services" and "STD services").

Clients Who Want to Become Pregnant

Providers should advise clients who wish to become pregnant in accordance with the recommendations of professional medical organizations, such as the American Society for Reproductive Medicine (ASRM) (*100*).

Providers should ask the client (or couple) how long she or they have been trying to get pregnant and when she or they hope to become pregnant. If the client's situation does not meet one of the standard definitions of infertility (see "Basic Infertility Services"), then she or he may be counseled about how to maximize fertility. Key points are as follows:

- The client should be educated about peak days and signs of fertility, including the 6-day interval ending on the day of ovulation that is characterized by slippery, stretchy cervical mucus and other possible signs of ovulation.
- Women with regular menstrual cycles should be advised that vaginal intercourse every 1–2 days beginning soon after the menstrual period ends can increase the likelihood of becoming pregnant.
- Methods or devices designed to determine or predict the time of ovulation (e.g., over-the-counter ovulation kits, digital telephone applications, or cycle beads) should be discussed.
- It should be noted that fertility rates are lower among women who are very thin or obese, and those who consume high levels of caffeine (e.g., more than five cups per day).
- Smoking, consuming alcohol, using recreational drugs, and using most commercially available vaginal lubricants should be discouraged as these might reduce fertility.

Basic Infertility Services

Providers should offer basic infertility care as part of core family planning services in accordance with the recommendations of professional medical organizations, such as ACOG, ASRM, and the American Urological Association (AUA) (*96*,*101*,*102*).

Infertility commonly is defined as the failure of a couple to achieve pregnancy after 12 months or longer of regular unprotected intercourse (*101*). Earlier assessment (such as 6 months of regular unprotected intercourse) is justified for women aged >35 years, those with a history of oligo-amenorrhea (infrequent menstruation), those with known or suspected uterine or tubal disease or endometriosis, or those with a partner known to be subfertile (the condition of being less than normally fertile though still capable of effecting fertilization) (*101*). An early evaluation also might be warranted if risk factors of male infertility are known to be present or if there are questions regarding the male partner's fertility potential (*102*). Infertility visits to a family planning provider are focused on determining potential causes of the inability to achieve pregnancy and making any needed referrals to specialist care (*101*,*102*). ASRM recommends that evaluation of both partners should begin at the same time (*101*).

Basic Infertility Care for Women

The clinical visit should focus on understanding the client's reproductive life plan (*24*) and her difficulty in achieving pregnancy through a medical history, sexual health assessment and physical exam, in accordance with recommendations developed by professional medical associations such as ASRM (*101*) and ACOG (*96*). The medical history should include past surgery, including indications and outcome(s), previous hospitalizations, serious illnesses or injuries, medical conditions associated with reproductive failure (e.g., thyroid disorders, hirsutism, or other endocrine disorders), and childhood disorders; results of cervical cancer screening and any follow-up treatment; current medication use and allergies; and family history of reproductive failure. In addition, a reproductive history should include how long the client has been trying to achieve pregnancy; coital frequency and timing, level of fertility awareness, and results of any previous evaluation and treatment; gravidity, parity, pregnancy outcome(s), and associated complications; age at menarche, cycle length and characteristics, and onset/severity of dysmenorrhea; and sexual history, including pelvic inflammatory disease, history of STDs, or exposure to STDs. A review of systems should emphasize symptoms of thyroid disease, pelvic or abdominal pain, dyspareunia, galactorrhea, and hirsutism (*101*).

The physical examination should include: height, weight, and body mass index (BMI) calculation; thyroid examination to identify any enlargement, nodule, or tenderness; clinical breast examination; and assessment for any signs of androgen excess. A pelvic examination should assess for: pelvic or abdominal tenderness, organ enlargement or mass; vaginal or cervical abnormality, secretions, or discharge; uterine size, shape, position, and mobility; adnexal mass or tenderness; and cul-de-sac mass, tenderness, or nodularity. If needed, clients should be referred for further diagnosis and treatment (e.g., serum progesterone levels, follicle-stimulating hormone/luteinizing hormone levels, thyroid function tests, prolactin levels, endometrial biopsy, transvaginal ultrasound, hysterosalpingography, laparoscopy, and clomiphene citrate).

Basic Infertility Care for Men

Infertility services should be provided for the male partner of an infertile couple in accordance with recommendations developed by professional medical associations such as AUA (*102*). Providers should discuss the client's reproductive life plan, take a medical history, and conduct a sexual health assessment. AUA recommends that the medical history include a reproductive history (*102*). The medical history should include systemic medical illnesses (e.g., diabetes mellitus), prior surgeries and past infections; medications (prescription and nonprescription) and allergies; and lifestyle exposures. The reproductive history should include methods of contraception, coital frequency and timing; duration of infertility and prior fertility; sexual history; and gonadal toxin exposure, including heat. Patients also should be asked about their female partners' history of pelvic inflammatory disease, their partners' histories of STDs, and problems with sexual dysfunction.

In addition, a physical examination should be conducted with particular focus given to 1) examination of the penis, including the location of the urethral meatus; 2) palpation of the testes and measurement of their size; 3) presence and consistency of both the vas deferens and epididymis; 4) presence of a varicocele; 5) secondary sex characteristics; and 6) a digital rectal exam (*102*). Male clients concerned about their fertility should have a semen analysis. If this test is abnormal, they should be referred for further diagnosis (i.e., second semen analysis, endocrine evaluation, post-ejaculate urinalysis, or others deemed necessary) and treatment. The semen analysis is the first and most simple screen for male fertility.

Infertility Counseling

Counseling provided during the clinical visit should be guided by information elicited from the client during the medical and reproductive history and the findings of the

physical exam. If there is no apparent cause of infertility and the client does not meet the definition above, providers should educate the client about how to maximize fertility (see "Clients Who Want to Become Pregnant"). ACOG notes the importance of addressing the emotional and educational needs of clients with infertility and recommends that providers consider referring clients for psychological support, infertility support groups, or family counseling (*96*).

Preconception Health Services

Providers of family planning services should offer preconception health services to female and male clients in accordance with CDC's recommendations to improve preconception health and health care (*24*).

Preconception health services are beneficial because of their effect on pregnancy and birth outcomes and their role in improving the health of women and men. The term preconception describes any time that a woman of reproductive potential is not pregnant but at risk of becoming pregnant, or when a man is at risk for impregnating his female partner.

Preconception health-care services for women aim to identify and modify biomedical, behavioral, and social risks to a woman's health or pregnancy outcomes through prevention and management. It promotes the health of women of reproductive age before conception, and thereby helps to reduce pregnancy-related adverse outcomes, such as low birthweight, premature birth, and infant mortality (*24*). Moreover, the preconception health services recommended here are equally important because they contribute to the improvement of women's health and well-being, regardless of her childbearing intentions. CDC recommends that preconception health services be integrated into primary care visits made by women of reproductive age, such as family planning visits (*24*).

In the family planning setting, providers may prioritize screening and counseling about preconception health for couples that are trying to achieve pregnancy and couples seeking basic infertility services. Women who are using contraception to prevent or delay pregnancy might also benefit from preconception health services, especially those at high risk of unintended pregnancy. A woman is at high risk of unintended pregnancy if she is using no method or a less effective method of contraception (e.g., barrier methods, rhythm, or withdrawal), or has a history of contraceptive discontinuation or incorrect use (*38*,*39*). A woman is at lower risk of unintended pregnancy if she is using a highly effective method, such as an IUD or implant, or has an established history of using methods of contraception, such as injections, pills, patch, or ring correctly and consistently (*38*,*39*). Clients who do not want to become pregnant should also be provided preconception health services, since they are recommended by USPSTF for the purpose of improving the health of adults.

Recommendations for improving the preconception health of men also have been identified, although the evidence base for many of the recommendations for men is less than that for women (*103*). This report includes preconception health services that address men as partners in family planning (i.e., both preventing and achieving pregnancy), their direct contributions to infant health (e.g., genetics), and their role in improving the health of women (e.g., through reduced STD/HIV transmission). Moreover, these services are important for improving the health of men regardless of their pregnancy intention.

In a family planning setting, all women planning or capable of pregnancy should be counseled about the need to take a daily supplement containing 0.4 to 0.8 mg of folic acid, in accordance with the USPSTF recommendation (Grade A) (*104*).

Other preconception health services for women and men should include discussion of a reproductive life plan and sexual health assessment (Boxes 2 and 4), as well as the screening services described below (*24*,*103*,*105*). Services should be provided in accordance with the cited clinical recommendations, and any needed follow up (further diagnosis, treatment) should be provided either on-site or through referral.

Medical History

For female clients, the medical history should include the reproductive history, history of poor birth outcomes (i.e., preterm, cesarean delivery, miscarriage, and stillbirth), environmental exposures, hazards and toxins (e.g., smoking, alcohol, other drugs), medications that are known teratogens, genetic conditions, and family history (*24*,*105*).

For male clients, the medical history should include asking about the client's past medical and surgical history that might impair his reproductive health (e.g., genetic conditions, history of reproductive failures, or conditions that can reduce sperm quality, such as obesity, diabetes mellitus, and varicocele) and environmental exposures, hazards and toxins (e.g., smoking) (*103*).

Intimate Partner Violence

Providers should screen women of childbearing age for intimate partner violence and provide or refer women who screen positive to intervention services, in accordance with USPSTF (Grade B) recommendations (*106*).

Alcohol and Other Drug Use

For female and male adult clients, providers should screen for alcohol use in accordance with the USPSTF recommendation (Grade B) for how to do so, and provide behavioral counseling

interventions, as indicated (*107*). Screening adults for other drug use and screening adolescents for alcohol and other drug use has the potential to reduce misuse of alcohol and other drugs, and can be recommended (*105*,*108*,*109*). However, the USPSTF recommendation for screening for other drugs in adults, and for alcohol and other drugs in adolescents, is an "I," and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of this screening (*107*,*110*).

Tobacco Use

For female and male clients, providers should screen for tobacco use in accordance with the USPSTF recommendation (*111*,*112*) for how to do so. Adults (Grade A) who use tobacco products should be provided or referred for tobacco cessation interventions, including brief behavioral counseling sessions (<10 minutes) and pharmacotherapy delivered in primary care settings (*111*). Adolescents (Grade B) should be provided intervention to prevent initiation of tobacco use (*112*).

Immunizations

For female and male clients, providers should screen for immunization status in accordance with recommendations of CDC's Advisory Committee on Immunization Practices (*113*) and offer vaccination, as indicated, or provide referrals to community providers for immunization. Female and male clients should be screened for age-appropriate vaccinations, such as influenza and tetanus–diphtheria–pertussis (Tdap), measles, mumps, and rubella (MMR), varicella, pneumococcal, and meningococcal. In addition, ACOG recommends that rubella titer be performed in women who are uncertain about MMR immunization (*108*). (For vaccines for reproductive health-related conditions, i.e., human papillomavirus and hepatitis B, see "Sexually Transmitted Disease Services.")

Depression

For all clients, providers should screen for depression when staff-assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow-up (*114*,*115*). Staff-assisted care supports are defined as clinical staff members who assist the primary care clinician by providing some direct depression care, such as care support or coordination, case management, or mental health treatment. The lowest effective staff supports consist of a screening nurse who advises primary care clinicians of a positive screen and provides a protocol facilitating referral to behavioral therapy.

Providers also may follow American Psychiatric Association (*116*) and American Academy of Child and Adolescent Psychiatry (*117*) recommendations to assess risk for suicide among persons experiencing depression and other risk factors.

Height, Weight, and Body Mass Index

For all clients, providers should screen adult (Grade B) and adolescent (Grade B) clients for obesity in accordance with the USPSTF recommendation, and obese adults should be referred for intensive counseling and behavioral interventions to promote sustained weight loss (*118*,*119*). Clients likely will need to be referred for this service. These interventions typically comprise 12 to 26 sessions in a year and include multiple behavioral management activities, such as group sessions, individual sessions, setting weight-loss goals, improving diet or nutrition, physical activity sessions, addressing barriers to change, active use of self-monitoring, and strategizing how to maintain lifestyle changes.

Blood Pressure

For female and male clients, providers should screen for hypertension in accordance with the USPSTF's recommendation (Grade A) that blood pressure be measured routinely among adults (*120*) and the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure's recommendation that persons with blood pressure less than 120/80 be screened every 2 years, and every year if prehypertensive (i.e., blood pressure 120–139/80–89) (*121*). Providers also may follow AAP's recommendation that adolescents receive annual blood pressure screening (*109*).

Diabetes

For female and male clients, providers should follow the USPSTF recommendation (Grade B) to screen for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) >135/80 mmHg (*122*).

Sexually Transmitted Disease Services

Providers should offer STD services in accordance with CDC's STD treatment and HIV testing guidelines (*36*,*123*,*124*). It is important to test for chlamydia annually among young sexually active females and for gonorrhea routinely among all sexually active females at risk for infection because they can cause tubal infertility in women if left untreated. Testing for syphilis, HIV/AIDS, and hepatitis C should be conducted as recommended (*36*,*123*,*124*). Vaccination for human papillomavirus (HPV) and hepatitis B are also important parts of STD services and preconception care (*113*).

STD services should be provided for persons with no signs or symptoms suggestive of an STD. STD diagnostic management recommendations are not included in these guidelines, so providers should refer to CDC's STD treatment guidelines

(36) when caring for clients with STD symptoms. STD services include the following steps, which should be provided at the initial visit and at least annually thereafter:

Step 1. Assess: The provider should discuss the client's reproductive life plan, conduct a standard medical history and sexual health assessment (see text box above), and check immunization status. A pelvic exam is not indicated in patients with no symptoms suggestive of an STD.

Step 2. Screen: A client who is at risk of an STD (i.e., sexually active and not involved in a mutually monogamous relationship with an uninfected partner) should be screened for HIV and the other STDs listed below, in accordance with CDC's STD treatment guidelines (*36*) and recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings (*123*). Clients also should follow CDC's recommendations for testing for hepatitis C (*124*), and the Advisory Committee on Immunization Practice's recommendations on reproductive health-related immunizations (*113*). It is important to follow these guidelines both to ensure that clients receive needed services and to avoid unnecessary screening.

Chlamydia

For female clients, providers should screen all sexually active women aged ≤25 years for chlamydia annually, in addition to sexually active women aged >25 years with risk factors for chlamydia infection (*36*). Women aged >25 years at higher risk include sexually active women who have a new or more than one sex partner or who have a partner who has other concurrent partners. Females with chlamydia infection should be rescreened for re-infection at 3 months after treatment. Pregnant women should be screened for chlamydia at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

For male clients, chlamydia screening can be considered for males seen at sites with a high prevalence of chlamydia, such as adolescent clinics, correctional facilities, and STD clinics (*36*,*125*,*126*). Providers should screen men who have sex with men (MSM) for chlamydia at anatomic sites of exposure, in accordance with CDC's STD treatment guidelines (*36*). Males with symptoms suggestive of chlamydia (urethral discharge or dysuria or whose partner has chlamydia) should be tested and empirically treated at the initial visit. Males with chlamydia infection should be re-screened for reinfection at 3 months (*36*).

Gonorrhea

For female clients, providers should screen clients for gonorrhea, in accordance with CDC's STD treatment guidelines (*36*). Routine screening for *N. gonorrhoeae* in all sexually active women at risk for infection is recommended annually (*36*). Women aged <25 years are at highest risk for gonorrhea infection. Other risk factors that place women at increased risk include a previous gonorrhea infection, the presence of other STDs, new or multiple sex partners, inconsistent condom use, commercial sex work, and drug use. Females with gonnorrhea infection should be re-screened for re-infection at 3 months after treatment. Pregnant women should be screened for gonorrhea at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

For male clients, providers should screen MSM for gonorrhea at anatomic sites of exposure, in accordance with CDC's STD treatment guidelines (*36*). Males with symptoms suggestive of gonorrhea (urethral discharge or dysuria or whose partner has gonorrhea) should be tested and empirically treated at the initial visit. Males with gonorrhea infection should be re-screened for reinfection at 3 months after treatment (*36*,*126*–*128*).

Syphilis

For female and male clients, providers should screen clients for syphilis, in accordance with CDC's STD treatment guidelines (*36*). CDC recommends that persons at risk for syphilis infection should be screened. Populations at risk include MSM, commercial sex workers, persons who exchange sex for drugs, those in adult correctional facilities and those living in communities with high prevalence of syphilis (*36*). Pregnant women should be screened for syphilis at the time of their pregnancy test if there might be delays in obtaining prenatal care (*36*).

HIV/AIDS

For female and male clients, providers should screen clients for HIV/AIDS, in accordance with CDC HIV testing guidelines (*123*). Providers should follow CDC recommendations that all clients aged 13–64 years be screened routinely for HIV infection and that all persons likely to be at high risk for HIV be rescreened at least annually (*123*). Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test. CDC further recommends that screening be provided after the patient is notified that testing will be performed as part of general medical consent unless the patient declines (opt-out screening) or otherwise prohibited by state law. The USPSTF also recommends screening for HIV (Grade A) (*129*).

Hepatitis C

For female and male clients, CDC recommends one-time testing for hepatitis C (HCV) without prior ascertainment of HCV risk for persons born during 1945–1965, a population with a disproportionately high prevalence of HCV infection

and related disease. Persons identified as having HCV infection should receive a brief screening for alcohol use and intervention as clinically indicated, followed by referral to appropriate care for HCV infection and related conditions. These recommendations do not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications. Rather, they define an additional target population for testing: persons born during 1945–1965 (*124*). USPSTF also recommends screening persons at high risk for infection for hepatitis C and one-time screening for HCV infection for persons in the 1945–1965 birth cohort (Grade B) (*130*).

Immunizations Related to Reproductive Health

Female clients aged 11–26 years should be offered either human papillomavirus (HPV) 2 or HPV4 vaccine for the prevention of HPV and cervical cancer if not previously vaccinated, although the series can be started in persons as young as age 9 years (*113*); recommendations include starting at age 11–12 years and catch up vaccine among females aged 13–26 who have not been vaccinated previously or have not completed the 3-dose series through age 26. Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged <19 years and all adults who are unvaccinated and do not have any documented history of hepatitis B infection (*113*).

Male clients aged 11–21 years (minimum age: 9 years) should be offered HPV4 vaccine, if not vaccinated previously; recommendations include starting at age 11–12 years and catch up vaccine among males aged 13–21 years who have not been vaccinated previously or have not completed the 3-dose series through age 21 years; vaccination is recommended among at-risk males, including MSM and immune-compromised males through age 26 years if not vaccinated previously or males who have not completed the 3-dose series through age 26 years. Heterosexual males aged 22–26 years may be vaccinated (*131*). Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged <19 years, and all unvaccinated adults who do not have a documented history of hepatitis B infection (*113*).

Step 3. Treat: A client with an STD and her or his partner(s) should be treated in a timely fashion to prevent complications, re-infection and further spread of the infection in the community in accordance with CDC's STD treatment guidelines; clients with HIV infection should be linked to HIV care and treatment (*36*,*123*). Clients should be counseled about the need for partner evaluation and treatment to avoid reinfection at the time the client receives the positive test results. For partners of clients with chlamydia or gonorrhea, one option is to schedule them to come in with the client; another option for partners who cannot come in with the client is expedited partner therapy (EPT), as permissible by state laws, in which medication or a prescription is provided to the patient to give to the partner to ensure treatment. EPT is a partner treatment strategy for partners who are unable to access care and treatment in a timely fashion. Because of concerns related to resistant gonorrhea, efforts to bring in for treatment partners of patients with gonorrhea infection are recommended; EPT for gonorrhea should be reserved for situations in which efforts to treat partners in a clinical setting are unsuccessful and EPT is a gonorrhea treatment of last resort.

All clients treated for chlamydia or gonorrhea should be rescreened 3 months after treatment; HIV-infected females with *Trichomonas vaginalis* should be linked to HIV care and rescreened for *T. vaginalis* at 3 months. If needed, the client also should be vaccinated for hepatitis B and HPV (*113*). Ideally, STD treatment should be directly observed in the facility rather than a prescription given or called in to a pharmacy. If a referral is made to a service site that has the necessary medication available on-site, such as the recommended injectable antimicrobials for gonorrhea and syphilis, then the referring provider must document that treatment was given.

Step 4. Provide risk counseling: If the client is at risk for or has an STD, high-intensity behavioral counseling for sexual behavioral risk reduction should be provided in accordance with the USPSTF recommendation (Grade B) (*132*). One high-intensity behavioral counseling model that is similar to the contraceptive counseling model is Project Respect (*133*), which could be implemented in family planning settings. All sexually active adolescents are at risk, and adults are at increased risk if they have current STDs, had an STD in the past year, have multiple sexual partners, are in nonmonogamous relationships, or are sexually active and live in a community with a high rate of STDs.

Other key messages to give infected clients before they leave the service site include the following: a) refrain from unprotected sexual intercourse during the period of STD treatment, 2) encourage partner(s) to be screened or to get treatment as quickly as possible in accordance with CDC's STD treatment guidelines (partners in the past 60 days for chlamydia and gonorrhea, 3 to 6 months plus the duration of lesions or signs for primary and secondary syphilis, respectively) if the partner did not accompany the client to the service site for treatment, and 3) return for retesting in 3 months. If the partner is unlikely to access treatment quickly, then EPT for chlamydia or gonorrhea should be considered, if permissible by state law.

A client using or considering contraceptive methods other than condoms should be advised that these methods do not protect against STDs. Providers should encourage a client who is not in a mutually monogamous relationship with an

uninfected partner to use condoms. Patients who do not know their partners' infection status should be encouraged to get tested and use condoms or avoid sexual intercourse until their infection status is known.

Related Preventive Health Services

For many women and men of reproductive age, a family planning service site is their only source of health care; therefore, visits should include provision of or referral to other preventive health services. Providers of family planning services that do not have the capacity to offer comprehensive primary care services should have strong links to other community providers to ensure that clients have access to primary care. If a client does not have another source of primary care, priority should be given to providing related reproductive health services or providing referrals, as needed.

For clients without a primary care provider, the following screening services should be provided, with appropriate follow-up, if needed, while linking the client to a primary care provider. These services should be provided in accordance with federal and professional medical recommendations cited below regarding the frequency of screening, the characteristics of the clients that should be screened, and the screening procedures to be used.

Medical History

USPSTF recommends that women be asked about family history that would be suggestive of an increased risk for deleterious mutations in BRCA1 or BRCA2 genes (e.g., receiving a breast cancer diagnosis at an early age, bilateral breast cancer, history of both breast and ovarian cancer, presence of breast cancer in one or more female family members, multiple cases of breast cancer in the family, both breast and ovarian cancer in the family, one or more family members with two primary cases of cancer, and Ashkenazi background). Women with identified risk(s) should be referred for genetic counseling and evaluation for BRCA testing (Grade B) (*134*). The USPSTF also recommends that women at increased risk for breast cancer should be counseled about risk-reducing medications (Grade B) (*135*).

Cervical Cytology

Providers should provide cervical cancer screening to clients receiving related preventive health services. Providers should follow USPSTF recommendations to screen women aged 21–65 years with cervical cytology (Pap smear) every 3 years, or for women aged 30–65 years, screening with a combination of cytology and HPV testing every 5 years (Grade A) (*136*).

Cervical cytology no longer is recommended on an annual basis. Further, it is not recommended (Grade D) for women aged <21 years (*136*). Women with abnormal test results should be treated in accordance with professional standards of care, which may include colposcopy (*96*,*137*). The need for cervical cytology should not delay initiation or hinder continuation of a contraceptive method (*42*).

Providers should also follow ACOG and AAP recommendations that a genital exam should accompany a cervical cancer screening to inspect for any suspicious lesions or other signs that might indicate an undiagnosed STD (*96*,*97*,*138*).

Clinical Breast Examamination

Despite a lack of definitive data for or against, clinical breast examination has the potential to detect palpable breast cancer and can be recommended. ACOG recommends annual examination for all women aged >19 years (*108*). ACS recommends screening every 3 years for women aged 20–39 years, and annually for women aged ≥40 years (*139*). However, the USPSTF recommendation for clinical breast exam is an I, and patients should be informed that there is insufficient evidence to assess the balance of benefits and harms of the service (*140*).

Mammography

Providers should follow USPSTF recommendations (Grade B) to screen women aged 50–74 years on a biennial basis; they should screen women aged <50 years if other conditions support providing the service to an individual patient (*140*).

Genital Examination

For adolescent males, examination of the genitals should be conducted. This includes documentation of normal growth and development and other common genital findings, including hydrocele, varicocele, and signs of STDs (*141*). Components of this examination include inspecting skin and hair, palpating inguinal nodes, scrotal contents and penis, and inspecting the perinanal region (as indicated).

Summary of Recommendations for Providing Family Planning and Related Preventive Health Services

The screening components for each family planning and related preventive health service are provided in summary checklists for women (Table 2) and men (Table 3). When considering how to provide the services listed in these recommendations (e.g., the screening components for each

service, risk groups that should be screened, the periodicity of screening, what follow-up steps should be taken if screening reveals the presence of a health condition), providers should follow CDC and USPSTF recommendations cited above, or, in the absence of CDC and USPSTF recommendations, the recommendations of professional medical associations. Following these recommendations is important both to ensure clients receive needed care and to avoid unnecessary screening of clients who do not need the services.

The summary tables describe multiple screening steps, which refer to the following: 1) the process of asking questions about a client's history, including a determination of whether risk factors for a disease or health condition exist; 2) performing a physical exam; and 3) performing laboratory tests in at-risk asymptomatic persons to help detect the presence of a specific disease, infection, or condition. Many screening recommendations apply only to certain subpopulations (e.g., specific age groups, persons who engage in specific risk behaviors or who have specific health conditions), or some screening recommendations apply to a particular frequency (e.g., a cervical cancer screening is generally recommended every 3 years rather than annually). Providers should be aware that the USPSTF also has recommended that certain screening services not be provided because the harm outweighs the benefit (see Appendix F).

When screening results indicate the potential or actual presence of a health condition, the provider should either provide or refer the client for the appropriate further diagnostic testing or treatment in a manner that is consistent with the relevant federal or professional medical associations' clinical recommendations.

Conducting Quality Improvement

Service sites that offer family planning services should have a system for conducting quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. Quality improvement is the use of a deliberate and continuous effort to achieve measurable improvements in the identified indicators of quality of care, which improve the health of the community (*142*). By improving the quality of care, family planning outcomes, such as reduced rates of unintended pregnancy, improved patient experiences, and reduced costs, are more likely to be achieved (*10*,*12*,*143*,*144*).

Several frameworks for conducting quality improvement have been developed (*144–146*). This section presents a general overview of three key steps that providers should take when conducting quality improvement of family planning services: 1) determine which measures are needed to monitor quality; 2) collect the information needed; and 3) use the findings to make changes to improve quality (*147*). Ideally, these steps will be conducted on a frequent (optimally, quarterly) and ongoing basis. However, since quality cuts across all aspects of a program, not all domains of quality can necessarily be considered at all times. Within a sustainable system of quality improvement, programs can opt to focus on a subset of quality dimensions and their respective measures.

Determining Which Measures Are Needed

Performance measures provide information about how well the service site is meeting pre-established goals (*148*). The following questions should be considered when selecting performance measures (*143*):

- Is the topic important to measure and report? For example, does it address a priority aspect of health care, and is there opportunity for improvement?
- What is the level of evidence for the measure (e.g., that a change in the measure is likely to represent a true change in health outcomes)? Does the measure produce consistent (reliable) and credible (valid) results about the quality of care?
- Are the results meaningful and understandable and useful for informing quality improvement?
- Is the measure feasible? Can it be implemented without undue burden (e.g., captured with electronic data or electronic health records)?

Performance measures should consider the quality of the structure of services (e.g., the characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure), the process by which care is provided (whether services are provided correctly and completely, and how clients perceive the care they receive), and the outcomes of that care (e.g., client behaviors or health conditions that result) (*149*). They also may assess each dimension of quality services (*10*,*13*). Examples of measures that can be used for monitoring the quality of family planning services (*150*) and suggested measures that might help providers monitor quality of care have been listed (Table 6). However, other measures have been developed that also might be useful (*151–153*). Service sites that offer family planning services should select, measure, and assess at least one intermediate or outcome measure on an ongoing basis, for which the service site can be accountable. Structure- and process-based measures that assess the eight dimensions of quality services may be used to better determine how to improve quality (*154*).

Collecting Information

Once providers have determined what information is needed, the next steps are to collect and use that information to improve the quality of care. Commonly used methods of data collection include the following:

TABLE 2. Checklist of family planning and related preventive health services for women

Screening components	Family planning services (provide services in accordance with the appropriate clinical recommendation)					Related preventive health services
	Contraceptive services*	Pregnancy testing and counseling	Basic infertility services	Preconception health services	STD services†	
History						
Reproductive life plan§	Screen	Screen	Screen	Screen	Screen	
Medical history§,**	Screen	Screen	Screen	Screen	Screen	Screen
Current pregnancy status§	Screen					
Sexual health assessment§,**	Screen		Screen	Screen	Screen	
Intimate partner violence §,¶,**				Screen		
Alcohol and other drug use§,¶,**				Screen		
Tobacco use§,¶	Screen (combined hormonal methods for clients aged ≥35 years)			Screen		
Immunizations§				Screen	Screen for HPV & HBV§§	
Depression§,¶				Screen		
Folic acid§,¶				Screen		
Physical examamination						
Height, weight and BMI§,¶	Screen (hormonal methods)††		Screen	Screen		
Blood pressure§,¶	Screen (combined hormonal methods)			Screen§§		
Clinical breast exam**			Screen			Screen§§
Pelvic exam§,**	Screen (initiating diaphragm or IUD)	Screen (if clinically indicated)	Screen			
Signs of androgen excess**			Screen			
Thyroid exam**			Screen			
Laboratory testing						
Pregnancy test **	Screen (if clinically indicated)	Screen				
Chlamydia§, ¶	Screen¶¶				Screen§§	
Gonorrhea§, ¶	Screen¶¶				Screen§§	
Syphilis§,¶					Screen§§	
HIV/AIDS§,¶					Screen§§	
Hepatitis C§,¶					Screen§§	
Diabetes§,¶				Screen§§		
Cervical cytology¶						Screen§§
Mammography¶						Screen§§

Abbreviations: BMI = body mass index; HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus; IUD = intrauterine device; STD = sexually transmitted disease.

* This table presents highlights from CDC's recommendations on contraceptive use. However, providers should consult appropriate guidelines when treating individual patients to obtain more detailed information about specific medical conditions and characteristics (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59(No. RR-4).

† STD services also promote preconception health but are listed separately here to highlight their importance in the context of all types of family planning visits. The services listed in this column are for women without symptoms suggestive of an STD.

§ CDC recommendation.

¶ U.S. Preventive Services Task Force recommendation.

** Professional medical association recommendation.

†† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. Medical Eligibility Criteria 1) or generally can be used (U.S. Medical Eligibility Criteria 2) among obese women (Source: CDC. U.S. medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§§ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of an infection or condition.

¶¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD treatment guidelines (Sources: CDC. STD treatment guidelines. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/std/treatment. CDC. Sexually transmitted diseases treatment guidelines, 2010. MMWR 2010;59[No. RR-12]). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4) women who have a very high individual likelihood of STD exposure (e.g. those with a currently infected partner) generally should not undergo IUD insertion (U.S. Medical Eligibility Criteria 3) (Source: CDC. US medical eligibility criteria for contraceptive use 2010. MMWR 2010;59[No. RR-4]). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

- **Review of medical records.** All records that detail service delivery activities can be reviewed, including encounters and claims data, client medical records, facility logbooks, and others. It is important that records be carefully designed, sufficiently detailed, provide accurate information, and have access restricted to protect confidentiality. The use of electronic health records can facilitate some types of medical record review.
- **Exit interview with the client.** A patient is asked (through either a written or in-person survey) to describe what happened during the encounter or their assessment of their satisfaction with the visit. Both quantitative (close-ended questions) and qualitative (open-ended questions) methods can be used. Limitations include a bias toward clients reporting higher degrees of satisfaction, and the

TABLE 3. Checklist of family planning and related preventive health services for men

Screening components and source of recommendation	Family planning services (provide services in accordance with the appropriate clinical recommendation)				Related preventive health services
	Contraceptive services*	Basic infertility services	Preconception health services†	STD services§	
History					
Reproductive life plan¶	Screen	Screen	Screen	Screen	
Medical history¶,††	Screen	Screen	Screen	Screen	
Sexual health assessment¶,††	Screen	Screen	Screen	Screen	
Alcohol & other drug use ¶,**,††			Screen		
Tobacco use¶,**			Screen		
Immunizations¶			Screen	Screen for HPV & HBV§§	
Depression¶,**			Screen		
Physical examination					
Height, weight, and BMI¶,**			Screen		
Blood pressure**,††			Screen§§		
Genital exam††		Screen (if clinically indicated)		Screen (if clinically indicated)	Screen§§
Laboratory testing					
Chlamydia¶				Screen§§	
Gonorrhea¶				Screen§§	
Syphilis¶,**				Screen§§	
HIV/AIDS¶,**				Screen§§	
Hepatitis C¶,**				Screen§§	
Diabetes¶,**			Screen§§		

Abbreviations: HBV = hepatitis B virus; HIV/AIDS = human immunodeficiency virus/acquired immunodeficiency syndrome; HPV = human papillomavirus virus; STD = sexually transmitted disease.

* No special evaluation needs to be done prior to making condoms available to males. However, when a male client requests advice on pregnancy prevention, he should be provided contraceptive services as described in the section "Provide Contraceptive Services."

† The services listed here represent a sub-set of recommended preconception health services for men that were recommended and for which there was a direct link to fertility or infant health outcomes (Source: Frey K, Navarro S, Kotelchuck M, Lu M. The clinical content of preconception care: preconception care for men. Am J Obstet Gynecol 2008;199[6 Suppl 2]:S389–95).

§ STD services also promote preconception health, but are listed separately here to highlight their importance in the context of all types of family planning visit. The services listed in this column are for men without symptoms suggestive of an STD.

¶ CDC recommendation.

** U.S. Preventive Services Task Force recommendation.

†† Professional medical association recommendation.

§§ Indicates that screening is suggested only for those persons at highest risk or for a specific subpopulation with high prevalence of infection or other condition.

provider's behavior might be influenced if she or he knows clients are being interviewed.

- **Facility audit.** Questions about a service site's structure (e.g., on-site availability of a broad range of FDA-approved methods) and processes (e.g., skills and technical competence of staff, referral mechanisms) can be used to determine the readiness of the facility to serve clients.
- **Direct observation.** A provider's behavior is observed during an actual encounter with a client. Evaluation of a full range of competencies, including communication skills, can be carried out. A main limitation is that the observer's presence might influence the provider's performance.
- **Interview with the health-care provider.** Providers are interviewed about how specific conditions are managed. Both closed- and open-ended questions can be used, although it is important to frame the question so that the 'correct' answer is not suggested. A limitation is that providers tend to over-report their performance.

Consideration and Use of the Findings

After data are collected, they should be tabulated, analyzed, and used to improve care. Staff whose performance was assessed should be involved in the development of the data collection tools and analysis of results. Analysis should address the following questions (*155*):

- What is the performance level of the facility?
- Is there a consistent pattern of performance among providers?
- What is the trend in performance?
- What are the causes of poor performance?
- How can performance gaps be minimized?

Given the findings, service site staff should use a systematic approach to identifying ways to improve the quality of care. One example of a systematic approach to improving the quality of care is the "Plan, Do, Study, and Act" (PDSA) model (*147*,*156*), in which staff first develop a plan for improving quality, then execute the plan on a small scale, evaluate feedback to confirm or adjust the plan, and finally, make the plan

TABLE 4. Suggested measures of the quality of family planning services

Type of measure and dimension of quality	Measure	Source
Health outcome	• Unintended pregnancy • Teen pregnancy • Birth spacing • Proportion of female users at risk for unintended pregnancy who adopt or continue use of an FDA-approved contraceptive method (measured for any method; highly effective methods; or long-acting reversible methods) [Intermediate outcome]	PIMS*
Safe (Structure)	• Proportion of providers that follow the most current CDC recommendations on contraceptive safety	
Effective (Structure, or the characteristics of the settings in which providers deliver health care, including material resources, human resources, and organizational structure)	• Site dispenses or provides on-site a full range of FDA-approved contraceptive methods to meet the diverse reproductive needs and goals of clients; short-term hormonal, long-acting reversible contraception (LARC), emergency contraception (EC). • Proportion of female users aged ≥24 years who are screened annually for chlamydial infection. • Proportion of female users aged ≥24 years who are screened annually for gonorrhea. • Proportion of users who were tested for HIV during the past 12 months. • Proportion of female users aged ≥21 years who have received a Pap smear within the past 3 years.	PIMS*
Client-centered (Process, or whether services are provided correctly and completely, and how clients perceive the care they receive)	• Proportion of clients who report the provider communicates well, shows respect, spends enough time with the client, and is informed about the client's medical history. • Proportion of clients who report that – Staff are helpful and treat clients with courtesy and respect. – His or her privacy is respected. – She or he receives contraceptive method that is acceptable to her or him.	CAHPS† RQIP§
Efficient (Structure)	• Site uses electronic health information technology or electronic health records to improve client reproductive health.	PIMS*
Timely (Structure and process)	• Average number of days to the next appointment. • Site offers routine contraceptive resupply on a walk-in basis. • Site offers on-site HIV testing (using rapid technology). • Site offers on-site HPV and hepatitis B vaccination.	PIMS*
Accessible (Structure and process)	• Site offers family planning services during expanded hours of operation. • Proportion of total family planning encounters that are encounters with ongoing or continuing users. • Proportion of clients who report that his or her care provider follows up to give test results, has up-to-date information about care from specialists, and discusses other prescriptions. • Site has written agreements (e.g., MOUs) with the key partner agencies for health care (especially prenatal care, primary care, HIV/AIDS) and social service (domestic violence, food stamps) referrals.	PIMS* CAHPS–PCMH item set on care coordination†
Equitable (Structure)	• Site offers language assistance at all points of contact for the most frequently encountered language(s).	PIMS*
Value	• Average cost per client.	CDC¶

Abbreviations: CAPHS = Agency for Healthcare Research and Quality's Consumer Assessment of Health Care Providers and Systems; FDA = Food and Drug Administration; HPV = human papillomavirus; MOU = memorandum of understanding; PIMS = Performance Information and Monitoring System; RQIP = Regional Quality Indicators Program.

* **Source:** Fowler C. Title X Family Planning Program Performance Information and Monitoring System (PIMS): Description of Proposed Performance Measures [DRAFT]. Washington, DC: Research Triangle Institute; 2012.

† **Source:** Agency for Healthcare Research and Quality. Consumer Assessment of Healthcare Providers and Systems (CAHPS). Available at https://www.cahps.ahrq.gov/default.asp.

§ **Source:** John Snow International. The Regional Quality Indicators Project (RQIP). Boston, MA: John Snow International; 2014. Available at http://www.jsi.com/JSIInternet/USHealth/project/display.cfm?ctid=na&cid=na&tid=40&id=2621.

¶ **Sources:** Haddix A, Corso P, Gorsky R. Costs. In: Haddix A, Teutsch S, Corso P, eds. Prevention effectiveness: a guide to decision analysis and economic evaluation. 2nd ed. Oxford, UK: Oxford University Press; 2003; Stiefel M, Nolan K. A guide to measuring the triple aim: population health, experience of care, and per capita cost. Cambridge, MA: Institute for Healthcare Improvements; 2012.

permanent. Examples of steps that may be taken to improve the quality of care include developing job aids, providing task-specific training for providers, conducting more patient education, or strengthening relationships with referral sites through formal memoranda of understanding (*146*).

Conclusion

The United States continues to face substantial challenges to improving the reproductive health of the U.S. population. The recommendations in this report can contribute to improved reproductive health by defining a core set of family planning

services for women and men, describing how to provide contraceptive and other family planning services to both adult and adolescent clients, and encouraging the use of the family planning visit to provide selected preventive health services for women and men. This guidance is intended to assist primary care providers to offer the family planning services that will help persons and couples achieve their desired number and spacing of children and increase the likelihood that those children are born healthy.

Recommendations are updated periodically. The most recent versions are available at http://www.hhs.gov/opa.

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Appendix A

How the Recommendations Were Developed

The recommendations were developed jointly under the auspices of CDC's Division of Reproductive Health (DRH) and the Office of Population Affairs (OPA), in consultation with a wide range of experts and key stakeholders. A multistage process that drew on established procedures for developing clinical guidelines (*1,2*) was used to develop the recommendations. In April 2010, an Expert Work Group (EWG) comprising family planning clinical providers, program administrators, representatives from relevant federal agencies, and representatives from professional medical organizations was created to advise OPA and CDC on the structure and content of the revised recommendations and to help make the recommendations more feasible and relevant to the needs of the field. This group made two key initial recommendations: 1) to examine the scientific evidence for three priority areas of focus identified as key components of family planning service delivery, (i.e., counseling and education, serving adolescents, and quality improvement); and 2) to guide providers of family planning services in the use of various recommendations for how to provide clinical care to women and men.

Developing Recommendations on Counseling, Adolescent Services, and Quality Improvement

Systematic reviews of the published literature from January 1985 through December 2010 were conducted for each priority topic to identify evidence-based and evidence-informed approaches to family planning service delivery. Standard methods for conducting the reviews were used, including the development of key questions and analytic frameworks, the identification of the evidence base through a search of the published as well as "gray literature" (i.e., studies published somewhere other than in a peer-reviewed journal), and a synthesis of the evidence in which findings were summarized and the quality of individual studies was considered, using the methodology of the U.S. Preventive Services Task Force (USPSTF) (*3*). Eight databases were searched (i.e., MEDLINE, PsychInfo, PubMed, CINAHL, Cochrane, EMBASE, POPLINE, and the U.K. National Clearinghouse Service Economic Evaluation Database) and were restricted to literature from the United States and other developed countries. Summaries of the evidence used to prepare these recommendations will appear in background papers that will be published separately.

In May 2011, three technical panels (one for each priority topic) comprising subject matter experts were convened to consider the quality of the evidence and suggest what recommendations might be justified on the basis of the evidence. CDC and OPA used this feedback to develop core recommendations for counseling, serving adolescents, and quality improvement. EWG members subsequently reviewed these core recommendations; EWG members differed from the subject matter experts in that they were more familiar with the family planning service delivery context and could comment on the feasibility and appropriateness of the recommendations as well as on their scientific justification. EWG members met to consider the core recommendations using 1) the quality of the evidence; 2) the positive and negative consequences of implementing the recommendations on health outcomes, costs or cost-savings, and implementation challenges; and 3) the relative importance of these consequences (e.g., the ability of the recommendations to have a substantial effect on health outcomes may be weighed more than the logistical challenges of implementing them) (*1*). In certain cases, when the evidence was inconclusive or incomplete, recommendations were made on the basis of expert opinion (see Appendix B). Finally, CDC and OPA staff considered the feedback from EWG members when finalizing the core recommendations and writing this report.

Developing Recommendations on Clinical Services

DRH and OPA staff members synthesized recommendations for clinical care for women and for men that were developed by >35 federal and professional medical organizations. They were assisted in this effort by staff from OPA's Office of Family Planning Male Training Center and from CDC's Division of STD Prevention, Division of Violence Prevention, Division of Immunization Services, and Division of Cancer Prevention and Control. The synthesis was needed because clinical recommendations are sometimes inconsistent with each other and can vary by the extent to which they are evidence-based. The clinical recommendations addressed contraceptive services, achieving pregnancy, basic infertility services, preconception health services, sexually transmitted disease services, and related health-care services.

An attempt was made to apply the Institute of Medicine's criteria for clinical practice guidelines when deciding which professional medical organizations to include in the review (*2*). However, many organizations did not articulate the process used to develop the recommendations fully, and many did not

conduct comprehensive and systematic reviews of the literature. In the end, to be included in the synthesis, the recommending organization had to be a federal agency or major professional medical organization that represents established medical disciplines. In addition, a recommendation had to be made on the basis of an independent review of the evidence or expert opinion and be considered a primary source that was developed for the United States.

In July 2011, two technical panels comprising subject matter experts on clinical services for women and men were convened to review the synthesis of federal and professional medical recommendations, reconcile inconsistent recommendations, and provide individual feedback to CDC and OPA about the implications for family planning service delivery. CDC and OPA used this individual feedback to develop core recommendations for clinical services. The core recommendations were subsequently reviewed by EWG members, and feedback was used to finalize the core recommendations and write this report.

Members of the technical panels recommended that contraceptive services, pregnancy testing and counseling, services to achieve pregnancy, basic infertility care, STD services, and other preconception health services should be considered family planning services. This feedback considered federal statute and regulation, CDC and USPSTF recommendations for clinical care, and EWG members' opinion.

Because CDC's preconception health recommendations include many services, the panel narrowed the range of preconception services that were included by using the following criteria: 1) the Select Panel on Preconception Care (*4*) had assigned an A or B recommendation to that service for women, which means that there was either good or fair evidence to support the recommendation that the condition be considered in a preconception care evaluation (Table 1), or 2) the service was included among recommendations made by experts in preconception health for males (*5*). Services for men that addressed health conditions that affect reproductive capacity or pregnancy outcomes directly were included as preconception health; services that addressed men's health but that were not related directly to pregnancy outcomes were considered to be related preventive health services.

The Expert Work Group noted that more preventive services are recommended than can be offered feasibly in some settings. However, a primary purpose of this report is to set a broad framework within which individual clinics will tailor services to meet the specific needs of the populations that they serve. In addition, EWG members identified specific subgroups that should have the greatest priority for preconception health services (i.e., those trying to achieve pregnancy and those at high risk of unintended pregnancy). Future operational research should provide more information about how to deliver these services most efficiently during multiple visits to clients with diverse needs.

Determining How Clinical Services Should Be Provided

Various federal agencies and professional medical associations have made recommendations for how to provide family planning services. When considering these recommendations, the Expert Work Group used the following hierarchy:

- Highest priority was given to CDC guidelines because they are developed after a rigorous review of scientific evidence. CDC guidelines tailor recommendations for higher risk individuals, (whereas USPSTF focuses on average risk individuals), who are more representative of the clients seeking family planning services.
- When no CDC guideline existed to guide the recommendations, the relevant USPSTF A or B recommendations (which indicate a high or moderate certainty that the benefit is moderate to substantial) were used. USPSTF recommendations are made on the basis of a thorough review of the available evidence.
- If neither a CDC nor a USPSTF A or B recommendation existed, the recommendations of selected major professional medical associations were considered as resources. The American Academy of Pediatrics' (AAP) Bright Futures guidelines (*6*) were used as the primary source of recommendations for adolescents when no CDC or USPSTF recommendations existed.
- For a limited number of recommendations, there were no federal or major professional medical recommendations, but the service was recommended by EWG members on the basis of expert opinion for family planning clients.

In some cases, a service was graded as an I recommendation by USPSTF for the general population (an I recommendation means that the current evidence is insufficient to assess the balance of benefits and harms of the service, so if the service is offered, patients should be informed of this fact), but either CDC, EWG members, or another organization recommended the service for women or men seeking family planning services. The situations in which this occurred and the reasons why the service was recommended despite its receiving an I recommendation by USPSTF have been summarized (Table 2). The approach used to consider the evidence and make recommendations that are used by USPSTF have been summarized (Tables 3 and 4) (*7*).

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TABLE 1. Select Panel on Preconception Care grading system

Quality of the evidence*	
I-a	Evidence was obtained from at least one properly conducted, randomized, controlled trial that was performed with subjects who were not pregnant.
I-b	Evidence was obtained from at least one properly conducted, randomized, controlled trial that was done not necessarily before pregnancy.
II-1	Evidence was obtained from well-designed, controlled trials without randomization.
II-2	Evidence was obtained from well-designed cohort or case-control analytic studies, preferably conducted by more than one center or research group.
II-3	Evidence was obtained from multiple-time series with or without the intervention, or dramatic results in uncontrolled experiments.
III	Opinions were gathered from respected authorities on the basis of clinical experience, descriptive studies and case reports, or reports of expert committees.
Strength of the recommendation	
A	There is good evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
B	There is fair evidence to support the recommendation that the condition be considered specifically in a preconception care evaluation.
C	There is insufficient evidence to recommend for or against the inclusion of the condition in a preconception care evaluation, but recommendation to include or exclude may be made on other grounds.
D	There is fair evidence to support the recommendation that the condition be excluded in a preconception care evaluation.
E	There is good evidence to support the recommendation that the condition be excluded in a preconception care evaluation.

Source: Jack B, Atrash H, Coonrod D, Moos M, O'Donnell J, Johnson K. The clinical content of preconception care: an overview and preparation of this supplement. Am J Obstet Gynecol 2008;199(6 Suppl 2):S266–79.

TABLE 2. Services included in these recommendations that received a U.S. Preventive Services Task Force (USPSTF) I recommendation

Service/screen	USPSTF recommendation	Why the service is recommended despite a USPSTF I recommendation
Alcohol	I for adolescents	The recommendations are consistent with CDC's recommendations on preconception health and AAP's Bright Futures* guidelines.
Other drugs	I for adolescents and adults	The recommendations are consistent with CDC's recommendations on preconception health and AAP's Bright Futures guidelines.
Clinical breast exam	I for all women	No CDC recommendation exists, but ACOG and ACS recommend conducting clinical breast exams, and the Expert Work Group endorsed the ACOG recommendation.
Chlamydia	I for all males	The recommendations are consistent with CDC's STD treatment guidelines.
Gonorrhea	I for all males	The recommendations are consistent with CDC's STD treatment guidelines.

Source: US Preventive Services Task Force. USPSTF recommendations. Available at http://www.uspreventiveservicestaskforce.org/recommendations.htm.
Abbreviations: AAP = American Academy of Pediatrics; ACS = American Cancer Society; ACOG = American Congress of Obstetricians and Gynecologists; STD = sexually transmitted disease.
* Source: Committee on Practice and Ambulatory Medicine, Bright Futures Periodicity Schedule Workgroup. 2014 recommendations for pediatric preventive health care. Pediatrics 2014;133;568.

TABLE 3. U.S. Preventive Services Task Force (USPSTF) grades, definitions, and suggestions for practice

Grade	Definition	Suggestions for practice
A	USPSTF recommends the service. There is high certainty that the net benefit is substantial.	This service should be offered or provided.
B	USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	This service should be offered or provided.
C	Clinicians may provide this service to selected patients depending on individual circumstances. However, for a majority of persons without signs or symptoms there is likely to be only a limited benefit from this service.	This service should be offered or provided only if other considerations support the offering or providing the service in an individual patient.
D	USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Use of this service should be discouraged.
I Statement	USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	The clinical considerations section of USPSTF recommendation statement should be consulted. If the service is offered, patients should be educated about the uncertainty of the balance of benefits and harms.

Source: US Preventive Services Task Force. USPSTF: methods and processes. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.

TABLE 4. Levels of certainty regarding net benefit

Level of certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as • the number, size, or quality of individual studies; • inconsistency of findings across individual studies; • limited generalizability of findings to routine primary care practice; and • lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes is insufficient because of • the limited number or size of studies, • important flaws in study design or methods, • inconsistency of findings across individual studies, • gaps in the chain of evidence, • findings not generalizable to routine primary care practice, • lack of information on important health outcomes, or • more information required to allow estimation of effects on health outcomes.

Source: US Preventive Services Task Force. USPSTF: methods and processes. Available at http://www.uspreventiveservicestaskforce.org/methods.htm.

* The US Preventive Services Task Force (USPSTF) defines certainty as the likelihood that the USPSTF assessment of the net benefit of a preventive service is correct. The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.

Appendix B

The Evidence, Potential Consequences, and Rationales for Core Recommendations

Sixteen core recommendations that were considered by the Expert Work Group (EWG) are presented below. Each recommendation is accompanied by a summary of the relevant evidence (full summaries of which will be published separately), a list of potential consequences of implementing the recommendation, and its rationale. When considering the recommendations, the Expert Work Group was divided into two groups (one comprising seven members and the other five members), and each group considered separate recommendations.

Definition of Family Planning Services

Recommendation: Primary care providers should offer the following family planning services: contraceptive services for women and men who want to prevent pregnancy and space births, pregnancy testing and counseling, help for clients who wish to achieve pregnancy, basic infertility services, sexually transmitted disease (STD) services and preconception health services to improve the health of women, men, and infants.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of federal statute and regulation (*1*,*2*), CDC clinical recommendations (*3*–*5*), and expert opinion.

Potential consequences: Adding preconception health services means that more women and men will receive preconception health services. The recommended services also will promote the health of women and men even if they do not have children. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered in some settings.

Rationale: Services to prevent and achieve pregnancy are core to the federal government's efforts to promote reproductive health. Adding preconception health as a family planning service is consistent with this mission; it emphasizes achieving a healthy pregnancy and also promotes adult health. Adding preconception health is also consistent with CDC recommendations to integrate preconception health services into primary care platforms (*3*). All seven EWG members agreed to this recommendation.

Preconception Health — Women

Recommendation: Preconception health services for women include the following screening services: reproductive life plan; medical history; sexual health assessment; intimate partner violence, alcohol, and other drug use; tobacco use; immunizations; depression; body mass index (BMI); blood pressure; chlamydia, gonorrhea, syphilis, and HIV/AIDS; and diabetes. All female clients also should be counseled about the need to take a daily supplement of folic acid. When screening results indicate the presence of a health condition, the provider should take steps either to provide or to refer the client for the appropriate further diagnostic testing and or treatment. Services should be provided in a manner that is consistent with established federal and professional medical associations' recommendations to enable clients who need services to receive them and to avoid over-screening.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of CDC's recommendations to improve preconception health and health care (*3*) and a review of preconception health services by an expert panel on preconception care for women (*6*).

Potential consequences: More women will receive specified preconception health services, which will improve the health of infants and women. The evidence base for preconception health is not fully established. There is a potential risk that a client with a positive screen will not be able to afford treatment if the client is uninsured and not eligible for public programs. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered.

Rationale: The potential benefits to the health of women and infants were thought by the panel to be greater than the costs, potential harms, and opportunity costs of providing these services. Implementation (e.g., training and monitoring of providers) can address the issues related to providers over-screening and not following the federal and professional medical recommendations. CDC will continue to monitor related research and modify these recommendations, as needed. Health-care reform might make follow-up care more available to low-income clients. All seven EWG members agreed to this recommendation.

Preconception Health — Men

Recommendation: Preconception health services for men include the following screening services: reproductive life plan; medical history; sexual health assessment; alcohol and other drug use; tobacco use; immunizations; depression; BMI; blood pressure; chlamydia, gonorrhea, syphilis, and HIV/AIDS; and diabetes. When screening results indicate the presence of a health condition, the provider should take

steps either to provide or to refer the client for the appropriate further diagnostic testing and or treatment. Services should be provided in a manner that is consistent with established federal and professional medical associations' recommendations to ensure that clients who need services receive them and to avoid over-screening.

Quality of evidence: A systematic review was not conducted; the recommendation was made on the basis of CDC's recommendations to improve preconception health and health care (*3*) and a review of preconception health services for men (*7*).

Potential consequences: More men will receive preconception health services, which might improve infant and men's health. The evidence base for preconception health is not well established and is less than that for women's preconception health. There is a risk of over-screening if recommendations are not followed. There is a potential risk that a client with a positive screen might not be able to afford treatment if the client is uninsured and not eligible for public programs. The human and financial cost of providing preconception health services might mean that fewer contraceptive and other services can be offered.

Rationale: The potential benefits to men and infant health were thought by the panel to be greater than the costs, potential harms, and opportunity costs of not providing these services. Implementation (e.g., training and monitoring of providers) can address the issues related to providers over-screening and not following the federal and professional medical recommendations. CDC will continue to monitor related research and modify these recommendations, as needed. Health-care reform might make follow-up care more available to low-income clients. All seven EWG members agreed to this recommendation.

Contraceptive Services — Contraceptive Counseling Steps

Recommendation: To help a client who is initiating or switching to a new method of contraception, providers should follow these steps, which are in accordance with the key principles for providing quality counseling: 1) establish and maintain rapport with the client; 2) obtain clinical and social information from the client; 3) work with the client interactively to select the most effective and appropriate contraceptive method for her or him; 4) provide a physical assessment related to contraceptive use, when warranted; and 5) provide the contraceptive method along with instructions about correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm understanding.

Quality of evidence: Twenty-two studies were identified that examined the impact of contraceptive counseling in clinical settings and met the inclusion criteria. Of the 16 studies that focused on adults or mixed populations (adolescents and adults) (*8–23*), 11 found a statistically significant positive impact of counseling interventions with low (*11*,*12*,*14–16*,*18–21*), moderate (*8*), or unrated (*22*) intensity on at least one outcome of interest; study designs included two cross-sectional surveys (*14*,*22*), one pre-post study (*21*), one prospective cohort study (*8*), one controlled trial (*15*), and six randomized controlled trials (RCTs) (*11*,*12*,*16*,*18–20*). Six studies examined the impact of contraceptive counseling among adolescents (*24–29*), with four finding a statistically significant positive impact of low-intensity (*27*) or moderate-intensity (*24*,*25*,*29*) counseling interventions on at least one outcome of interest; study designs included two pre-post studies (*24*,*30*), one controlled trial (*29*), and one RCT (*27*). In addition, five studies were identified that examined the impact of reminder system interventions in clinical settings on family planning outcomes and met the inclusion criteria (*31–35*); of these, two found a statistically significant positive impact of reminder systems on perfect oral contraceptive compliance, a retrospective historical nonrandomized controlled trial that examined daily reminder email messages (*31*) and a cohort study that examined use of a small reminder device that emitted a daily audible beep (*34*). In addition, two studies examined the impact of reminder systems among depot medroxyprogesterone acetate users (DMPA) (*33*,*35*) with one, a retrospective cohort study, finding a statistically significant positive impact of receiving a wallet-sized reminder card with the date of the next DMPA injection and a reminder postcard shortly before the next injection appointment on timely DMPA injections. Statements about safety and unnecessary medical examinations and tests are made on the basis of CDC guidelines on contraceptive use (*36*,*37*).

Potential consequences: Fewer clients will use methods that are not safe for them, there will be increased contraceptive use, increased use of more effective methods, increased continuation of method use, increased use of dual methods, increased knowledge, increased satisfaction with services, and increased use of repeat or follow-up services.

Rationale: Making sure that a contraceptive method is safe for an individual client is a fundamental responsibility of all providers of family planning services. Removing medical barriers to contraceptive use is key to increasing access to contraception and helping clients prevent unintended pregnancy. Consistent use of contraceptives is needed to prevent unintended pregnancies, so appropriate counseling is critical to ensure clients make the best possible choice of methods for their unique circumstances, and are supported in continued

use of the chosen method. The principles of quality counseling, from which the steps listed in the recommendations are based, are supported by a substantial body of evidence and expert opinion. Future research to evaluate the five principles will be monitored and the recommendations modified, as needed. All seven EWG members agreed to this recommendation.

Contraceptive Services — Tiered Approach to Counseling

Recommendation: For clients who might want to get pregnant in the future and prefer reversible methods of contraception, providers should use a tiered approach to presenting a broad range of contraceptive methods (including long-acting reversible contraception such as intrauterine devices and contraceptive implants), in which the most effective methods are presented before less effective methods.

Quality of evidence: National surveys have demonstrated low rates of LARC use overall (*38,39*). However, Project CHOICE has demonstrated high uptake of long-acting reversible contraception (approximately two thirds of clients when financial barriers are removed) and a very substantial reduction in rates of unintended pregnancy (*40*). Further, a recent study of postpartum contraceptive use shows that 50% of teen mothers with a recent live birth are using long-acting reversible contraception postpartum in Colorado, which demonstrates high levels of acceptance in the context of a statewide program to remove financial barriers (*41*).

Potential consequences: Use of long-acting reversible contraception has the potential to help many more persons prevent unintended pregnancy because of its ease of use, safety, and effectiveness. Several questions were raised about ethical issues in using a tiered approach to counseling. First, is it ethical to educate about long-acting reversible contraception when the methods are not all available on-site? Second, conversely, is it ethical not to inform clients about the most effective methods? In other health service areas, the standard of care is to inform the client about the most effective treatment (e.g., blood pressure medications), so the client can make a fully informed decision, and this standard should apply in this instance as well. On the basis of historic experiences, there is a need to ensure that methods always are offered on a completely voluntary and noncoercive basis. Health-care reform might make contraceptive services more available to the majority of clients.

Rationale: Providers have an obligation to inform clients about the most effective methods available, even if they cannot provide them. Further, health-care reform will reduce the financial barriers to long-acting reversible contraception for many persons. The potential increase in use of long-acting reversible contraception and other more effective methods is likely to help reduce rates of unintended pregnancy. All seven EWG members agreed to this recommendation.

Contraceptive Services — Broad Range of Methods

Recommendation: A broad range of methods should be available on-site or through referral.

Quality of evidence: Three descriptive studies from the review of quality improvement literature identified contraceptive choice as an important aspect of quality care (*42–44*).

Potential consequences: Clients will be more likely to select a method that they will use consistently and correctly.

Rationale: A central tenet of quality health care is that it be client-centered. Being able to provide a client with a method that best fits her or his unique circumstances is essential for that reason. All seven EWG members agreed to this recommendation.

Contraceptive Services — Education

Recommendation: The content, format, method, and medium for delivering education should be evidence-based.

Quality of evidence: Seventeen studies were identified that met the inclusion criteria for this systematic review. Of these, 15 studies looked at knowledge of correct method use or contraceptive risks and benefits, including side effects and method effectiveness (*45–59*). All but one study (*56*) found a statistically significant positive impact of educational interventions on increased knowledge. These studies included six randomized controlled trials with low risk for bias.

Potential consequences: Clients will make more informed decisions when choosing a contraceptive method. More clients will be satisfied with the process of selecting a contraceptive method.

Rationale: Knowledge obtained through educational activities, as integrated into the larger counseling model, is a critically important precondition for the client's ability to make informed decisions. The techniques described in the recommendations have a well-established evidence base for increasing knowledge and satisfaction with services. This knowledge lays the foundation for further counseling steps that will increase the likelihood of correct and consistent use, and increased satisfaction will increase return visits to the service site, as needed. Four of seven EWG members agreed to this recommendation; three members did not express an opinion.

Contraceptive Services — Confirm Understanding

Recommendation: A check box or written statement should be available in the medical record that can be used to document that the client expressed understanding of the most important information about her/his chosen contraceptive method. The teach-back method may be used to get clients to express the most important points by repeating back messages about risks and benefits and appropriate method use and follow-up. Documentation of understanding using the teach-back method and a check box or written statement can be used in place of a written method-specific informed consent.

Quality of evidence: Two studies from outside the family planning literature (one cohort study and one controlled trial with unclear randomization) (*60,61*) and a strong recommendation by members of the Technical Panel on Counseling and Education were considered.

Potential consequences: More clients will make informed decisions, adherence to contraceptive and treatment plans will improve, and reproductive and other health conditions will be better controlled.

Rationale: Asking providers to document in the record that the client is making an informed decision will increase providers' attention to this task. This recommendation will replace a previous requirement that providers obtain method-specific informed consent from each client (in addition to a general consent form). Six of seven EWG members agreed to this recommendation.

Adolescent Services — Comprehensive Information

Recommendation: Providers should provide comprehensive information to adolescent clients about how to prevent pregnancy and STDs. This should include information about contraception and that avoiding sex (abstinence) is an effective way to prevent pregnancy and STDs.

Quality of evidence: A systematic review was not conducted because other recent reviews were available that have shown a substantial impact of comprehensive sexual health education on reduced adolescent risk behavior (*62–66*). The evidence for abstinence-only education was more limited: CDC's Community Guide concluded that there was insufficient evidence (*67*), but the Department of Health and Human Services' Office of Adolescent Health has identified two abstinence-based programs as having evidence of effectiveness (*68*).

Potential consequences: Teens will make more informed decisions and will delay initiation of sexual intercourse. The absence of harmful effects from comprehensive sexual health education was noted.

Rationale: The benefits of informing adolescents about all ways to prevent pregnancy are substantial. Ultimately, each adolescent should make an informed decision that meets her or his unique circumstances, based on the counseling provided by the provider. Six of seven EWG members agreed to this recommendation.

Adolescent Services — Use of Long-Acting Reversible Contraception

Recommendation: Education about contraceptive methods should include an explanation that long-acting reversible contraception is safe and effective for nulliparous women (women who have not been pregnant or given birth), including adolescents.

Quality of evidence: CDC guidelines on contraceptive use (*37*) provide evidence that long-acting reversible contraception is safe and effective for adolescents and nulliparous women.

Potential consequences: More providers will encourage adolescents to consider long-acting reversible contraception; more adolescents will choose long-acting reversible contraception, resulting in reduced rates of teen pregnancy, including rapid repeat pregnancy.

Rationale: Long-acting reversible contraception is safe for adolescents (*37*). As noted above, providers should inform clients about the most effective methods available. The potential increase in use of long-acting reversible contraception and other more effective methods by adolescents is substantial and is likely to lead to further reductions in teen pregnancy. Three EWG members agreed to this recommendation; two EWG members abstained.

Adolescent Services — Confidential Services

Recommendation: Confidential family planning services should be made available to adolescents, while observing state laws and any legal obligations for reporting.

Quality of evidence: Six descriptive studies documented one or more of the following: that confidentiality is important to adolescents; that many adolescents reported they will not use reproductive health services if confidentiality cannot be assured; and that adolescents might not be honest in discussing reproductive health with providers if confidentiality cannot be assured (*69–74*). One RCT showed a slight reduction in use of services after receiving conditional confidentiality, compared with complete confidentiality (*75*). One study showed a

positive association between confidentiality and intention to use services (*73*).

Potential consequences: Consequences might include an increased intention to use services, increased use of services, and reduced rates of teen pregnancy. However, explaining the need to report under certain circumstances (rape, child abuse) might deter some adolescent clients from using services. Further, some parents/guardians might not agree that adolescents should have access to confidential services.

Rationale: Minors' rights to confidential reproductive health services are consistent with state and federal law. The risks of not providing confidential services to adolescents are great and likely to result in an increased rate of teen pregnancies. Finally, this recommendation is consistent with the recommendations of three professional medical associations that endorse provision of confidential services to adolescents (*76–78*). All seven EWG members agreed to this recommendation.

Adolescent Services — Family-Child Communication

Recommendation: Providers should encourage and promote family-child communication about sexual and reproductive health.

Quality of evidence: From the family planning literature, 16 parental involvement programs (most using an RCT study design) were found to be positively associated with at least one short-term (13 of 16 studies) or medium-term (four of seven studies) outcome (*79–94*). However, only one of these studies was linked to clinical services (*80*); others were implemented in community settings.

Potential consequences: Consequences might include increased parental/guardian involvement and communication, improved knowledge/awareness, increased intentions to use contraceptives, and the adoption of more pro-social norms that support parent-child communication about sexual health.

Rationale: The literature provides strong evidence that increased communication between a child and her/his parent/guardian will lead to safer sexual behavior among teens, and numerous community-based programs have created an evidence base for how to strengthen parents/guardians' ability to hold those conversations. Although less is known about how to do so in a clinical setting, providers can refer their clients to programs in the community, and principles from the community-based approaches can be used to help providers develop appropriate approaches in the clinical setting. Research in this area will be monitored, and the recommendations will be revised, as needed. Four of five EWG members who provided input agreed to this recommendation; one member abstained.

Adolescent Services — Repeat Teen Pregnancy

Recommendation: Providers should refer pregnant and parenting adolescents to home visiting and other programs that have been shown to provide needed support and reduce rates of repeat teen pregnancy.

Quality of evidence: Three of four studies of clinic-based programs (using retrospective case-control cohort, ecological evaluation, and prospective cohort study designs) showed that comprehensive teen pregnancy prevention programs (programs with clinical, school, case management, and community components) were associated with both medium- and long-term outcomes (*95–98*). In addition, several randomized trials of community-based home visiting programs, and an existing systematic review of the home visiting literature, demonstrated a protective impact of these programs on preventing repeat teen pregnancy and other relevant outcomes (*99–103*).

Potential consequences: Consequences might include decreased rapid repeat pregnancy and abortion rates, and increased use of contraceptives.

Rationale: There is sufficient evidence to recommend that providers link pregnant and parenting teens to community and social services that might reduce rates of rapid repeat pregnancy. Three of seven EWG members agreed to an earlier version of this recommendation. Other members wanted to remove a clause about prioritizing the contraceptive needs of pregnant/parenting teens because they felt that all clients should be treated as priority clients. This suggestion was adopted, but the EWG did not have a chance to vote again on the modified recommendation.

Contraceptive Method Availability

Recommendation: Family planning programs should stock and offer a broad a range of FDA-approved contraceptive methods so that the needs of individual clients can be met. These methods are optimally available on-site, but strong referrals can serve to make methods not available on-site real options for clients.

Quality of evidence: No research was identified that explicitly addressed the question of whether having a broad range of methods was associated with short-, medium-, or long-term reproductive health outcomes. However, as noted above, three descriptive studies from the review of quality improvement literature identified contraceptive choice as an important aspect of quality care (*42–44*).

Potential consequences: Consequences might include increased use of contraception and increased use of reproductive

health services. It also was noted that there are sometimes high costs to stocking certain methods (e.g., intrauterine devices and contraceptive implants).

Rationale: Having a broad range of contraceptive methods is central to client-centered care, a core aspect of providing quality services. Individual clients need to have a choice so they can select a method that best fits their particular circumstances. This is likely to result in more correct and consistent use of the chosen methods. The benefits of this recommendation were weighed more heavily than the negative outcomes (e.g., additional cost). All five EWG members agreed to this recommendation.

Youth-Friendly Services

Recommendation: Family planning programs should take steps to make services "youth-friendly."

Quality of evidence: Of 20 studies that were identified, six looked at short-, medium-, or long-term outcomes with mixed designs (one group time series, one cross-sectional, three prospective cohort, and one nonrandomized trial); protective effects were found on long-term (two of three studies), medium-term (three of three), and short-term (three of three) outcomes (*29*,*30*,*104–107*). One of these six studies (*29*), plus 13 other descriptive studies (for a total of 14 studies), presented adolescents' or providers' views on facilitators for adolescent clients in using youth-friendly family planning services. Key factors described were confidentiality (13 of 14), accessibility (11 of 14), peer involvement (three of 14), parental or familial involvement (four of 14), and quality of provider interaction (11 of 14) (*105–121*). Four of these studies (*111*,*112*,*114*,*121*) plus one other descriptive study (*108*) described barriers to clinics adopting and implementing youth-friendly family planning services.

Potential consequences: Consequences might include increased use of reproductive health services by adolescents, improved contraceptive use, use of more effective methods, more consistent use of contraception, and reduced rates of teen pregnancy. It is also likely to lead to improved satisfaction with services and greater knowledge about pregnancy prevention among adolescents. It is possible that there will be higher costs, and some uncertainty regarding the benefits due to a relatively weak evidence base.

Rationale: Existing evidence has demonstrated the importance of specific characteristics to adolescents' attitudes and use of clinical services. The potential benefits of providing youth-friendly services outweigh the potential costs and weak evidence base. All five EWG members agreed to this recommendation. Some thought that it should be cast as an example of comprehensively client-centered care, rather than an end of its own.

Quality Improvement

Recommendation: Family planning programs should have a system for quality improvement, which is designed to review and strengthen the quality of services on an ongoing basis. Family planning programs should select, measure, and assess at least one outcome measure on an ongoing basis, for which the service site can be accountable.

Quality of evidence: A recent systematic review (*122*) was supplemented with 10 articles that provided information related to client and/or provider perspectives regarding what constitutes quality family planning services (*42–44*,*113*,*123–128*). These studies used a qualitative (k = 4) or cross-sectional (k = 6) study design. Ten descriptive studies identified client and provider perspectives on what constitutes quality family planning services, which include stigma and embarrassment reduction (n = 9), client access and convenience (n = 8); confidentiality (n = 3); efficiency and tailoring of services (n = 6); client autonomy and confidence (n = 5); contraceptive access and choice (n = 4); increased time of patient-provider interaction (n = 3); communication and relationship (n = 3); structure and facilities (n = 2); continuity of care (n = 2). Well-established frameworks for guiding quality improvement efforts were referenced (*122*,*129–132*).

Potential consequences: Consequences might include increased use by clients of more effective contraceptive methods, clients might be more likely to return for care, client satisfaction might improve, and there might be reduced rates of teen and unintended pregnancy, and improved spacing of births.

Rationale: Research, albeit limited, has demonstrated that quality services are associated with improved client experience with care and adoption of more protective contraceptive behavior. Further, these recommendations on quality improvement are consistent with those made by national leaders in the quality improvement field. Research is either under way or planned to validate a core set of performance measures, and the recommendations will be updated as new findings emerge. All five EWG members agreed to these recommendations.

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Appendix C

Principles for Providing Quality Counseling

Counseling is a process that enables clients to make and follow through on decisions. Education is an integral component of the counseling process that helps clients to make informed decisions. Providing quality counseling is an essential component of client-centered care.

Key principles of providing quality counseling are listed below and may be used when providing family planning services. The model was developed in consultation with the Technical Panel on Contraceptive Counseling and Education and reviewed by the Expert Work Group. Although developed specifically for providing contraceptive counseling, the principles are broad and can be applied to health counseling on other topics. Although the principles are listed here in a particular sequence, counseling is an iterative process, and at every point in the client encounter it is necessary to determine whether it is important to readdress and emphasize a given principle.

Principles of Quality Counseling

Principle 1. Establish and Maintain Rapport with the Client

Establishing and maintaining rapport with a client is vital to the encounter and achieving positive outcomes (*1*). This can begin by creating a welcoming environment and should continue through every stage of the client encounter, including follow-up. The contraceptive counseling literature indicates that counseling models that emphasized the quality of the interaction between client and provider have been associated with decreased teen pregnancy, increased contraceptive use, increased use of more effective methods, increased use of repeat or follow-up services, increased knowledge, and enhanced psychosocial determinants of contraceptive use (*2–5*) .

Principle 2. Assess the Client's Needs and Personalize Discussions Accordingly

Each visit should be tailored to the client's individual circumstances and needs. Clients come to family planning providers for various services and with varying needs. Standardized questions and assessment tools can help providers determine what services are most appropriate for a given visit (*6*). Contraceptive counseling studies that have incorporated standardized assessment tools during the counseling process have resulted in increased contraceptive use, increased correct use of contraceptives, and increased use of more effective methods (*2,7,8*). Contraceptive counseling studies that have personalized discussions to meet the individual needs of clients have been associated with increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, increased use of dual-method contraceptives to prevent both sexually transmitted diseases (STDs) and pregnancy, increased quality and satisfaction with services, increased knowledge, and enhanced psychosocial determinants of contraceptive use *(4,7,9–12)*.

Principle 3. Work with the Client Interactively to Establish a Plan

Working with a client interactively to establish a plan, including a plan for follow-up, is important. Establishing a plan should include setting goals, discussing possible difficulties with achieving goals, and developing action plans to deal with potential difficulties. The amount of time spent establishing a plan will differ depending on the client's purpose for the visit and health-care needs. A client plan that requires behavioral change should be made on the basis of the client's own goals, interests, and readiness for change (*13–15*). Use of computerized decision aids before the appointment can facilitate this process by providing a structured yet interactive framework for clients to analyze their available options systematically and to consider the personal importance of perceived advantages and disadvantages *(16,17)*. The contraceptive counseling literature indicates that counseling models that incorporated goal setting and development of action plans have been associated with increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, and increased knowledge *(2,9,18–20)*. Furthermore, contraceptive counseling models that incorporated follow-up contacts resulted in decreased teen pregnancy, increased contraceptive use, increased correct use of contraceptives, increased use of more effective methods, increased continuation of method use, increased use of dual-method contraceptives to prevent both STDs and pregnancy, increased use of repeat or follow-up services, increased knowledge, and enhanced psychosocial determinants of contraceptive use *(2,3,7,11,21,22)* . From the family planning education literature, computerized decision aids have helped clients formulate questions and have been associated with increased knowledge, selection of more effective methods, and increased continuation and compliance (*23–25*).

Principle 4. Provide Information That Can Be Understood and Retained by the Client

Clients need information that is medically accurate, balanced, and nonjudgmental to make informed decisions and follow through on developed plans. When speaking with clients or providing educational materials through any medium (e.g., written, audio/visual, or computer/web-based), the provider must present information in a manner that can be readily understood and retained by the client. Strategies for making information accessible to clients are provided (see Appendix D).

Principle 5. Confirm Client Understanding

It is important to ensure that clients have processed the information provided and discussed. One technique for confirming understanding is to have the client restate the most important messages in her or his own words. This teach-back method can increase the likelihood of the client and provider reaching a shared understanding, and has improved compliance with treatment plans and health outcomes *(26,27)*. Using the teach-back method early in the decision-making process will help ensure that a client has the opportunity to understand her or his options and is making informed choices (*28*).

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Appendix D

Contraceptive Effectiveness

Providers should counsel clients about the effectiveness of different contraceptive methods. Method effectiveness is measured as the percentage of women experiencing an unintended pregnancy during the first year of use, and is estimated for both typical and perfect use (Table).

TABLE. Percentage of women experiencing an unintended pregnancy during the first year of typical use* and the first year of perfect use† of contraception and the percentage continuing use at the end of the first year — United States

Method	% of women experiencing an unintended pregnancy within the first year of use		% of women continuing use at 1 year§
	Typical use	Perfect use	
No method¶	85.0	85.0	
Spermicides**	28.0	18.0	42.0
Fertility awareness-based methods	24.0		47.0
Standard days method††		5.0	
2-day method††		4.0	
Ovulation method††		3.0	
Symptothermal method		0.4	
Withdrawal	22.0	4.0	46.0
Sponge			36.0
Parous women	24.0	20.0	
Nulliparous women	12.0	9.0	
Condom§§			
Female	21.0	5.0	41.0
Male	18.0	2.0	43.0
Diaphragm¶¶	12.0	6.0	57.0
Combined pill and progestin-only pill	9.0	0.3	67.0
Evra patch	9.0	0.3	67.0
NuvaRing	9.0	0.3	67.0
Depo-Provera	6.0	0.2	56.0
Intrauterine contraceptives			
ParaGard (copper T)	0.8	0.6	78.0
Mirena (LNG)	0.2	0.2	80.0
Implanon	0.05	0.05	84.0
Female sterilization	0.5	0.5	100.0
Male sterilization	0.15	0.1	100.0

Emergency Contraceptives: Emergency contraceptive pills or insertion of a copper intrauterine contraceptive after unprotected intercourse substantially reduces the risk of pregnancy.***
Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.†††
Source: Adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, eds. Contraceptive technology: 20th revised ed. New York, NY: Ardent Media; 2011.

* Among typical couples who initiate use of a method (not necessarily for the first time), the percentage of couples who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides and the diaphragm are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill, and Depo-Provera are taken from the 1995 and 2002 National Survey of Family Growth corrected for underreporting of abortion. See the text for the derivation of estimates for the other methods.

† Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage of couples who experience an accidental pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method.

§ Among couples attempting to avoid pregnancy, the percentage of couples who continue to use a method for 1 year.

¶ The percentages becoming pregnant in columns labeled "typical use" and "perfect use" are based on data from populations in which contraception is not used and from women who cease using contraception to become pregnant. Among such populations, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage of women who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

** Foams, creams, gels, vaginal suppositories, and vaginal film.

†† The Ovulation and 2-day methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19. The Symptothermal method is a double-check method based on evaluation of cervical mucus to determine the first fertile day and evaluation of cervical mucus and temperature to determine the last fertile day.

§§ Without spermicides.

¶¶ With spermicidal cream or jelly.

*** Ella, Plan B One-Step, and Next Choice are the only dedicated products specifically marketed for emergency contraception. The label for Plan B One-Step (1 dose is 1 white pill) says to take the pill within 72 hours after unprotected intercourse. Research has indicated that all of the brands listed here are effective when used within 120 hours after unprotected intercourse. The label for Next Choice (1 dose is 1 peach pill) says to take one pill within 72 hours after unprotected intercourse and another pill 12 hours later. Research has indicated that that both pills can be taken at the same time with no decrease in efficacy or increase in side effects and that they are effective when used within 120 hours after unprotected intercourse. The Food and Drug Administration has in addition declared the following 19 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel (1 dose is 2 white pills), Nordette (1 dose is 4 light-orange pills), Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills), Jolessa, Portia, Seasonale or Trivora (1 dose is 4 pink pills), Seasonique (1 dose is 4 light-blue-green pills), Enpresse (1 dose is 4 orange pills), Lessina (1 dose is 5 pink pills), Aviane or LoSeasonique (one dose is 5 orange pills), Lutera or Sronyx (1 dose is 5 white pills), and Lybrel (1 dose is 6 yellow pills).

††† However, for effective protection against pregnancy to be maintained, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches age 6 months.

Appendix E

Strategies for Providing Information to Clients

The client should receive and understand the information she or he needs to make informed decisions and follow treatment plans. This requires careful attention to how information is communicated. The following strategies can make information more readily comprehensible to clients:

Strategies for Providing Information to Clients

Educational materials should be provided that are clear and easy to understand. Educational materials delivered through any one of a variety of media (for example, written, audio/visual, computer/web-based) need to be presented in a format that is clear and easy to interpret by clients with a 4th to 6th grade reading level (*1–3*). Many adults have only a basic ability to obtain, process, and understand health information necessary to make decisions about their health (*4*). Making easy-to-access materials enhances informed decision-making (*1–3*). Test all educational materials with the intended audiences for clarity and comprehension before wide-scale use.

The following evidence-based tools provide recommendations for increasing the accessibility of materials through careful consideration of content, organization, formatting, and writing style:

- Health Literacy Universal Precautions Toolkit, provided by the Agency for Healthcare Research and Quality (available at http://www.ahrq.gov/qual/literacy),
- Toolkit for Making Written Material Clear and Effective, provided by the Centers for Medicare and Medicaid Services (available at http://www.cms.gov/WrittenMaterialsToolkit), and
- Health Literacy Online, provided by the Office of Disease Prevention and Health Promotion (available at http://www.health.gov/healthliteracyonline).

Information should be delivered in a manner that is culturally and linguistically appropriate. In presenting information it is important to be sensitive to the client's cultural and linguistic preferences (*5*,*6*). Ideally information should be presented in the client's primary language, but translations and interpretation services should be available when necessary. Information presented must also be culturally appropriate, reflecting the client's beliefs, ethnic background, and cultural practices. Tools for addressing cultural and linguistic differences and preferences include

- Health Literacy Universal Precautions Toolkit, provided by the Agency for Healthcare Research and Quality (available at http://www.ahrq.gov/qual/literacy), and
- Toolkit for Making Written Material Clear and Effective, Part 11; Understanding and using the "Toolkit Guidelines for Culturally Appropriate Translation," provided by the Centers for Medicare and Medicaid Services (available at http://www.cms.gov/outreach-and-education/outreach/writtenmaterialstoolkit/downloads/toolkitpart11.pdf).

The amount of information presented should be limited and emphasize essential points. Providers should focus on needs and knowledge gaps identified during the assessment. Many clients immediately forget or remember incorrectly much of the information provided. This problem is exacerbated as more information is presented (*7–9*). Limiting the amount of information presented and highlighting important facts by presenting them first improves comprehension (*10–14*).

Numeric quantities should be communicated in a way that is easily understood. Whenever possible, providers should use natural frequencies and common denominators (for example, 85 of 100 sexually active women are likely to get pregnant within 1 year using no contraceptive, as compared with 1 in 100 using an IUD or implant), and display quantities in graphs and visuals. Providers also should avoid using verbal descriptors without numeric quantities (for example, sexually active women using an IUD or implant almost never become pregnant). Finally, they should quantify risk in absolute rather than relative terms (for example, "the chance of unintended pregnancy is reduced from 8 in 100 to 1 in 100 by switching from oral contraceptives to an IUD" versus the chance of unintended pregnancy is reduced by 87%). Numeracy is more highly correlated with health outcomes than the ability to read or listen effectively (*15*). The strategies listed above can help clients interpret numeric quantities correctly (*16–28*).

Balanced information on risks and benefits should be presented and messages framed positively. In addition to discussing risks, contraindications, and warnings, providers should discuss the advantages and benefits of contraception. In presenting this information, providers should express risks and benefits in a common format (for example, do not present risks in relative terms and benefits in absolute terms), and frame messages in positive terms (for example "99 out of 100 women find this a safe method with no side effects," versus "1 out of 100 women experience noticeable side effects"). Many clients prefer to receive a balance of information on risks and benefits (*29*), and using a common format avoids bias in presentation of information (*18*,*22*,*26*,*30*). Framing messages positively increases acceptance and comprehension (*18*,*22*,*31*,*32*).

Active client engagement should be encouraged. Providers should use educational materials that encourage active information processing (e.g., questions, quizzes, fill-in-the-blank, web-based games, and activities). In addition, they should be sure the client has an opportunity to discuss the information provided, and when speaking with a client, providers should engage her or him actively. Research has indicated that interactive materials improve knowledge of contraceptive risks, benefits, and correct method use (*33*–*35*). Clients also value spoken information (*29*,*36*); and educational materials, when delivered by a provider, more effectively increase knowledge (*10*,*37*). In particular, presenting information in a question and answer format is more effective than simply presenting the information (*10*,*15*,*37*–*41*).

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Appendix F

Screening Services For Which Evidence Does Not Support Screening

The following services have been given a D recommendation from the U.S. Preventive Services Task Force (USPSTF), which indicates that the potential harms of routine screening outweigh the benefits. Providers should not perform these screening services.

The USPSTF has recommended against offering the following services to women and men:

- **Asymptomatic bacteriuria:** USPSTF recommends against screening for asymptomatic bacteriuria in men and nonpregnant women (*1*).
- **Gonorrhea:** USPSTF recommends against routine screening for gonorrhea infection in men and women who are at low risk of infection (*2*).
- **Hepatitis B:** USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection (*3*).
- **Herpes simplex virus (HSV):** USPSTF recommends against routine serological screening for HSV in asymptomatic adolescents and adults (*4*).
- **Syphilis:** USPSTF recommends against screening of asymptomatic persons who are not at increased risk of syphilis infection (*5*).

The USPSTF has recommended against offering the following services to women:

- **BRCA mutation testing for breast and ovarian cancer susceptibility:** USPSTF recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk of deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2) (*6*). However, USPSTF continues to recommend that women whose family history is associated with an increased risk of deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.
- **Breast self-examination:** USPSTF recommends against teaching breast self-examination (*7*).
- **Cervical cytology:** USPSTF recommends against routine screening for cervical cancer with cytology (Pap smear) in the following groups: women aged <21 years, women aged >65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer, women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia grade 2 or 3) or cervical cancer. USPSTF recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women aged <30 years (*8*).
- **Ovarian cancer:** USPSTF recommends against routine screening for ovarian cancer (*9*).

The USPSTF has recommended against offering the following services to men:

- **Prostate cancer:** USPSTF recommends against prostate-specific antigen (PSA)-based screening for prostate cancer (*10*).
- **Testicular cancer:** USPSTF recommends against screening for testicular cancer in adolescent or adult males (*11*).

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Competing interests for the development of these guidelines were not assessed.

*These persons made important contributions to a discussion about community outreach and participation. A decision was made to narrow the focus of this report to clinical services, so recommendations informed by the input of these persons will be published separately.

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

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

Plaintiff,

v.

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

Defendants.

DECLARATION OF KATHRYN KOST IN SUPPORT OF A MOTION FOR A PRELIMINARY INJUNCTION

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

I, Kathryn Kost, declare as follows:

1. I am Acting Vice President of Domestic Research at the Guttmacher Institute, where I have worked in a full-time or consulting capacity since 1989.

2. I hold a B.A. in sociology from Reed College and a Ph.D. in sociology, specializing in demography, from Princeton University.

3. The Guttmacher Institute is a private, independent, nonprofit, nonpartisan corporation that advances sexual and reproductive health and rights through an interrelated program of research, policy analysis, and public education. The Institute's overarching goal is to ensure quality sexual and reproductive health for all people worldwide by conducting research according to the highest standards of methodological rigor and promoting evidence-based policies. It produces a wide range of resources on topics pertaining to sexual and reproductive health and publishes two peer-reviewed journals.

4. The information and analysis Guttmacher generates on reproductive health and rights issues are widely used and cited by researchers, policymakers, the media and advocates across the ideological spectrum. Guttmacher began as the Center for Family Planning Development in the late 1960s and contributed research to Congress in its creation of Title X. In the early 2010s, Guttmacher experts were among those selected to participate in the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs' (OPA) development of the national standards of care for family planning services. The Department of Health and Human Services (HHS) frequently invokes Guttmacher research, including in the context of Title X.[1,2]

5. Over the course of more than 30 years, I have designed, executed, analyzed, and supervised numerous quantitative and qualitative research studies in the field of reproductive

[1] U.S. Department of Health and Human Services (HHS), Compliance with statutory program integrity requirements, *Federal Register*, 2019, 84(42):7714–7791, https://www.federalregister.gov/documents/2019/03/04/2019-03461/compliance-with-statutory-program-integrity-requirements.

[2] Healthy People 2020, Family planning, objectives, 2018, https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning/objectives.

health care, including those on contraceptive use and failure, unintended pregnancy, maternal and child health, and analysis of trends in key demographic and reproductive health measures. My peer-reviewed research has been published in dozens of articles, including first-authored work in *Demography*, *Perspectives on Sexual and Reproductive Health*, *Contraception*, *Family Planning Perspectives*, *Studies in Family Planning* and other public health, medical and demographic journals. My education, training, responsibilities and publications are set forth in greater detail in my curriculum vitae, a true and correct copy of which is attached as Exhibit A. I submit this declaration as an expert on reproductive health care, family planning, and unintended pregnancy, and the impact on individuals, families, and public health from access to contraception and related care, or interference with that care, in the United States.

6. I understand that this lawsuit involves a challenge to the federal government's newly issued regulations regarding the Title X family planning program (the "New Rule," published at 84 Fed. Reg. 7714). In addition to my own expertise on family planning topics, including for example, on demographic trends in unintended pregnancy and disparities in its incidence, and on contraception, including access to it as well as its use, efficacy, and importance for the prevention of unintended pregnancy, in my role as Acting Vice President of Domestic Research at Guttmacher, I lead a team of researchers whose specialties include publicly funded family planning programs.

7. As discussed in more detail below, research over many decades establishes that Title X projects have been extremely effective in expanding access to modern contraceptive technologies, including the most effective methods, for patients with limited economic means. As a result, Title X projects have helped significantly diminish the rate of unintended pregnancies in the United States. Research also shows that Title X providers are especially effective in gaining patients' trust, treating particularly marginalized populations, offering a broad range of effective options for patients' personal, voluntary decision-making, and helping individuals take control of their own reproductive plans and lives. Since its inception, the Title X program has provided high-quality family planning care to low-income individuals, improved public health, and saved public expense at all levels of government.

8. In my expert opinion, the New Rule, if implemented, would force the Title X program in counterproductive directions that are contrary to evidence-based family planning research and that would significantly undermine the individual and public health benefits of Title X in multiple ways.

9. The New Rule would immediately harm the quality of care provided in Title X-funded health centers; deprive patients of non-directive pregnancy options counseling, including referrals; compromise Title X patients' ability to obtain timely, acceptable and effective contraceptive methods; and increase (rather than continue to help diminish) individuals' risk of unintended pregnancy.

10. In addition, many of the high-quality, experienced providers that have been the hallmark of Title X care for years would be pushed from the program. The departure of these providers from the network, without similarly effective providers to take their place, would result in a reduction in patients served and further hamstring the Title X program.

11. Ultimately, the New Rule would fundamentally subvert the Title X program's purpose of helping to close the gap in contraceptive access between individuals and couples with more resources and those with less, ensuring that low-income individuals can count on receiving the highest standard of family planning care. The evidence-based clinical recommendations that guide the delivery of Title X set the bar for what high-quality family planning care should look like: services that are comprehensive, timely, affordable, voluntary, confidential and respectful of all who seek them. The New Rule would effectively transform Title X from the gold standard of family planning care to a program that prioritizes providers' religious or moral beliefs over patient-centered care—with the government's imprimatur. This would erode the nearly 50-year legacy of Title X–funded sites serving as trusted providers of evidenced-based, high-quality, ethical medical care.

12. The negative consequences of the New Rule would impact not only current and future patients, but also their children and families, public health, government budgets, and the nation's health care infrastructure.

I. THE TITLE X PROGRAM REDUCES SYSTEMIC GAPS IN ACCESS TO HIGH-QUALITY FAMILY PLANNING SERVICES.

A. Title X Expands Access to Wanted Family Planning Services Among Low-Income Individuals

13. The Title X Family Planning Program is the nation's only federal program devoted exclusively to providing family planning services.[3]

14. At President Richard Nixon's urging and with strong bipartisan support, Congress established the Title X program in 1970 to make modern contraceptive options and the clinical care they required just as accessible to low-income women as they were to more affluent women.[4] Studies in the 1960s showed that women with low incomes wanted the same number of children as more affluent women, yet had more children than they desired because they lacked access to modern contraceptives.[5]

15. Title X helps low-income individuals maintain reproductive health; avoid pregnancies they do not want; and determine the number, timing, and spacing of their children, all of which contribute to the health and social and economic well-being of patients, their families and communities. In addition to providing access to the most advanced contraceptive methods, comprehensive counseling and information, and related medical services, Title X providers also offer basic clinical infertility services (infertility counseling and screening), as well as pregnancy testing and nondirective counseling on all pregnancy options, including referral upon request regarding prenatal care, adoption, and abortion.[6] Title X funding can also support clinical services addressing other aspects of patients' sexual and reproductive health, including STI testing,

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[3] Institute of Medicine, *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*, Washington, DC: The National Academies Press, 2009, https://www.nap.edu/catalog/12585/a-review-of-the-hhs-family-planning-program-mission-management.

[4] Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

[5] Ryder NB and Westoff CF, *Reproduction in the United States*, Princeton, NJ: Princeton University Press, 1971.

[6] Office of Population Affairs (OPA), HHS, *Program Requirements for Title X Funded Family Planning Projects*, Washington, DC: OPA, 2014, https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf.

counseling and treatment, cervical and breast cancer screening and prevention, and screening for high blood pressure, diabetes and depression, or other preconception issues.[7,8]

16. For any health services outside a provider's scope of care, Title X program regulations and guidelines require referrals to and coordination with other health care providers, social service agencies, and other resources, including but not limited to those that are publicly funded.[9,10]

17. Since the program's inception, Title X funds have been prohibited from use in programs where abortion is a method of family planning.[11] Title X providers, however, are explicitly required to offer patients who are pregnant factual, nondirective information and counseling, including referrals, on all pregnancy options, including abortion, that the patient wishes to consider.[12,13]

B. The Title X Program Requires the Provision of High-Quality Family Planning Care

18. The principles of high-quality, ethical care defined in the Title X statute, regulations and program guidelines apply to all women, men and adolescents served by a Title X project.[14]

19. A central tenet of Title X family planning care is that it is voluntary and non-coercive. This is critical, because history has shown that family planning programs can and have been abused as a tool of social control: Deliberate campaigns have been waged, for example, to

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[7] Ibid.

[8] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[9] OPA, HHS, *Program Requirements for Title X Funded Family Planning Projects*, Washington, DC: OPA, 2014, https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf.

[10] 42 CFR 59.5.

[11] 42 USC 300.

[12] P.L. 115-141, Mar. 23, 2018.

[13] 42 CFR 59.5.

[14] Institute of Medicine, *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*, Washington, DC: The National Academies Press, 2009, https://www.nap.edu/catalog/12585/a-review-of-the-hhs-family-planning-program-mission-management.

limit the fertility of women of color, low-income women, incarcerated women, and women with disabilities.[15]

20. Title X's authorizing statute requires that projects offer clients a broad range of contraceptive methods from which they can choose. This protection helps ensure that individuals seeking contraceptive care are not coerced into using any method they do not want, and to help ensure individuals can in fact obtain the methods that will work best for them. The statute also expressly prohibits conditioning individuals' participation in other publicly funded programs on the acceptance of family planning services.[16]

21. Voluntary decision-making necessarily depends on access to information. Title X standards promote informed decision-making by offering neutral and complete factual counseling, with regard to contraceptives, pregnancy, and other Title X clinical care.

22. In addition to this foundational principle, Title X care is also governed by standards published by OPA, which administers the Title X program, and the CDC, under the title: "Providing Quality Family Planning Services" ("the QFP").[17] The QFP resulted from an exhaustive, multi-year process involving numerous panels of experts from around the country. They were tasked with developing national, evidence-based clinical recommendations intended to serve as the national standard of care for all providers of family planning services, whether publicly funded or not.[18] The QFP is periodically updated by CDC and OPA, including as recently as December 2017.

23. The Title X Family Planning Guidelines, through which HHS implements the Title X program, require Title X grantees to adhere to the QFP.[19]

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[15] Gold RB, Guarding against coercion while ensuring access: a delicate balance, *Guttmacher Policy Review*, 2014, 17(3):8–14, https://www.guttmacher.org/gpr/2014/09/guarding-against-coercion-while-ensuring-access-delicate-balance.

[16] 42 USC 300.

[17] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[18] Godfrey EM et al., Developing federal clinical care recommendations for women, *American Journal of Preventive Medicine*, 2015, 49(2):S6–S13.

[19] OPA, HHS, Program Requirements for Title X Funded Family Planning Projects,

24. The QFP recommends offering a full range of Food and Drug Administration (FDA)-approved contraceptive methods and counseling that highlights methods' effectiveness in helping to prevent pregnancy, further explaining that: "Contraceptive counseling is … a process that enables clients to make and follow through on decisions about their contraceptive use."[20] The selected contraceptive method(s) are preferably provided to the patient onsite and in multiple cycles (if applicable), the patient should be able to start their chosen methods immediately (unless medically contraindicated), and clinicians should assist patients in their decision-making through patient-centered planning and counseling discussions.[21]

25. The QFP also sets the standard of care for pregnancy testing and counseling, which are core family planning services supported by Title X. Indeed, 100% of Title X sites offer pregnancy testing.[22] The QFP specifically instructs that "[positive pregnancy] test results should be presented to the client, followed by a discussion of options and appropriate referrals. Options counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG and AAP."[23] Both ACOG and AAP are explicit in their recommendations that all pregnant individuals, including adolescents, be provided with factual, nondirective pregnancy options counseling that includes information on and timely referral for abortion services.[24][25]

Washington, DC: OPA, 2014, https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf, see p.5.

[20] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[21] Ibid.

[22] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[23] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[24] American College of Obstetricians and Gynecologists (ACOG), *Guidelines for Women's Health Care: A Resource Manual*, fourth ed., Washington, DC: ACOG, 2014.

[25] Committee on Adolescence, American Academy of Pediatrics, Counseling the adolescent about pregnancy options, *Pediatrics*, 1998, 101(5):938–940.

26. Leading professional medical associations, including those referenced by the QFP, state unequivocally that it is unethical to withhold relevant information about options from patients or mislead patients as to their options, when patients indicate a desire for information.[26,27]

27. The QFP further stresses that "every effort should be made to expedite" referrals for pregnant patients and that initial prenatal counseling is to be provided only for "clients who are considering or choose to continue the pregnancy."[28]

28. Taken together, these provisions of the QFP ensure that patients are able to make informed decisions about and truly consent to their own health care.[29]

C. Title X Patients Reflect the Program's Priorities

29. In 2017, Title X-funded providers served approximately 4.0 million individual family planning patients, providing 6.6 million family planning visits.[30] These numbers demonstrate that many patients visit their Title X provider multiple times in a given year.

30. Consistent with the program's prioritization of low-income individuals, in 2017, 90% (3.6 million) of Title X patients had household incomes that qualified them for either free or reduced-cost services under Title X:[31] Sixty-seven percent (2.7 million) had family incomes at or below 100% of the federal poverty level, and 23% (932,000) had incomes ranging from 101% to

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[26] ACOG, Guidelines for Women's Health Care: A Resource Manual, fourth ed., Washington, DC: ACOG, 2014.

[27] American Academy of Physician Assistants (AAPA), Guidelines for Ethical Conduct for the PA Profession, 2013, https://www.aapa.org/wp-content/uploads/2017/02/16-EthicalConduct.pdf.

[28] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[29] Hasstedt K, Unbiased information on and referral for all pregnancy options are essential to informed consent in reproductive health care, *Guttmacher Policy Review*, 21:1–5, https://www.guttmacher.org/gpr/2018/01/unbiased-information-and-referral-all-pregnancy-options-are-essential-informed-consent.

[30] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[31] Ibid.

250% of that threshold.[32] In 2017, the federal poverty level was $12,060 for a single-person household, and $20,420 for a household of three.[33]

31. In 2017, 42% (1.7 million) of Title X patients were uninsured, 38% (1.5 million) had some form of public health insurance (reflecting household incomes low enough to qualify for public coverage), and 19% (760,000) had private health insurance.[34] Although increases in health insurance coverage in recent years suggest somewhat greater overall access to health care for Title X patients, the proportion of uninsured Title X patients is still more than triple the national proportion among all women of reproductive age (12%).[35] Furthermore, some 17% of insured patients are not in a position to use their insurance to pay for the clinic visit.[36] The most common reasons given by insured clients for not using their coverage were that the services they were going to receive were not covered under their plan (31%) or that someone might find out about their visit if they did so (28%).[37]

32. In 2017, 47% of Title X patients (1.9 million) were aged 20 to 29, 35% (1.4 million) were 30 or older, and 17% (693,724) were younger than 20.[38] This shows that while the greatest proportion of Title X patients are young adults in their 20s, Title X providers serve individuals of all reproductive ages.

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[32] Ibid.

[33] Office of the Assistant Secretary for Planning and Evaluation, HHS, U.S. federal poverty guidelines used to determine financial eligibility for certain federal programs, 2017, https://aspe.hhs.gov/poverty-guidelines.

[34] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[35] Guttmacher Institute, Gains in insurance coverage for reproductive-age women at a crossroads, *News in Context*, Dec. 4, 2018, https://www.guttmacher.org/article/2018/12/gains-insurance-coverage-reproductive-age-women-crossroads.

[36] Kavanaugh ML, Zolna MR and Burke K, Use of health insurance among clients seeking contraceptive services at Title X-funded facilities in 2016, *Perspectives on Sexual and Reproductive Health*, 2018, 50(3):101–109, https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

[37] Ibid.

[38] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

33. In 2017, 31% (1.2 million) of Title X patients self-identified with at least one of the Office of Management and Budget's nonwhite race categories: Black or African American, Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, or more than one race. Thirty-three percent (1.3 million) of Title X patients identified as Hispanic or Latino.[39]

34. In 2017, 14% (553,241) of Title X patients reported having limited English language proficiency.[40]

II. TITLE X-SUPPORTED SERVICES YIELD ENORMOUS BENEFITS TO INDIVIDUALS, FAMILIES AND PUBLIC HEALTH

A. Title X-Supported Contraceptive Care Helps Individuals Avoid Pregnancies They Do Not Want, and Time and Space Wanted Pregnancies

35. In 2015, the most recent year for which these numbers are available, the contraceptive care delivered by Title X-supported providers helped women avoid an estimated 822,000 unintended pregnancies, which would have resulted in an estimated 387,000 births and 278,000 abortions.[41,42] Without the contraceptive care provided by these Title X-funded health centers that year, the U.S. rates of unintended pregnancy and abortion would have been 31% higher, and the adolescent unintended pregnancy rate would have been 44% higher.[43]

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[39] Ibid.

[40] Ibid.

[41] Frost JJ, et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015*, New York: Guttmacher Institute, 2017, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

[42] The numbers of pregnancies, births and abortions prevented by contraceptive services provided by Title X-supported sites are derived by first estimating the number of pregnancies that would occur over one year among women using the mix of contraceptive methods found among all patients receiving contraceptive care. This is compared to the number of pregnancies that would occur among a hypothetical group of similar women who do not have access to publicly funded services. This methodology relies on updated information on contraceptive failure rates for different methods, use of national survey data to construct the hypothetical cohort, and a number of adjustments that align the results with actual numbers of pregnancies occurring to women using contraceptive methods. For more detailed methodology, see:

Frost JJ et al., *Contraceptive Needs and Services, 2010: Methodological Appendix*, New York: Guttmacher Institute, 2013, https://www.guttmacher.org/sites/default/files/report_downloads/contraceptive-needs-methodology_0.pdf; Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

[43] Frost JJ, et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015*, New

36. This impact comes from Title X's expansion of low-income individuals' ability to freely choose from among a broad range of acceptable and effective contraceptive methods, along with related counseling and clinical services.[44]

37. The ability to obtain contraceptive methods that best meet an individual's needs helps that person feel satisfied with their chosen methods, and women who are satisfied with their current contraceptive methods are more likely to use them consistently and correctly.[45] For example, only 35% of satisfied oral contraceptive users have skipped at least one pill in the past three months, compared with 48% of dissatisfied users.[46]

38. Consistent and correct contraceptive use increases individuals' likelihood of successfully avoiding unintended pregnancies: The women at risk for unintended pregnancy (those who are sexually active and able to become pregnant but are not pregnant and do not want to become pregnant) who consistently and correctly use a contraceptive method account for only 5% of unintended pregnancies.[47]

39. True choice in contraceptive methods is also important because U.S. women and couples rely on a broad mix of contraceptive methods and sometimes use two or more methods at

York: Guttmacher Institute, 2017, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

[44] Sonfield A, Why family planning policy and practice must guarantee a true choice of contraceptive methods, *Guttmacher Policy Review*, 2017, 20:103–107, https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods.

[45] Frost JJ and Darroch JE, Factors associated with contraceptive choice and inconsistent method use, United States, 2004, *Perspectives on Sexual and Reproductive Health*, 2008, 40(2):94–104, https://www.ncbi.nlm.nih.gov/pubmed/18577142.

[46] Ibid.

[47] Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

once.[48,49] Furthermore, most individual women rely on multiple methods over the course of their reproductive lives, with 86% having used three or more methods by their early 40s.[50]

40. The ability to make an informed choice from a broad range of method options is also important to ensuring individuals can obtain and use the contraceptive methods that best fulfill their own needs and priorities, which may include not only preventing pregnancy, but also managing potential side effects, drug or hormonal interactions, perceived risk of HIV and other STIs, and many other considerations.[51]

41. Offering patients a wide choice of contraceptive methods—or the choice to use no method at all—is also essential to guarding against reproductive coercion, and requires considerable resources and provider expertise, which Title X expressly facilitates.[52]

42. Title X sites facilitate choice by providing a greater number of contraceptive method options to their patients, as compared to other publicly funded health centers that do not receive Title X support and provide contraceptive care to at least 10 women each year[53] —70% of

[48] Kavanaugh ML and Jerman J, Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, *Contraception*, 2017, 97(1):14-21, https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012.

[49] Kavanaugh ML and Jerman J, Concurrent multiple methods of contraception in the United States, poster presented at the North American Forum on Family Planning, Atlanta, Oct. 14–16, 2017.

[50] Daniels K, Mosher WD and Jones J, Contraceptive methods women have ever used: United States, 1982–2010, *National Health Statistics Reports*, 2013, No. 62, https://www.cdc.gov/nchs/products/nhsr.htm.

[51] Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(2):194–200, https://www.guttmacher.org/journals/psrh/2012/09/contraceptive-features-preferred-women-high-risk-unintended-pregnancy.

[52] Sonfield A, Why family planning policy and practice must guarantee a true choice of contraceptive methods, *Guttmacher Policy Review*, 2017, 20:103–107, https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods.

[53] Together, these sites are also referred to as "safety-net family planning centers." This group includes health centers that offer contraceptive care to the general public and use public funds (e.g., federal, state or local funding though programs such as Title X, Medicaid or the federally qualified health center program) to provide free or reduced-fee services to at least some clients. Sites must serve at least 10 contraceptive clients per year to be counted among this group. These sites are operated by a diverse range of provider agencies, including public health departments, Planned Parenthood affiliates, hospitals, federally qualified health centers and other

which are operated by federally qualified health centers (FQHCs).[54] *See infra*, Section D. Seventy-two percent of Title X sites offer a full range of FDA-approved reversible contraceptive methods, compared to 49% of non-Title X sites.[55] Title X-supported centers offer a choice of 12 methods, on average, and 85% offer at least one long-acting reversible method, such as the IUD or contraceptive implant.[56]

43. Title X-supported centers are also more likely than non-Title X providers to offer contraceptives on site rather than give a prescription that women must fill at a pharmacy or a referral to another provider for insertion of an IUD or implant. Seventy-two percent of Title X–funded centers provide oral contraceptive supplies and refills on site, compared with only 40% of sites not funded by the program.[57] Similarly, among Title X sites, 41% offer same-day insertion of IUDs or implants, compared to 27% of non-Title X sites.[58] Minimizing the number of trips a woman must make to obtain her contraceptive methods makes it easier for her to successfully use those methods, especially for those who juggle the demands of school, family and work, or who rely on public or perhaps a borrowed mode of transportation—all common complicating factors in patients' lives.

44. Among the 3.1 million sexually active female patients at risk of unintended pregnancy who visited a Title X site in 2017, 70% (2.2 million) left their last visit with a contraceptive method deemed either most or moderately effective at preventing pregnancy.[59] This

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independent organizations.

[54] Zolna MR and Frost JJ, special tabulations of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Census, https://www.guttmacher.org/report/publicly-funded-contraceptiveservices-us-clinics-2015.

[55] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[56] Ibid.

[57] Ibid.

[58] Zolna MR, special tabulations of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Survey, https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[59] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

is unsurprising, given that an important feature for most individuals seeking contraceptive care is how well a method works to prevent pregnancy.[60] "Most effective" methods include vasectomy, female sterilization, implant, or IUD, and "moderately effective" methods include injectable contraception, vaginal ring, contraceptive patch, pills, diaphragm, or cervical cap.[61] These methods require a prescription or services provided by a medical professional. In contrast, the contraceptive methods that can be purchased over the counter at a neighborhood drugstore for a comparatively low cost—male condoms and spermicide—are far less effective at preventing pregnancy than methods that require a prescription or a visit to a health care provider, which have higher up-front and ongoing costs.[62]

45. While long-acting reversible contraceptives ("LARC"), such as implants and IUDs are very effective, they are also costly.[63] Without any third-party payer to help defray the expense, the total cost to the patient of initiating one of these methods generally exceeds $1,000.[64] Oral contraceptives, which are nearly twice as effective as condoms in practice, require a prescription and have ongoing monthly costs.[65] Many methods would cost a patient at least $50 per month, or upwards of $600 per year.[66]

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[60] Lessard LN et al., Contraceptive features preferred by women at high risk of unintended pregnancy, *Perspectives on Sexual and Reproductive Health*, 2012, 44(2):194–200, https://www.guttmacher.org/journals/psrh/2012/09/contraceptive-features-preferred-women-high-risk-unintended-pregnancy.

[61] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[62] Hatcher RA et al., C*ontraceptive Technology*, 21st ed., New York: Ayer Company Publishers, Inc., 2018.

[63] Ibid.

[64] Eisenberg D, McNicholas C and Peipert JF, Cost as a barrier to long-acting reversible contraceptive (LARC) use in adolescents, *Journal of Adolescent Health*, 2013, 52(4):S59–S63, http://www.jahonline.org/article/S1054-139X(13)00054-2/fulltext.

[65] Sundaram A et al., Contraceptive failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth, *Perspectives on Sexual and Reproductive Health*, 2017, 49(1):7-16, https://www.guttmacher.org/journals/psrh/2017/02/contraceptive-failure-united-states-estimates-2006-2010-national-survey-family.

[66] Planned Parenthood, How do I get birth control pills? No date, https://www.plannedparenthood.org/learn/birth-control/birth-control-pill/how-do-i-get-birth-control-pills.

46. Title X providers work hard to ensure that women are able to start their method at the same time that they request it. For example, Title X–supported centers are particularly likely to use the so-called "quick start" protocol (87% of them did so in 2015, as compared to only 66% of all publicly funded health centers delivering contraceptive care not supported by Title X), under which clients who choose to use oral contraceptives begin taking them immediately, rather than waiting until a certain point in their menstrual cycles, as some providers require.[67]

47. Title X–supported centers are also particularly likely to prescribe contraception without requiring a pelvic exam (88%, as compared to only 76% of non-Title X supported clinics),[68] a practice in line with evidence-based guidelines issued by the World Health Organization[69] and the American College of Obstetricians and Gynecologists.[70]

48. Title X support also helps clinicians to obtain the necessary training and spend the needed time during a patient visit to provide in-depth contraceptive counseling and explore options with clients.[71] On the whole, clinicians at Title X-supported sites spend more time with patients during initial contraceptive visits than do clinicians at non-Title X sites—especially those clients with specific needs, such as those who are younger, have limited English proficiency or have other complex medical or personal issues.[72]

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[67] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[68] Ibid.

[69] World Health Organization (WHO), *Selected Practice Recommendations for Contraceptive Use*, 3rd ed., Geneva: WHO, 2016, https://www.who.int/reproductivehealth/publications/family_planning/SPR-3/en/.

[70] ACOG, The utility and indications for routine pelvic examinations, Committee Opinion No. 754, *Obstetrics & Gynecology*, 2018, 132:e174–180, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/The-Utility-of-and-Indications-for-Routine-Pelvic-Examination.

[71] Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*, New York: Guttmacher Institute, 2014, https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

[72] Frost JJ et al., *Variation in Service Delivery Practices Among Clinics Providing Publicly Funded Family Planning Services in 2010*, New York: Guttmacher Institute, 2012, https://www.guttmacher.org/report/variation-service-delivery-practices-among-clinics-providing-publicly-funded-family-planning.

B. Title X-Supported Care Helps Prevent Preterm or Low-Birth-Weight Births and Other Negative Health Outcomes

49. The contraceptive services provided at Title X family planning visits also help prevent poor birth outcomes. In 2010 (the most recent year for which these estimates are available), the contraceptive services provided by Title X-supported providers helped individuals and couples to avert an estimated 87,000 preterm or low-birth-weight births.[73,74]

50. Contraceptive use enables women to plan their pregnancies, and women who plan generally recognize their pregnancies earlier on, in turn allowing women more time to engage in behaviors that promote healthy pregnancies, such as taking prenatal vitamins, and reducing or stopping smoking and drinking.[75]

51. Moreover, by enabling women to plan their pregnancies, contraceptive use can decrease individuals' risk for pregnancy-related morbidity and mortality.[76] The risk of such adverse outcomes is particularly high for individuals who are near the end of their reproductive years and for those with medical conditions that may be exacerbated by pregnancy.[77] Although reversible contraceptives—like virtually all medications and medical devices—are not without

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[73] Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

[74] The numbers of preterm or low-birth-weight births that are prevented among women obtaining contraceptive services from Title X sites are derived by first estimating the overall number of births that are prevented, and then using national data to estimate the proportion of unintended births to women with the same characteristics as those going to clinics that are preterm or low-birth-weight. For more detailed methodology, see: Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

[75] Kost K and Lindberg L, Pregnancy intentions, maternal behaviors and infant health: investigating relationships with new measures and propensity score analysis, *Demography*, 2015, 52(1):83–111, https://www.guttmacher.org/sites/default/files/pdfs/pubs/journals/kost-lindberg-demography_s13524-014-0359-9.pdf.

[76] Kavanaugh ML and Anderson RM, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Center*s, New York: Guttmacher Institute, 2013, https://www.guttmacher.org/report/contraception-and-beyond-health-benefits-services-provided-family-planning-centers.

[77] Berg C et al., Pregnancy-related mortality in the United States, 1998 to 2005, *Obstetrics & Gynecology*, 2010, 116(6):1302–1309.

risk, the likelihood of serious health risks is lower than that for pregnancy or childbirth, which can be an important consideration for individual patients.[78][79]

C. Title X-Supported Services Contribute to the Prevention, Early Detection and Treatment of STIs

52. Title X-supported STI testing and screening also yields considerable benefits for individuals' and their partners' sexual and reproductive health. Testing for chlamydia, gonorrhea and/or HIV are conducted routinely as part of family planning visits.[80] Chlamydia and gonorrhea testing can help prevent additional health problems, such as pelvic inflammatory disease, ectopic pregnancy and infertility.[81,82,83] Testing can do so directly, by detecting an infection early and facilitating treatment, and indirectly, because treating an infection prevents its spread to a client's current sexual partners and to any future partners they may have.[84]

53. Similarly, HIV testing and early detection help facilitate treatment and reduce transmission of the virus to partners, because they may lead to less risky behavior after a positive test result and to reduced infectivity after entry into treatment.[85]

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[78] Speidel JJ et al., Pregnancy: not a disease but still a health risk, *Contraception*, 2013, 88(4):481–484.

[79] Harlap S, Kost K and Forrest JD, *Preventing Pregnancy, Protecting Health*: *A New Look at Birth Control in the United States*, New York: Guttmacher Institute, 1991.

[80] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[81] Kavanaugh ML and Anderson RM, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers*, New York: Guttmacher Institute, 2013, https://www.guttmacher.org/report/contraception-and-beyond-health-benefits-services-provided-family-planning-centers.

[82] Centers for Disease Control and Prevention (CDC), Chlamydia- CDC Fact Sheet, *Fact Sheet*, Atlanta: CDC, 2017, https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm.

[83] CDC, Gonorrhea- CDC Fact Sheet, *Fact Sheet*, Atlanta: CDC, 2017, https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea.htm.

[84] Workowski KA and Bolan GA, Sexually transmitted diseases treatment guidelines, 2015, *Morbidity and Mortality Weekly Report*, 2015, Vol. 64, No. 3, https://www.cdc.gov/std/tg2015/default.htm.

[85] Marks G et al., Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States implications for HIV prevention programs, *Journal of Acquired Immune Deficiency Syndromes*, 2005, 39(4):446–453.

54. In 2017, Title X providers tested 61% (939,300) of female patients under age 25 for chlamydia, and they performed 2.4 million gonorrhea tests (6.1 tests per 10 patients), 1.2 million confidential HIV tests (3.0 tests per 10 patients), and 709,000 syphilis tests (1.8 tests per 10 patients).[86] Of the confidential HIV tests performed, 2,200 (1.8 per 1,000 tests performed) were positive.[87]

55. In 2010 (the most recent year for which these data are available), the STI testing, screening and related services provided by Title X-supported providers helped to avert an estimated 63,000 STIs.[88]

D. Title X-Supported Services Contribute to the Prevention and Early Detection of Cervical Cancer

56. Title X funding and services also support the provision of services intended to aid in the prevention and early detection of cervical cancer as part of routine family planning care, namely Pap tests, human papillomavirus (HPV) testing and HPV vaccinations.[89] Pap tests—now often performed in conjunction with HPV tests in accordance with clinical recommendations—help to detect abnormal cervical cells and cases of precancer, which allows for early treatment that prevents cervical cancer cases and deaths.[90,91] HPV vaccinations help protect clients against the viral strains of HPV most commonly linked to cervical cancer; they also provide some

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[86] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[87] Ibid.

[88] Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

[89] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[90] Sonfield A, Beyond preventing unplanned pregnancy: the broader benefits of publicly funded family planning services, *Guttmacher Policy Review*, 2014, 17(4):2–6, https://www.guttmacher.org/gpr/2014/12/beyond-preventing-unplanned-pregnancy-broader-benefits-publicly-funded-family-planning.

[91] CDC, Gynecological cancers: what should I know about screening, 2018, https://www.cdc.gov/cancer/cervical/basic_info/screening.htm.

protection against HPV-attributable cancers of the vulva, vagina, anus, rectum, and oropharynx.[92,93]

57. In 2017, Title X-supported sites provided Pap tests to screen for cervical cancer to 18% (649,300) of female patients. Fourteen percent of those Pap tests yielded indeterminate or abnormal results, prompting further evaluation and possible treatment.[94]

58. In 2010 (the most recent year for which these data are available), the cervical cancer prevention services provided by Title X-supported providers helped to prevent an estimated 2,000 cases of cervical cancer.[95]

E. Title X Provides a Gateway to Health Coverage and Care

59. For 60% of Title X patients, that Title X-supported provider was their sole source of medical care in the last year, making these providers critical sources of care in their own right.[96] However, Title X providers have also long served as entry points to the broader health care system for many individuals, as the high-quality, low-cost, confidential services they offer enable many people to walk through Title X providers' doors when they would not be willing or able to walk through others.[97]

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[92] Sonfield A, Beyond preventing unplanned pregnancy: the broader benefits of publicly funded family planning services, *Guttmacher Policy Review*, 2014, 17(4):2–6, https://www.guttmacher.org/gpr/2014/12/beyond-preventing-unplanned-pregnancy-broader-benefits-publicly-funded-family-planning.

[93] CDC, Human papillomavirus: why is HPV vaccine important, 2017, https://www.cdc.gov/hpv/hcp/hpv-important.html.

[94] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[95] Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

[96] Kavanaugh ML, Zolna MR and Burke K, Use of health insurance among clients seeking contraceptive services at Title X-funded facilities in 2016, *Perspectives on Sexual and Reproductive Health*, 2018, 50(3):101–109, https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

[97] Gold RB, The role of family planning centers as gateways to health coverage and care, *Guttmacher Policy Review*, 2011, 14(2):15–19, https://www.guttmacher.org/gpr/2011/06/role-family-planning-centers-gateways-health-coverage-and-care.

60. Title X sites have long engaged in outreach and enrollment assistance efforts helping eligible people obtain comprehensive health insurance coverage, particularly since the ACA's implementation.[98]

61. Title X providers' referral relationships help ensure that individuals who need them can obtain services and supports outside their family planning visit. Ninety-nine percent of sites have formal or informal referral relationships with other providers; 97% refer to other public providers, including FQHCs and other community clinics offering primary care, and 90% refer to private providers, including ob-gyns and private physicians or group practices.[99] Sixty-two percent of Title X sites refer patients to social service agencies, and nearly half to home visiting programs or services.

F. Title X-Supported Services Help Individuals to Achieve Their Educational, Workforce and Economic Goals

62. By enabling individuals and couples to more reliably time and space pregnancies, the Title X program promotes individuals' continued educational and professional advancement, contributing to the enhanced economic stability of individuals and their families. In a 2011 national survey of more than 2,000 women obtaining family planning care from Title X sites focused on reproductive health care, women reported that over the course of their lives, contraception had enabled them to take better care of themselves or their families (63%), support themselves financially (56%), complete their education (51%), or get or keep a job (50%).[100]

63. When asked why they were seeking contraceptive services at that moment, women provided similar answers, including not being able to afford to care for a baby or another baby at that time (65%), not being ready to have children (63%), feeling that contraception gives them

[98] Hasstedt K, Building it is not enough: family planning providers poised for key role in helping people obtain coverage under the Affordable Care Act, *Guttmacher Policy Review*, 2014, 17(4):7–13, https://www.guttmacher.org/gpr/2014/12/building-it-not-enough-family-planning-providers-poised-key-role-helping-people-obtain.

[99] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[100] Frost JJ and Lindberg LD, Reasons for using contraception: perspectives of U.S. women seeking care at specialized family planning clinics, *Contraception*, 2013, 87(4):465–472.

better control over their life (60%) and wanting to wait to have a baby until life is more stable (60%).[101]

64. Economic analyses have found positive associations between women's ability to obtain and use oral contraceptives and their ability to obtain higher levels of education, participate in the labor force and obtain higher-paying jobs, in turn contributing to a narrowing of the gender-based wage gap.[102]

65. Given its connections to so many central aspects of people's lives, it makes sense that the ability to determine for oneself whether and when to have children is also related to an individual's mental health and happiness. Individuals and couples who experience an unintended pregnancy that ends in birth are particularly likely to experience depression, anxiety and a decreased perception of happiness.[103]

G. Title X Investment Yields Considerable Public Savings

66. In addition to promoting positive health and other outcomes for individuals, couples and families, and the broader public, Title X-supported services also yield considerable savings of government expenditures. Title X-supported services—including contraceptive care, STI testing, and cervical cancer testing and prevention—save approximately $7 for every public dollar invested.[104] This amounted to an estimated $8.1 billion in gross federal and state government savings in 2010 (the most recent year for which these data are available), by avoiding public expenditures that would have otherwise been made for medical care associated with unintended pregnancies, STIs and cervical cancer. The federal and state governments realized an

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[101] Ibid.

[102] Sonfield A et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*, New York: Guttmacher Institute, 2013, https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.

[103] Gipson JD, Koenig MA and Hindin MJ, The effects of unintended pregnancy on infant, child, and parental health: a review of the literature, *Studies in Family Planning*, 2008, 39(1):18–38.

[104] Frost JJ et al., Return on investment: a fuller assessment of the benefits and cost savings of the US publicly funded family planning program, *Milbank Quarterly*, 2014, 92(4):667–720, https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12080.

estimated $7 billion in net savings that year, after subtracting the cost of delivering Title X-supported services.[105]

III. TITLE X FUNDS SUPPORT A NATIONWIDE NETWORK OF HEALTH CENTERS THAT ARE CRITICAL, TRUSTED SOURCES OF HIGH-QUALITY CARE FOR THEIR PATIENTS

67. The Title X program's ability to serve four million patients each year[106] and advance the extensive individual, familial and societal benefits articulated above depends on the participation of health care providers with the expertise, staff and resources necessary to deliver a truly broad range of contraceptive options and counseling, and related clinical services, to considerable numbers of patients.

68. In 2017, Title X funds supported a network of over 1,000 provider organizations, including both non-profit and public entities, which operated 3,858 service sites.[107]

69. In 2015, among Title X-supported centers, sites operated by Planned Parenthood represented 13% of sites and served 41% of all contraceptive patients; those operated by state or local health departments represented 48% of sites and served 28% of patients; sites operated by federally qualified health centers (FQHCs) accounted for 26% of sites and served 19% of patients; and other independent agencies operated 9% of all sites and served 7% of patients.[108] Seventy-two percent of Title X sites focus on the provision of reproductive health services,[109] including all of those operated by Planned Parenthood affiliates, and a majority of those operated by public health departments (81%), hospitals (70%), and other independent providers (86%).[110]

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[105] Ibid.

[106] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[107] Ibid.

[108] Frost JJ et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015*, New York: Guttmacher Institute, 2017, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

[109] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[110] Zolna MR and Frost JJ, special tabulations of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Survey, https://www.guttmacher.org/report/publicly-funded-

70. Reproductive health-focused sites serve a considerable majority of Title X patients. These sites provide contraceptive care to an estimated 2.7 million women each year, or seven in 10 who rely on Title X for such services.[111] (Patients served by the small number of reproductive health–focused sites that FQHCs report operating are not included in this estimate.)

71. Many women prefer to obtain contraceptive services from reproductive health–focused health centers over primary care–focused sites in their communities: Six in 10 women obtaining services at a reproductive health-focused provider report having made a visit to another provider in the last year, but chose the specialized provider for their contraceptive care; the remaining four in 10 of these women report that the reproductive health–focused provider was their only source of care in the last year, despite having other options in their communities.[112]

72. Leading reasons patients provided for preferring to visit reproductive–health focused sites over other, non-specialized sites include: "The staff here treat me respectfully" (84%), "Services here are confidential" (82%), and "The staff here know about women's health" (80%).[113]

IV. THE NEW RULE WOULD IMMEDIATELY HARM PATIENTS AND PUBLIC HEALTH BY IMPOSING SUBSTANDARD CARE AND DISRUPTING THE TITLE X SAFETY NET OF PROVIDERS

73. The New Rule would immediately impose substandard care on those who rely on Title X-funded providers by eliminating the requirement that Title X sites all offer nondirective pregnancy options counseling to patients who are pregnant and forbidding abortion referrals except in the case of medical emergency. This change deprives patients of information and referrals regarding all options, including abortion, if they are pregnant and is contrary to the QFP and medical ethics. Additionally, the New Rule would allow providers to deprive patients of full

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family-planning-clinic-survey-2015.

[111] Ibid.

[112] Frost J, Gold RB and Bucek A, Specialized family planning clinics in the United States: why women choose them and their role in meeting women's health care needs, *Women's Health Issues*, 2012, 22(6):519–525, https://www.guttmacher.org/article/2012/11/specialized-family-planning-clinics-united-states-why-women-choose-them-and-their.

[113] Ibid.

information or provide them with misleading information, inhibit informed decision-making, and delay patients from obtaining the care they may desire.

74. In addition, the New Rule would require that all pregnant patients be referred for prenatal care, regardless of their wishes. Furthermore, while not mandatory, clinicians would be allowed to provide information on "maintaining the health of the mother and unborn child," even when it is not requested by the patient, in direct violation of Title X's central tenet that all services are voluntarily received and free from coercion.

75. The New Rule would also curtail contraceptive options for Title X clients by deemphasizing the provision of modern, medically approved contraceptive methods, diverting funds away from core family planning services, and encouraging a shift toward "non-traditional" providers that are permitted to offer a single or limited method(s) of contraception.

76. In addition to the direct, immediate impacts on patient care and public health, the New Rule would also create a massive disruption in the Title X network of providers that would compound the harms to patient and public health. The New Rule would put Title X grantees and the providers now participating in the Title X program in the untenable bind of choosing between two bad options: Either (1) agreeing to provide care that does not adhere to medical or ethical standards, because they want to continue providing at least some Title X–supported services for their low-income patients, or (2) deciding that they must exit the program because they are unwilling to comply with the New Rule's requirements for substandard care, and do so mid-grant, when the New Rule goes into effect. Title X grantees and providers may also be forced to exit the program because the New Rule would impose significant new costs and hurdles that are not tenable and would interfere with Title X's effectiveness even if they could be feasibly implemented—including new "financial and physical" separation requirements that also impose considerable limits on providers' use of funding for infrastructure.

77. Many current providers would feel compelled to choose the second option and leave the Title X program in the middle of the current funding cycle. The New Rule erroneously assumes that there would be sufficient available capacity and willingness among other health care providers—particularly, among primary care providers, such as FQHCs—to take their place. The

inevitable result would be a considerable disruption in the current Title X network and gaps in capacity.

78. The departure of providers would be acutely felt in areas of the country that do not have another safety-net family planning center. Twenty-one percent of Title X sites are in counties that do not have another safety-net family planning center.[114] Moreover, in one-fifth of all 3,142 U.S. counties, a Title X site is the only safety-net family planning center. If any of these sites were to no longer participate in Title X as a consequence of this rule, it would make it exceedingly difficult for low-income individuals in those areas to obtain high-quality, affordable family planning care.

79. Furthermore, the New Rule does not address the inevitable difficulty OPA would face in finding new, comparably qualified providers to fill this gap during its next funding cycle. HHS offers only a single letter submitted in response to the Proposed Rule as evidence of the existence of providers that might be able to fill the gap.[115] The letter and, in turn, HHS rely on 2009 and 2011 online surveys of "faith-based medical professionals" to suggest individual practitioners would increasingly participate in Title X under the New Rule, helping to fill the gap in service delivery. However, the evidence presented in the letter does not support HHS' conclusion. These surveys asked health care providers broadly about the importance of "conscience protections" to their ability to practice medicine, but did not assess providers' interest in participating in Title X or delivering family planning services specifically. Moreover, the letter and HHS offer no estimates of how many providers might newly participate, or their capacity to serve large numbers of contraceptive patients—critical considerations in contemplating the loss of current Title X providers that each serve thousands of patients each year. In fact, the letter suggests that faith-based organizations are unlikely to seek federal funding

[114] Zolna MR and Frost JJ, special tabulations of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Census, https://www.guttmacher.org/report/publicly-funded-contraceptiveservices-us-clinics-2015.

[115] Imbody J, Comments re: RIN 0937-ZA00 Compliance with Statutory Program Integrity Requirements, July 31, 2018, https://www.regulations.gov/document?D=HHS-OS-2018-0008-69125.

without extensive grants training and restructuring of the grants process, activities that are not part of the new rule and that would take many years to implement, leaving huge gaps in service delivery for many years to come. The comment letter further asserts that FQHCs could fill the gap in Title X service delivery, an unrealistic suggestion addressed extensively in Section D, below.

80. Even if some new resources or new providers could be found, there would still be significant short-term and potentially long-term harms as patients are inevitably left without the high-quality, affordable Title X–supported care they rely on for months or longer.

81. The New Rule, if implemented, would thus trigger a downward spiral within the Title X program that harms patients, providers, grantees and public health right away and in a growing fashion from the effective date, and that current data and conditions indicate would be very hard to stop or reverse. Some patients would be effectively excluded from the program and others would receive inadequate care.

82. Taken together, and without any intervention, these changes would inevitably increase some people's risks for unintended pregnancy, undetected and untreated STIs, and cervical cancer, among other health effects.

83. Moreover, as soon as the New Rule takes effect, all current Title X grantees, sub-recipients and individual providers would be forced to choose between compromising national standards of care and central ethical requirements, or exiting the Title X program.

A. The New Rule Would Involve Providers in and Subject Patients to Directive, Involuntary Pregnancy Counseling that Misleads and Denies Wanted Abortion Referral

84. If the New Rule is allowed to take effect as planned, patients would immediately be treated with substandard care following positive pregnancy tests, in the form of falsely limited pregnancy options counseling, misleading responses or outright denials to requests for abortion referrals, and forced referrals for prenatal care, regardless of the patient's wishes or medical needs. Pregnant patients could only be referred for abortion services in the event of a medical emergency, and would be denied referral if abortion was "only" medically indicated.

85. The New Rule would eliminate the long-standing guarantee that all pregnant patients at Title X-funded sites be offered unbiased, factual, and comprehensive counseling—including referrals upon request. Such nondirective counseling is necessary to ensuring patients are able to make informed, voluntary decisions about their own health care. These changes not only violate congressional directives,[116] but also the federal government's own standard of care as articulated in the QFP, described above.[117] Moreover, they also ignore bedrock principles of medical ethics.[118,119,120,121]

86. The New Rule would also unnecessarily limit pregnancy options counseling to physicians and "advanced practice providers" with "at least a graduate level degree." This definition excludes highly trained providers who also play an important role in delivering counseling in Title X settings, such as registered nurses, public health nurses, health educators and clinical social workers.[122] Although Guttmacher does not have data specific to clinicians offering pregnancy options counseling, data from 2010 show that 65% of Title X sites and 64% of all safety-net family planning centers focused on reproductive health rely on trained health educators, registered nurses and other qualified providers (excluding physicians and advanced practice clinicians) to counsel patients in selecting contraceptive methods.[123] Given the critical

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[116] P.L. 115-141, Mar. 23, 2018.

[117] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[118] ACOG, *Guidelines for Women's Health Care: A Resource Manual*, fourth ed., Washington, DC: ACOG, 2014.

[119] Committee on Adolescence, American Academy of Pediatrics, Counseling the adolescent about pregnancy options, *Pediatrics*, 1998, 101(5):938–940.

[120] AAPA, Guidelines for Ethical Conduct for the PA Profession, 2013, https://www.aapa.org/wp-content/uploads/2017/02/16-EthicalConduct.pdf.

[121] AWHONN, AWHONN position statement: Health care decision making for reproductive care, *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 2016, 45(5):718, http://www.jognn.org/article/S0884-2175(16)30229-5/fulltext.

[122] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[123] Frost JJ et al., *Variation in Service Delivery Practices Among Clinics Providing Publicly Funded Family Planning Services in 2010*, New York: Guttmacher Institute, 2012,

role these clinicians play in contraceptive counseling, needlessly excluding them from pregnancy options counseling stands to harm patients' experiences and service delivery.

87. Regarding the substance of permissible pregnancy options counseling, the New Rule would allow physicians and advance practice practitioners to deliver counseling that excludes information on abortion, rendering that counseling far from "nondirective." Even more directive, those clinicians would be forced to provide information about prenatal care, even when the patient does not request or actively does not want such information, and required to discuss a prenatal or adoption option with a patient that only wishes to discuss abortion.

88. The New Rule would effectively require clinicians to deny abortion referrals entirely. Providers would have the option of offering pregnant patients an intentionally misleading provider list that must include only "licensed, qualified comprehensive primary health care providers (including providers of prenatal care)." At best, that list would provide incomplete and confusing information as "some, but not the majority" of sites could also offer abortion, though neither the list nor clinic staff would be permitted to identify those sites as abortion providers. At worst, patients requesting abortion could be given a referral list without any abortion providers, without the patient's knowledge or understanding that the referral list was in no way responsive to their request.

89. Additionally, there is also no guarantee that any comprehensive primary care sites offering abortion would be available in patients' communities to even include on the list, and the rule bars clinicians from telling patients about other, specialized abortion providers. For example, in 2018, in eight states (Kentucky, Louisiana, Mississippi, Missouri, South Dakota, North Dakota, West Virginia and Wyoming), the only providers known to offer abortions in the state are specialized abortion providers, including Planned Parenthood clinics and independent providers.[124] There are no comprehensive primary care sites that are known to offer abortion

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https://www.guttmacher.org/sites/default/files/report_pdf/clinic-survey-2010.pdf.

[124] Abortion Care Network, *Communities Need Clinics: Independent Abortion Care Providers and the Future of Abortion Access in the United States*, Minneapolis: Abortion Care Network, 2018, https://www.abortioncarenetwork.org/wp-content/uploads/2019/01/communities-need-clinics-FINAL-2018.pdf.

services in these states, making it effectively impossible to put any abortion providers on the misleading referral list permissible under the New Rule. Moreover, there are likely similar situations in many areas of many other states, because there are no known primary care providers that also offer abortion, or perhaps only private practice physicians who offer abortion care only to their established patients. As a result, under the New Rule, Title X patients in these states and areas would not even be able to obtain obscured referral information from their Title X provider.

90. All of these restrictive options would harm and confuse all patients, but may be particularly problematic for adolescents, those with limited English proficiency, or other especially marginalized populations.

91. Beyond denying abortion referrals to patients who request them, the New Rule mandates that all pregnant patients at Title X sites be referred for prenatal care, regardless of the patient's wishes. Moreover, though not required, pregnant patients may be provided prenatal counseling, may be referred to social services or adoption agencies, and may be given "information about maintaining the health of the mother and unborn child"—again, all regardless of the patient's wishes. These provisions are coercive not only in requiring or allowing for services to be provided even for women who do not want them, but also because they force all patients toward the particular pregnancy outcome of childbirth, regardless of the patient's own wishes and in violation of the voluntary, patient-centered foundations of Title X care.[125,126,127,128]

92. Restricting pregnancy options counseling, including abortion referrals, and directing pregnant patients only toward childbirth would ultimately threaten their health and well-

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[125] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[126] ACOG, Informed consent, Committee Opinion No. 439, *Obstetrics & Gynecology*, 2009, 114(2):401–408, https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Informed-Consent.

[127] AAPA, Guidelines for Ethical Conduct for the PA Profession, 2013, https://www.aapa.org/wp-content/uploads/2017/02/16-EthicalConduct.pdf.

[128] AWHONN, AWHONN position statement: Health care decision making for reproductive care, *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 2016, 45(5):718, http://www.jognn.org/article/S0884-2175(16)30229-5/fulltext.

being in a number of ways. First, limiting information and referrals only to those related to carrying a pregnancy to term would misleadingly deprive patients of broader information about relative risks and suggests that pregnancy and childbirth are a woman's safest options. In fact, pregnancy and delivery pose decidedly greater medical and health risks than abortion.[129]

93. Second, denying a woman information about and access to her full range of options once she knows that she is pregnant would interfere with her ability to obtain additional services in a timely manner. For women who choose to terminate a pregnancy, abortion is particularly safe when obtained in the first trimester of pregnancy and risks increase with any delay.[130] Moreover, it often becomes more difficult for a woman to obtain an abortion as pregnancy progresses due to a lack of providers and increased cost.[131,132,133]

94. Third, denying Title X patients' access to information concerning their ability to obtain abortions would especially jeopardize the health and well-being of patients with certain medical conditions. Multiple professional medical associations have asserted that the inability to make a fully informed decision on how to proceed with a pregnancy would be especially harmful for women with severe diabetes, heart conditions, HIV/AIDS and estrogen-dependent tumors—all conditions that could be exacerbated by continuing a pregnancy.[134] Yet the New Rule would

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[129] Raymond EG and Grimes DA, The comparative safety of legal induced abortion and childbirth in the United States, *Obstetrics & Gynecology*, 2012, 119(2):215–219.

[130] Weitz TA et al., Safety of aspiration abortion performed by nurse practitioners, certified nurse midwives, and physician assistants under a California legal waiver, *American Journal of Public Health*, 2013, 103(3):454–461, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3673521/.

[131] Jerman J and Jones RK, Secondary measures of access to abortion services in the United States, 2011 and 2012: gestational age limits, cost, and harassment, *Women's Health Issues*, 2014, 24(4):419– 424, https://www.guttmacher.org/article/2014/07/secondary-measures-access-abortion-services-united-states-2011-and-2012-gestational.

[132] Jones RK, Upadhyay UD and Weitz TA, At what cost? Payment for abortion care by U.S. women, *Women's Health Issues*, 2013, 23(3):e173–e178, https://www.guttmacher.org/article/2013/05/what-cost-payment-abortion-care-us-women.

[133] Jerman J et al., Barriers to abortion care and their consequences for patients traveling for services: qualitative findings from two states, *Perspectives on Sexual and Reproductive Health*, 2017, 49(2):95–102, https://www.guttmacher.org/journals/psrh/2017/04/barriers-abortion-care-and-their-consequences-patients-traveling-services.

[134] Letter from American Academy of Nurse Practitioners et al. to Deputy Assistant

forbid direct referrals to abortion providers for a patient with these types of conditions, even if the patient so desires.

95. Finally, forcing clinicians to deny patients the full scope of information and referral would interfere in the provider-patient relationship and reinforce what experts have described as "the historical imbalance of power in gender relations and in the physician-patient relationship…and the intersection of gender bias with race and class bias" that are particularly present in obstetrics and gynecology, and in reproductive health care broadly.[135] Forcing providers to sabotage rapport they have built with patients may cause those patients to retreat from seeking health care; 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.[136,137]

B. The New Rule Would Diminish Contraceptive Choice and Access for Title X Patients

96. Another way in which the New Rule would directly impede patient care is by curtailing contraceptive options for Title X clients by: (1) deemphasizing the provision of modern, medically approved contraceptive methods; and (2) reshaping the Title X network to favor "diverse" providers, including those that offer only a single method or limited methods of contraception.

97. The New Rule deemphasizes the provision of modern methods of contraception in several ways. First, it would remove the requirement that the range of family planning methods

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Secretary for Population Affairs, HHS, Nov. 1, 1987.

[135] ACOG, Informed consent, Committee Opinion No. 439, *Obstetrics & Gynecology*, 2009, 114(2):401–408, https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Informed-Consent.

[136] Gold RB, Guarding against coercion while ensuring access: a delicate balance, *Guttmacher Policy Review*, 2014, 17(3):8–14, https://www.guttmacher.org/gpr/2014/09/guarding-against-coercion-while-ensuring-access-delicate-balance.

[137] Center for Reproductive Rights (CRR), National Latina Institute for Reproductive Justice and SisterSong Women of Color Reproductive Justice Collective, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care*, New York: CRR, 2014, https://www.reproductiverights.org/document/reproductive-injustice-racial-and-gender-discrimination-in-us-health-care.

offered by a Title X project must be "medically approved" methods. As stated above, in 2017, 70% (2.2 million) of the 3.1 million sexually active female Title X patients at risk of unintended pregnancy left their last visit with a method deemed either most or moderately effective at preventing pregnancy, all of which require a prescription or services provided by a medical professional.[138] Notably, just 15,300 female Title X patients (less than 0.5%) chose some fertility awareness-based method in 2017.[139]

98. Second, the New Rule would also distort the long-standing interpretation of the statutory requirement that Title X projects provide a "broad range of acceptable and effective family planning methods and services." Historically, this requirement has meant that projects must provide a broad range of contraceptive options, in addition to other care or services. Now, a Title X project could apparently satisfy this requirement by providing only a limited choice of modern contraceptive care so long as they offer a seemingly broad range of "methods and services" overall. For instance, it appears that the rule would allow a Title X project to include abstinence-only-until-marriage counseling, and natural family planning or other fertility awareness–based methods together with just a few other contraceptive options, to represent a "broad range" of "methods and services."

99. Third, the New Rule would open the door for Title X funds to go to entities that commonly do not have any medical staff and are not able or willing to provide many or all modern methods of contraception; such sites would not be required to provide information or referrals about other methods. Entities such as antiabortion counseling centers and abstinence-only programs approach "family planning" in a way that would undermine Title X's core tenets of ensuring patients' contraceptive choices are broad, voluntary and free from coercion. Shifting Title X dollars to such entities would harm patients and jeopardize the documented benefits of Title X as identified above.

[138] Fowler CI et al., *Title X Family Planning Annual Report: 2017 National Summary*, Research Triangle Park, NC: RTI International, 2018, https://www.hhs.gov/opa/title-x-family-planning/fp-annual-report/index.html.

[139] Ibid.

100. Moreover, the administration twists what it means to ensure patients have a meaningfully broad range of contraceptive options. Individuals' ability to obtain the methods that are best for them and successfully avoid pregnancy depends not just on having a provider nearby, but also on the range of options available at those sites. Seventy-four percent of reproductive health–focused providers offer a full range of contraceptive methods onsite;[140] directing Title X funds away from such providers and toward ideologically motivated single-method sites would sharply diminish patients' access to a broad range of options. And while the rule clarifies that contraceptive methods are expected to be provided as part of a Title X project, a project may stretch across an entire state and dozens of widely separated sites.

101. Collectively, the provisions of the New Rule would interfere with Title X patients' ability to learn about, obtain and use their preferred method of contraception. This would fundamentally undermine the program's long history as the gold standard of family planning care, and its congressionally defined purpose: "to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services."[141] Without intervention, the New Rule would result in some individuals' increased risk of unintended pregnancy and the consequent harms that follow, as described above.

C. The New Rule's Additional, More Onerous Separation Requirements, And Other Mandates Would Also Force Many Providers Out of the Program, and Create Dislocation and Disruption That Would Start Immediately and Build

102. The New Rule would modify the long-standing requirement that Title X funds be used solely for Title X purposes and separately accounted for in detail by all Title X projects by imposing a series of additional, more onerous, "financial and physical" separation requirements. These separation requirements would create new, significant obstacles for many current Title X providers to remain in the program. This includes not only the approximately one in 10 sites that offer abortions outside their Title X projects and using non–Title X funds,[142] but also any

[140] Zolna MR and Frost JJ, Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[141] P.L. 91-572, Dec. 24, 1970.

[142] Zolna MR, special tabulations from the Guttmacher Institute's 2015 Publicly Funded

provider engaging in any of the wide range of services that fall under the administration's construct of prohibited abortion-related activities, including abortion referral. These providers would be forced to either exit the program, alter the scope of services they provide in their communities, or incur substantial new costs in an attempt to separate their services in a manner that HHS deems acceptable.

103. The latter scenario would require providers to lease or purchase new office space, find and hire new staff, procure exam tables, medical equipment, and office systems. In light of the New Rule's infrastructure spending prohibitions, it is not clear whether any or how much of a provider's Title X's funds could be used to satisfy the separation requirements. These costs would have to come directly out of providers' coffers and would leave ever fewer dollars available for actually providing family planning care. The costs to completely separate one health center into two standalone clinics, with different staff and systems, are costs that could quickly swamp providers and make their participation in Title X financially irrational and practically infeasible.

104. Incurring such extensive costs would be impractical for many Title X providers whose resources are already stretched thin trying to meet the demand for services in their communities. Title X providers must accept all patients, regardless of their ability to pay, and sites routinely struggle with inadequate reimbursement from public and private third-party payers. For instance, a 2016 Guttmacher Institute analysis found that Medicaid reimbursement for family planning services provided by Title X clinics typically covers less than half the actual cost of delivering these services.[143] This makes Title X grants themselves a main source of funding that safety-net providers would rely on for the type of infrastructure investments necessary under the New Rule's separation requirements. Plus, Title X funding nationwide is already insufficient because it has been flat for years.[144]

Family Planning Clinic Survey, https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[143] Sonfield A et al., *Assessing the Gap Between the Cost of Care for Title X Family Planning Providers and Reimbursement from Medicaid and Private Insurance*, New York: Guttmacher Institute, 2016, https://www.guttmacher.org/report/assessing-gap-between-cost-care-title-x-family-planning-providers-and-reimbursement-medicaid.

[144] OPA, HHS, Funding history, 2018, https://www.hhs.gov/opa/title-x-family-

105. The proposed restrictions on "activities that encourage, promote or advocate for abortion"—which include providing speakers or educators, attending conferences, paying membership dues, and developing or disseminating materials—are also subject to the separation requirements, as are any activities that may assist patients in obtaining abortions, including referral. Separating these activities to meet HHS's requirements may further constrain providers' willingness and ability to participate in Title X, as many may determine that participation would either too significantly limit their activities or impose too great a financial burden.

106. Moreover, given the extensive degree to which separation between Title X–funded activities and the wide range of prohibited abortion-related activities would be required, the rule might impose onerous separation requirements not just to individual health centers offering abortion or abortion-related services, but also to agencies operating multiple health centers where only a subset of sites do so. As such, entire agencies may determine the New Rule's demands would compromise their services or their finances too significantly to remain in the program, demonstrating the rule's potential to impact the Title X provider network as a whole.

107. Notably, to justify its extensive financial and physical separation requirements, HHS leans heavily on Guttmacher publications on Title X as supposed proof that Title X funds support the physical "infrastructure" of sites that also provide abortions—and thereby fund abortions themselves.[145] This framing is inaccurate and misleading. The cited Guttmacher analyses unambiguously refer to the basic and underlying infrastructure of the family planning safety net—the systems and activities directly necessary to providers' ability to deliver high-quality family planning services to those who need them. Such expenditures are wholly appropriate uses of Title X funds, as detailed by a 2009 panel convened by the Institute of

planning/about-title-x-grants/funding-history/index.html.

[145] HHS, Compliance with statutory program integrity requirements, *Federal Register*, 2019, 84(42):7714–7791, https://www.federalregister.gov/documents/2019/03/04/2019-03461/compliance-with-statutory-program-integrity-requirements. See p.7773–7774.

Medicine to provide an independent evaluation of the Title X program, and fund the Title X project–nothing else.[146,147]

108. Additionally, the rule's impact would extend beyond sites that offer abortion or engage in any of the New Rule's prohibited abortion-related activities. For instance, the rule's restrictions on abortion referral and requirement of prenatal care referral regardless of the patient's wishes are antithetical to ethical and professional standards on voluntary decision-making and would harm the patient-provider relationship. Many current providers consider these requirements unethical, and may therefore feel compelled to leave the Title X network.

109. Already, at least four states with Title X grants and all Planned Parenthood grantees or sub-recipients have made clear to HHS that they would be forced by the New Rule to exit the Title X program, if they should go into effect.[148]

110. Planned Parenthood health centers serve 41% of women who rely on Title X sites for contraceptive care.[149] In order to serve all the women who currently obtain contraceptive care at Title X–supported Planned Parenthood health centers nationwide, Guttmacher analyses estimate that other Title X sites—if they were to stay in the program, which the rule's expected impact indicates many may not—would have to increase their client caseloads by 70%, on average.[150] The impact would also be more severe in some locations: without Title X–supported Planned Parenthood sites, other providers in 13 states would have to at least double their contraceptive client caseloads to maintain the program's current reach in their states.

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[146] Institute of Medicine, *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*, Washington, DC: The National Academies Press, 2009, https://www.nap.edu/read/12585/chapter/6#123.

[147] Ibid.

[148] Planned Parenthood Federation of America, Comments re: RIN 0937-ZA00 Compliance with Statutory Program Integrity Requirements, July 31, 2018.

[149] Frost JJ et al., *Publicly Funded Contraceptive Services at U.S. Clinics*, 2015, New York: Guttmacher Institute, 2017, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

[150] Frost JJ and Zolna MR, Response to inquiry concerning the impact on other safety-net family planning providers of "defunding" Planned Parenthood, memo to Senator Patty Murray, Senate Health, Education, Labor and Pensions Committee, New York: Guttmacher Institute, June 15, 2017, https://www.guttmacher.org/article/2017/06/guttmacher-murray-memo-june-2017.

Furthermore, Planned Parenthood is the only Title X provider in 38 counties in the country, out of the 415 counties in which the organization operates.

111. Finally, findings from a nationally representative 2016 survey of women obtaining services at Title X–funded health centers reinforce the gap that would be left by Planned Parenthood's exit: Twenty-six percent of clients at Planned Parenthood sites reported that it was the only place they could get the services they need.[151]

112. All of these scenarios would result in considerable disruptions to the Title X provider network, and there is no evidence that the remaining providers would be able to compensate for these losses. Indeed, available evidence only underscores the challenges that remaining providers would face in accommodating massive increases in their contraceptive patient populations. *See infra*, Section D. Therefore, if the New Rule goes into effect and providers are forced to leave the network, it would lead to significant, broad-based harm because it would be more difficult for the patients who rely on Title X to obtain any, much less high-quality, family planning care.

D. Primary Care–Focused Sites Would Not Be Able to Absorb the Displaced Patient Population

113. While primary care–focused sites and federally qualified health centers (FQHCs) specifically have become an increasingly integral part of the Title X provider network in some areas,[152] these providers could not serve the entire existing Title X population. As discussed above, reproductive health-focused sites serve a considerable majority of Title X patients—seven in 10 women who rely on Title X for contraceptive care.[153]

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[151] Kavanaugh ML, Zolna MR and Burke K, Use of health insurance among clients seeking contraceptive services at Title X-funded facilities in 2016, *Perspectives on Sexual and Reproductive Health*, 2018, 50(3):101–109, https://www.guttmacher.org/journals/psrh/2018/06/use-health-insurance-among-clients-seeking-contraceptive-services-title-x.

[152] Frost JJ et al., *Publicly Funded Contraceptive Services at U.S. Clinics, 2015*, New York: Guttmacher Institute, 2017, https://www.guttmacher.org/report/publicly-funded-contraceptive-services-us-clinics-2015.

[153] Zolna MR and Frost JJ, special tabulations of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Survey, https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

114. FQHCs currently account for the majority (52%) of primary care–focused sites in the Title X network.[154] If FQHCs that offer contraceptive care were asked to serve all of the women who rely on many different types of providers for Title X–supported contraceptive care, these FQHCs would have to at least double their contraceptive client caseloads in 41 states, and at least triple them in 27 states.[155,156] Nationwide, this would add up to an additional 3.1 million contraceptive clients that FQHCs would need to serve. FQHCs themselves report they could not handle large increases to their client caseloads; only 6% said they could sustain a caseload increase of 50% or greater, and the majority said they could increase their caseloads by at most 24%.[157] That is far below what Guttmacher's analysis projects those FQHCs would have to do in most states, if they were to take the entire Title X client load.

115. Additionally, in 33% of the just over 2,000 counties that have a Title X provider, there is no FQHC site providing contraceptive services.[158] In another 47% of counties with a Title X site, the FQHC sites that offer contraceptive care would have to at least double their contraceptive client caseloads in order to serve all of those currently served by other Title X sites. In 24% of all counties with a Title X site, FQHCs would have to serve at least six times their current number of contraceptive clients. Put another way, 2.8 million (91%) of the contraceptive clients currently served by Title X–supported centers that are not FQHCs are in the 1,625

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[154] Zolna MR, special tabulations of the Guttmacher Institute's 2015 Publicly Funded Family Planning Clinic Survey, https://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[155] Frost JJ and Zolna MR, Response to inquiry concerning the availability of publicly funded contraceptive care to U.S. women, memo to Senator Patty Murray, Senate Health, Education, Labor and Pensions Committee, New York: Guttmacher Institute, May 3, 2017, https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017.

[156] Only six in 10 FQHCs nationwide report delivering contraceptive care to at least 10 women each year, the threshold to be counted among the nation's safety-net family planning centers.

[157] Wood SF et al., *Community Health Centers and Family Planning in an Era of Policy Uncertainty*, Menlo Park, CA: Kaiser Family Foundation, 2018, https://www.kff.org/report-section/community-health-centers-and-family-planning-in-an-era-of-policy-uncertainty-report/.

[158] Frost JJ and Zolna MR, Response to inquiry concerning the availability of publicly funded contraceptive care to U.S. women, memo to Senator Patty Murray, Senate Health, Education, Labor and Pensions Committee, New York: Guttmacher Institute, May 3, 2017, https://www.guttmacher.org/article/2017/05/guttmacher-murray-memo-2017.

counties where FQHC sites would have to at least double their capacity, or where there is *no* FQHC site providing contraceptive care.

116. The inability of FQHCs to absorb the volume of displaced patients from even any short-term disruption to the Title X network is salient because the New Rule would attempt to shift the program's emphasis away from centers focused on reproductive health and toward FQHCs and other primary care–focused providers. Specifically, the New Rule would require that Title X providers "offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site."

117. Not only would the rule seek to shift patients' contraceptive care to providers that cannot realistically be expected to serve huge influxes of Title X patients, but it would also deny many Title X patients access to the reproductive health–focused providers they trust. Reproductive health-focused providers are particularly likely to offer their patients a broad range of contraceptive methods in a timely manner, and to implement protocols that help patients start their chosen methods quickly.[159] As a consequence, the primary care provider provision of the rule would make it more difficult for marginalized patient populations to obtain high-quality, low-cost family planning care, if they can access care at all, given capacity constraints and areas without such a provider.

118. Finally, the New Rule is unnecessary to promote referral and linkages between Title X and primary care. Existing Title X regulations require Title X projects to "provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs."[160] Moreover, Title X providers screen for numerous health issues (such as high blood pressure, diabetes and depression) and customarily establish referral

[159] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[160] 42 CFR 59.5.

arrangements both to and from other providers.[161] According to a recent Guttmacher Institute analysis, 99% of Title X–funded providers reported making referrals of some kind to other providers: 97% reported referring patients to other public providers and 90% reported referring patients to private providers.[162]

E. Data from State-Administered Programs Show Excluding Providers Offering Abortion-Related Services Has Reduced Family Planning Patients Served and Highlights Some of the Harms That Would Result from Provider Network Disruption

119. Policies enacted in Texas and Iowa demonstrate the impact of excluding providers that directly offer abortion or are affiliated with abortion providers from publicly funded programs. In order to exclude abortion providers and affiliates, including Planned Parenthood health centers and others, from their respective programs, both states opted to forgo federal Medicaid funding to cover family planning services for people otherwise ineligible for Medicaid (a "Medicaid family planning expansion") in favor of entirely state-administered family planning programs. Excluding providers that offer abortion or are affiliated with a site that does from these publicly funded programs mirror what the New Rule, in part, would do to Title X. Officials in both Texas and Iowa suggested that other providers would replace those excluded, and that residents' care would not be affected.[163,164] However, these changes resulted in widespread disruption of their programs' provider networks, leading to diminished access to contraceptive services and ongoing difficulty for individuals finding alternative providers.

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[161] Gavin L et al., Providing quality family planning services: recommendations of CDC and the U.S. Office of Population Affairs, *Morbidity and Mortality Weekly Report*, 2014, Vol. 63, No. RR-4, https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html.

[162] Zolna MR and Frost JJ, *Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols*, New York: Guttmacher Institute, 2016, http://www.guttmacher.org/report/publicly-funded-family-planning-clinic-survey-2015.

[163] Poppe R, Abbott requests federal Medicaid exemption for Texas Healthy Women Program, *Texas Public Radio*, Jan. 24, 2018, http://www.tpr.org/post/abbott-requests-federal-medicaid-exemption-texas-healthy-women-program.

[164] Petroski W, Planned Parenthood to close four Iowa clinics after legislative defunding, *Des Moines Register*, May 18, 2017, https://www.desmoinesregister.com/story/news/2017/05/18/planned-parenthood-close-four-iowa-clinics-after-legislative-defunding/330284001/.

120. After Texas made a series of changes to its family planning program starting in 2011—which included disqualifying agencies providing abortion—the reach and effectiveness of the state's program drastically declined. The state reported a nearly 15% decrease in enrollees statewide between 2011 and 2015.[165] The state further reported that claims and prescriptions for contraceptive methods declined 41% over the same four-year period.[166,167]

121. Analyses conducted by the Austin-based Center for Public Policy Priorities (CPPP) offer a more comprehensive view: Between 2011 and 2016, program enrollment declined by 26% and the proportion of women getting health care services in the program declined by nearly 40%.[168] CPPP further reports substantial declines (41%) in the number of women accessing contraceptives through the program, as well as in utilization of highly effective contraceptive methods, including long acting reversible contraception (35% reduction) and injectable contraception (31% reduction).[169]

122. In 2017, then-governor of Iowa Terry Branstad signed an appropriations bill that imposed similar restrictions on the state's Medicaid family planning expansion.[170] Recent data provided by the state showed the new, state-administered program covered a total of only 970 family planning services from April through June of 2018, a 73% decline from the 3,637 services

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[165] Texas Health and Human Services Commission, *Final Report of the Former Texas Women's Health Program: Fiscal Year 2015 Savings and Performance*, Austin: Texas Health and Human Services, 2017, https://hhs.texas.gov/reports/2017/03/former-texas-womens-health-program-fiscal-year-2015-savings-performance.

[166] Ibid.

[167] Texas' 2017 program evaluation notes an increase in client enrollment in the program from the previous year, but does not provide consistent data on enrollment and contraceptive service delivery that would enable comparisons to 2011, when the policy went into effect. See: THHC, *Final Report of the Former Texas Women's Health Program: Fiscal Year 2015 Savings and Performance*, Austin: THHS, 2017, https://hhs.texas.gov/reports/2017/03/former-texas-womens-health-program-fiscal-year-2015-savings-performance.

[168] Center for Public Policy Priorities, Comments on the Draft Healthy Texas Women Section 1115 Demonstration Waiver Application, June 12, 2017, https://forabettertexas.org/images/CPPP_comments_on_HTW_draft_waiver_application.pdf.

[169] Ibid.

[170] Petroski W, Planned Parenthood to close four Iowa clinics after legislative defunding, *Des Moines Register*, May 18, 2017, https://www.desmoinesregister.com/story/news/2017/05/18/planned-parenthood-close-four-iowa-clinics-after-legislative-defunding/330284001/.

covered in April through June of 2017, the last three months of the previous family planning program, when abortion providers and affiliates were still included in the program.[171] Furthermore, the number of patients enrolled in the program fell by more than half, with enrollment dropping from 8,570 in June 2017, the last month of the previous program, to 4,177 in June 2018.[172]

F. Summary of the New Rule's Negative Impacts on Patients, Public Health and Government Costs

123. If the New Rule is allowed to take effect, Title X patients would face substandard care and a compromised network of providers. The rule would diminish access to modern, medically approved family planning services and counseling, and unbiased, comprehensive information on the full range of pregnancy options for low-income individuals. For current and prospective Title X patients who would be given fewer contraceptive choices or deterred from seeking Title X–supported care, this would mean an increased risk of unintended pregnancies, low-birth-weight or preterm births, STIs and cervical cancer. For the pregnant patients who decide on or want information about abortion, this would mean an increased risk of delayed care and medical complications. As risks increase for individual patients, on aggregate the Title X population at large would experience these harms and public health would suffer.

124. The New Rule would also likely push a number of high-quality health care providers dedicated to the provision of a full package of family planning services out of Title X, because of mandated compromises to providers' professional and ethical standards, and untenable operational requirements. Title X funds would instead be made available to entities focusing on efforts that deviate from the program's core purpose. This disruption of a well-established program would further compromise the considerable benefits to individuals and overall public health that Title X–supported providers have demonstrably delivered for decades.

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[171] Leys T and Rodriguez B, State family planning services decline 73 percent in fiscal year as $2.5M goes unspent, *Des Moines Register*, Oct. 18, 2018, https://www.desmoinesregister.com/story/news/health/2018/10/18/iowa-health-care-family-planning-contraception-services-planned-parenthood-abortion-medicaid/1660873002/.

[172] Ibid.

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

Kathryn Kost
Acting Vice President of Domestic Research
Guttmacher Institute

SA2018101519

Pages 1 - 102

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE EDWARD M. CHEN

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, vs. ALEX AZAR, in his official Capacity as Secretary of the U.S. Department of Health & Human Services; U.S. DEPARTMENT of HEALTH & HUMAN SERVICES, Defendants.	No. C 19-1184 EMC
ESSENTIAL ACCESS HEALTH, INC.; MELISSA MARSHALL, M.D., Plaintiffs, vs. 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.	No. C 19-1195 EMC San Francisco, California Thursday April 18, 2019 12:30 p.m.

TRANSCRIPT OF PROCEEDINGS

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

Reported By: ***Debra L. Pas, CSR 11916, CRR, RMR, RPR***
Official Reporter - US District Court
Computerized Transcription By Eclipse

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DR. MELISSA MARSHALL

– – –

THURSDAY - APRIL 19, 2019 **12:34 P.M.**

P R O C E E D I N G S

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THE CLERK: Calling Case 19-1184, State of California versus Azar, et al, related to 19-1195, Essential Access Health versus Azar, et al.

Counsel, please approach the podium and state your appearances for the record.

MS. YBARRA: Good afternoon, Your Honor. Michelle Ybarra from Keker, Van Nest and Peters for Essential Access Health.

I'm joined by my partner Tina Sessions and our clients, Essential Access Health represented here today by Julie Rabinovitz, the president and CEO, and plaintiff Dr. Melissa Marshall.

THE COURT: All right. Thank you, Ms. Ybarra.

MS. RICH: And Anna Rich on behalf of the State of California. And I have with me my colleague Brenda Ayón Verduzco.

THE COURT: All right. Good afternoon, Ms. Rich.

MR. BURNHAM: Good afternoon, Your Honor. James Burnham on behalf of the United States, with my colleague Robert C. Merritt.

THE COURT: All right. Thank you, and welcome.

MR. BURNHAM: Thank you, Your Honor.

THE COURT: All right. I have a series of topics that, of course, we want to discuss and I'll let you organize yourselves in terms of who will address these.

Just a note that we are on CourtCall, so there are folks listening in as well as the audience here in the courtroom.

So let's start with the question of irreparable harm. Obviously, that's a prerequisite to preliminary injunctive relief. Why don't you summarize -- I know there are a series of a very deep record in terms of the potential consequences of the Final Rule, but why don't you enunciate the ones that you think are most compelling and for which there is both evidence in the record and perhaps lack of any rebuttal evidence.

MS. YBARRA: Yes, Your Honor.

If I could begin, if you would indulge me in just a brief bit of table setting. As you know, this case concerns the ability of 1 million Californians and many others around the country to have continued access to quality sexual and reproductive care, and that includes access to long-acting contraceptives, screening for STDs, breast and cervical cancer exams, and other critical potentially live-saving healthcare.

In support of our P.I. motions plaintiff submitted declarations from over a dozen third parties, including distinguished leaders in public health, heads of healthcare organizations and clinics, practicing physicians, community leaders and experts in the field of reproductive care, and we

believe we have made an overwhelming showing of irreparable and imminent harm faced by plaintiffs and the patients they serve should the regulations take effect on May 3rd.

And specifically in the record to your question, Your Honor, we've shown that the regulations would force an exodus from the Title X program, not only in California, but around the country; would force layoffs in staffs at Title X funded healthcare organizations --

THE COURT: All right. Let's talk about the exodus, the actual closure of clinics. There is one indication I think in the record that Planned Parenthood, which serves, I think, what, 40 percent of clients -- or patients of yours?

MS. YBARRA: Your Honor, the evidence in the record about Planned Parenthood's participation in the program is that Planned Parenthood has stated that they could no longer participate in the Title X program given the unlawful regulations at issue here.

Planned Parenthood's participation or discontinued participation in the program is specifically detailed in the Tosh declaration at Paragraph 38. 650 Planned Parenthood affiliates nationwide would exit the program should the rule become effective on May 3rd.

THE COURT: When you say "exits the program," would that mean that they would no longer operate or operate at a much lower scale because of the loss of Title X -- how much

funding, for instance, of Planned Parenthood's funding comes from Title X?

MS. YBARRA: I don't have that figure -- that figure at my fingertips for Planned Parenthood nationwide, Your Honor, but when I say "exit the program," I mean they would no longer be able to participate and receive Title X funds to continue the work that they do. That is --

THE COURT: How devastating will that be? Because one of the things we're talking about, actual declination -- decline in the accessibility of services available and part of that is indicated by the exodus from the Title X program.

But does that mean many of these offices will have to scale down? Will close? Do we have any evidence about the net effect of loss of Title X?

MS. YBARRA: Yes, Your Honor. If I could broaden this -- take this a little broader than the just Planned Parenthood affiliates because we have ample evidence in the record about the effect of the Title X network in California, the Title X network administered and operated by Essential Access Health.

THE COURT: Yep.

MS. YBARRA: Essential Access Health submitted a declaration from Julie Rabinovitz and stated there that Essential Access has surveyed its sub-recipient grantees who received Title X funds and operate hundreds of clinics around

the state. And sub-recipients representing 233 clinic sites that serve over 774,000 patients will leave or consider leaving the program if, for example, the gag rule is implemented. That's at the Rabinovitz declaration at Paragraph 42.

One provider has already informed Essential Access that they are leaving the program as a direct result of the regulations and that -- we submitted a supplemental Rabinovitz declaration in connection with our reply brief.

So the effects are already beginning and the rule is not yet even effective.

THE COURT: Okay, but it raises the same question. They will leave the program, substantial numbers of people affecting potentially over three-quarters of a million patients.

The question is: When they leave the program, what will that mean? Is this the death knell for many of these programs? They will have to scale down significantly? What -- just some idea. Is Title X a small part of the budget or a huge part of the typical budget of these grantees?

MS. YBARRA: Title X provides critical operational funding for many of the grantees and we have detailed what the effect will be for them in the record. I will give you some more specifics here.

For example, the Fresno Economic Opportunity Commission operates a teen pregnancy options counseling and STI screening

service, transporting teens to receive these services. They have submitted a declaration, the Thomas declaration attached to Essential Access's P.I. motion detailing that without Title X funds, this program called HEARTT, H-E-A-R-T-T, will cease to exist. They will be unable to continue operating that. And so that critical service provided to a vulnerable community, teenagers here, will no longer be available.

We have sworn statements by other sub-recipients detailing similar curtailing of services. For example, in the Thomas -- excuse me. In the Nestor declaration, the San Francisco Department of Public Health describes how they will have to substantially curtail the number of programs that Title X currently funds, including STI testing, pregnancy testing, counseling, increased access to contraceptives and evidence-based sex education curricula and outreach, in addition to pop-up clinics.

We have -- the record and the sub-recipient declarations that we have submitted are full of specific examples like this of how services will have to be cut, layoffs will have to ensue, and patient's access to quality care will be diminished.

THE COURT: Do we have any estimate as to the aggregate impact? Are there specific examples? Like HEARTT, in the San Francisco Public Health Department. Has there been any attempt to -- and I know it's hard because it's -- you know, hard to know exactly what's going to happen, but is there

some indication of how many fewer patients in the -- at the end of the day will be able to be served, for instance?

MS. YBARRA: I think that's a difficult thing to quantify in the way that you're asking, Your Honor.

We do have -- we do have evidence in the record about the benefits that Title X funding has provided and the numbers of people that it has reached in the way it currently operates.

And we know, inferring from all of these reduction in services that we've detailed in these declarations by sub-recipients, that that is going to substantially diminish. I can't give you an exact number.

THE COURT: How much in Title X funds does Essential Access Health get a year? What's the --

MS. YBARRA: They --

THE COURT: That are distributed to the various sub-grantees?

MS. YBARRA: Yes. They are at 20 million. Approximately 20 million for fiscal year 2019. And that was an award -- they were just awarded that at the beginning of this month, and that is roughly 93 percent of the Title X funds allocated to California entirely.

THE COURT: So, and that money then gets redistributed through sub-grants?

MS. YBARRA: Yes, Your Honor. To their sub-recipient grantees who operate 70 healthcare agencies around the state

and those agencies, in turn, operate hundreds of clinics around the state, including in hard to reach -- including in rural areas where access to quality healthcare is otherwise hard to come by.

THE COURT: So that's one example of a harm in sort of absolute terms or concrete terms, that it is some exodus from the program and some scaling down. One can assume if you lose $20 million, there is going to be some scaling down of programs, if not complete closure.

MS. YBARRA: Absolutely, Your Honor. The Fresno Economic Opportunities Commission Community Health Center Clinic that I referred to earlier in the Thomas declaration at Paragraph 16, Jane Thomas there details that Fresno will have to cut medical providers and support staff and maybe even close its doors. She says it will be difficult for Fresno to continue operating in the absence of Title X funds.

THE COURT: All right. What's -- can you -- why don't you articulate another kind of harm in addition to actual closures and scaling down of services?

MS. YBARRA: Of course. Ms. Rich, please go ahead.

MS. RICH: Well, I think that the -- the declarations show that one of the ways that the Title X program here in California uses that $20 million is investments in outreach and education. Last year there were 500,000 individuals who were reached with outreach and education through the current network

of Title X funded clinics.

And many of the declarations that we've provided show that those are going to be some of the first positions that will be cut when those funds are lost, are these investments in outreach and education, because those kind of activities are not -- don't have another source of funding.

And we've shown that the effect of that lack of connection to communities to healthcare providers will make it harder to access contraception, and the difficulties in accessing contraception, in turn, directly lead to an increase in unintended pregnancies, mis-timed pregnancies, all of which are associated with very serious complications, including with childbirth, including a negative effect on maternal and child health.

From the State's perspective, of course, this is going to be a harm to the public fisc because the State's Medicaid program is the insurer for the large majority of low income Title X patients and, therefore, the costs associated with reduced access to contraception or reduced access to high quality screening and testing for sexually transmitted diseases, preventive care for cervical cancer, all of those things, the complications that will arise with fewer people getting access to the services will end up harming the public fisc.

THE COURT: And has there been any attempt to

quantify, again on an aggregate basis, what the consequences might be?

MS. RICH: Yeah. I don't think we have a total number for you because for the reasons that Ms. Ybarra has described.

But for the -- for instance, it is -- the cost of a preterm pregnancy and a preterm labor, which is a risk that is raised when someone is unable to plan their pregnancies accordingly, is many thousands of dollars per individual patient.

THE COURT: Has there been any estimate based on experiences elsewhere, whether it be Texas or anywhere else, what the rate of unexpected or unwanted pregnancies might occur when folks are denied access to family planning services?

MS. RICH: I don't remember the specific rate, but I would direct the Court's attention to Dr. Brindis's declaration. She presented information both in her comment letter and in her declaration that showed that there was indeed a significant increase in Texas, which experimented with something very similar to the Final Rule in unintended pregnancies.

And as I said, we've got abundant evidence in the record about all of the harms that are associated with that.

THE COURT: All right. And, of course, there is the cost of compliance with the physical separation that has been

estimated typically by each grantee who has to make some changes to be in the six figure range?

MS. YBARRA: Yes, Your Honor. And that six figure range -- that figure is actually $116,000 on average per agency.

In addition to those compliance costs for sub-recipient agencies, Essential Access itself will incur substantial cost as an organization. It estimates that compliance with the rule would cost it approximately $325,000 in the first year of the effectiveness of the new rule alone and approximately $212,000 every year after. That's the Rabinovitz declaration Paragraph 66.

So those are direct monetary costs and harms that will befall Essential Access almost immediately.

THE COURT: And what about the resulting lack of or impediment to access to information and abortion services of the clientele as a result of what some have referred to as the gag rule.

What estimate -- is there an estimate as to how that rule might impact the service population?

MS. YBARRA: Well, your Honor, we addressed that in a couple of ways in our moving papers.

First, Dr. Marshall, who is also a named plaintiff in this case, has submitted a declaration where she details how the effect of the gag rule is to essentially strip her of her

professional and medical judgment that prenatal care is not medically necessary for a patient who desires to terminate a pregnancy; that that will destroy trust and unravel her relationships with her patients and undermine her effectiveness as a healthcare provider. And further that the provision of inaccurate, incomplete information that the rule forces Dr. Marshall to provide will dramatically delay or even block her patient's access to care where the patient is a pregnant woman seeking time sensitive treatment. That will have the effect of increasing the risk to the patient's health and those consequences, of course, could be irreversible.

So we've fully detailed how that is going to effect Dr. Marshall's relationships with her patients and her patient's health in her declaration at Paragraphs 16 to 22.

THE COURT: All right. I understand that on an individual level, perhaps on an anecdotal level. I guess I'm asking whether there has been any evidence, again in a larger scale, how much impact does this have?

For instance, again in another state where there have been access prohibitions, restrictions or perhaps under the 1988 guidelines while they existed under *Rust versus Sullivan* up until 1993 were there any studies that show what happened in the field?

MS. YBARRA: I think the best evidence in the record on that is the -- is in the Brindis declaration that Ms. Rich

referred to, as well as the Kost declaration, Paragraphs 119 and on that look at what -- how those rules played out and how patient populations were harmed.

As to the 1988 regulations, it's our understanding that those were only actually fully implemented for about a month. So they are not empirical studies to draw guidance from on that front.

THE COURT: They are only implemented for a month? So during the pendency of *Rust versus Sullivan* they weren't in effect?

MS. RICH: Correct, Your Honor.

THE COURT: The repeal, was it in 1993?

MS. RICH: That was when the HHS fully repealed the 1988 regulations, I believe.

THE COURT: So --

MS. RICH: But as we just explained, they had not been -- they had been largely stayed by litigation and, also, they were, I believe, dialed back somewhat in 1991.

THE COURT: So there was a change after *Rust* to the regulations? *Rust* was decided in 1991?

MS. RICH: Right.

THE COURT: All right. Let me hear from the Department, from the government, what your response is to the assertions of irreparable harm. Do you contest the factual showing?

MR. BURNHAM: Yes, on irreparable harm. Let me -- if I could just frame it to kind of start out?

The Final Rule doesn't cut off Title X funding for anybody; right? So the Final Rule is not directly going to cause any of the harms that have been asserted, even if those harms are substantiated.

Now, I think the primary harm that the plaintiffs --

THE COURT: You are saying there is a question of causation.

MR. BURNHAM: Absolutely. And so that's going to be my next point, Your Honor.

So I think the primary harm that they are advancing is harm to patients, but that is fairly speculative because it's pretty removed from the Final Rule. So that is assuming that that there will be sub-recipients, not Essential Access itself.

At one point it was mentioned that Essential Access gets $20 million a year. It actually just got its grant for this year about a month ago. There is no suggestion, I don't think, that they are going to leave the program.

So Essential Access I don't think has said that they will leave the program rather than comply with the Final Rule. So their funding will be fine in the main.

THE COURT: That funding is really used to be -- they are kind of a major grantor, general grantor to sub-grantees.

MR. BURNHAM: Yes, Your Honor, absolutely.

I'm saying there is no suggestion anywhere that the $20 million will no longer be going to California, and thus the patients who live in California, because people won't want to comply with the Final Rule.

The suggestion, I think, is only that there are certain sub-recipients who might think the Final Rule is offensive to their understanding of medical ethics or their way of doing medicine, so they will refuse to accept Title X grants in the future if accepting those grants requires compliance with the Final Rule.

Figuring out the effect of that is highly speculative. I mean, as far as I can tell, there was only mention of one program in Fresno that has definitively said: We are going to shut down rather than comply with the Final Rule.

And, indeed, one of the things that hasn't been addressed is the possibility that new providers will emerge, who are happy to provide medical services in compliance with the Final Rule when their Title X funding --

THE COURT: I know that was part of the justification, part of the cost benefit analysis and part of the presentation by the Government that there will be substitute new grantees, there will be increased competition in the field.

MR. BURNHAM: Right.

THE COURT: I would ask you what is the evidence of

that?

MR. BURNHAM: Well, I think -- I mean, the evidence of that is that they are only -- I mean, the plaintiffs who have the burden of proof of establishing irreparable harm have only found, I think, one program in Fresno that has set it will shut down.

So HHS in the Final Rule making found that nationwide in the preamble that there is going to be other -- likely to be other sub-recipients -- well, not only sub-recipients, but other programs that emerge that are happy to comply with the Final Rule. I think the Court has to give deference to that factual determination by the agency --

THE COURT: Well, that begs the question, and we'll get there, of whether I have to give that kind of deference.

I have a factual question. What's the evidence of that? What in the -- other than being in the preamble and a statement, is there any evidence, any empirical studies, any surveys, any --

MR. BURNHAM: Well, I think it's just intuitive, Your Honor. I mean, the medical marketplace is as fluid as any other marketplace.

And so all the Final Rule is saying is that people in Title X programs can't provide referrals for abortion. They can still counsel on abortion -- we'll talk about that, I'm sure, when we discuss the merits -- and that there has to be

physical and financial separation.

So, you know -- sorry. And so I think -- you know, I just don't think there is any basis to think all these programs are going to just shut down because the operators of the programs think that being able to provide referrals for abortion is more important than their ability to continue to access federal funding.

I mean, Title X by its nature is a year-to-year grant program. So anyone who wants Title X funding can only get it for a year on a yearly basis and can come comply for it.

And so I just, you know, have some overwhelming evidence that everyone in California or large numbers of programs in California will say, you know, we would rather forego federal funding than comply with the requirements of the Final Rule. I don't see how plaintiffs can establish irreparable harm, even if that is irreparable harm as far as the programs are concerned, because you don't have any patients that have come to the Court and become plaintiffs in this lawsuit. So the chain of causation is pretty attenuated from the plaintiffs that are actually here.

One of the other harms -- unless Your Honor has more questions on that.

THE COURT: Well, I want to ask Essential Access, what about that? If you get 20 million and you fear that if this regulation goes into effect on May 3rd and that some of

your sub-grantees will decline, what happens to the 20 million? Why don't you explain what happens to that?

MS. YBARRA: The 20 million doesn't just automatically get redistributed to other sub-grantees within the program, Your Honor.

And Mr. Burnham is improperly conflating, I think, a clinic completely closing its door with the standard that plaintiffs have to show here. Just because a clinic stays open but with a skeleton crew and on reduced hours and is unable to serve and meet the needs of the community -- the patient community it formerly did does not mean it has not suffered irreparable harm.

Separate from that, I want to address a couple of things. The idea that new entrants to the grant program could enter mid cycle at the point that we're at now is incorrect. They will not be eligible for Title X funds. The funding award has already been made for this -- for next year. So there --

THE COURT: The funding award to your sub-grantees has been made.

MS. YBARRA: Those contracts are being negotiated right now. I think that this issue has thrown a big question mark over who exactly is going to participate.

THE COURT: So if the regulations or the Final Rule is allowed to go in effect, that's what I'm asking, you've got the overall grant and now you're in the sub-grant stage; right?

MS. YBARRA: Yes.

THE COURT: What happens if you have a number of -- as you forecast a number of sub-grantees, perhaps a large number, who would rather not -- are not able to comply or choose not to comply with Title X, not to accept the money and all the burdens that come with it, what happens?

MS. YBARRA: To the extent a sub-award has been made, those funds would need to be relinquished for a sub-recipient who is no longer able to participate in the program.

Separate from that, Your Honor, the Government has not addressed and has ignored today the separate harm that Essential Access suffers itself as an organization, which is organizational harm to its mission, which the Courts recognize as cognizable and irreparable. And we discuss at Page 26 of our opening motion.

Essential Access has had a mission for decades to promote and champion quality sexual and reproductive care for all and it achieves that mission through the delivery of family planning services and related preventive health services given by its 70 sub-recipient agencies.

Essential Access's network being decimated in the way that the Final Rule threatens to do is a huge blow to its mission. And that's a separate --

THE COURT: I understand that, and that is a basis for organizational standing. And you can assert irreparable

harm to the organization, but if we're balancing -- at some point we're going to have to balance the hardships.

It's one thing to balance the hardship of one organization against the Government's asserted interest. It's another thing to balance the interest of hundreds of thousands, if not millions, of people.

That's why I'm asking about what happens in the larger picture if the regulation goes into effect?

MS. RICH: I'd like to speak to the effect that the Final Rule will have on the quality of the current Title X network, which I think is one of the current overarching concerns that goes to Your Honor's question.

Currently Essential Access is choosing the Title X recipients, those who get Title X grants based on their quality and based on their ability to make rapid and effective use of Title X funds.

And Dr. Brindis has looked in quite a bit of detail in her past research on the quality of the existing Title X network here in California and found that they are indeed able to serve more patients, offer more culturally competent care, serve more limited English proficient patients, serve more LGBT patients.

There are a number of different factors in which the current set of Title X grantees operating under the current or longstanding rules are higher quality. And there is -- we've shown, and I think that the experiments in Texas and Iowa show

that there is not a comparable quality of family planning providers waiting in the wings ready to come in and take those Title X dollars and offer a similar level of services to the existing Title X network.

There is one other point that I wanted to make sure I got in on the irreparable harm issue, which is the state also has its own irreparable harm because of the interference that the Final Rule will have on state agencies' abilities to do their jobs. That includes the state Medicaid agency's ability to set minimum clinical standards for family -- for publicly funded family planning practitioners, and that includes the state regulatory agency's ability to license providers and to discipline providers when necessary.

And I would direct the Court's attention to the Cantwell declaration that is about the state Medicaid program impacts and Dr. Morris's declaration which speaks to the Board of Registered Nursing's interests in this case.

THE COURT: Maybe you can give me an example of how the state agencies' abilities to set, I think you said minimum standards in --

MS. RICH: In clinical practice for family management.

Yes. So a good example would be in the current state of the law here in California and based on how Essential Access has operated and the current Title X rules, anyone who wants to

get a Title X grant here in California has to be willing to at least provide a referral for a long-acting reversible contraception, such as an IUD. That's considered a minimum qualification to be a MediCal licensed family planning provider.

The Final Rule opens the door for recipients who are not willing to provide a referral for an IUD, for instance. And that is an example of the kind of decrease in quality that will ultimately have a negative impact, both on --

THE COURT: Which provision of the Final Rule -- maybe show me the ones that are in the Complaint, I don't know if you have the section number, that would impede that -- interfere with that licensing minimal standard requirement.

MS. RICH: I think it's the removal of the requirement that family planning methods be medically approved, which opens the door to, for instance, a Title X provider whose sole focus is on adoption, for instance, and is not supportive of contraception.

THE COURT: Well, that's harm of a slightly different nature than the impediment to choice.

MS. RICH: Correct.

THE COURT: Right?

MS. RICH: Right. Yeah. That's a type of harm that goes to the quality of Title X services.

THE COURT: All right. And your first point is that

the -- yes, that the quality of services -- that even if you can subcontract or find another subcontractee, the existing network now has been qualified and proven effective, so it's like losing your best employees.

MS. RICH: Exactly.

THE COURT: Your response?

MR. BURNHAM: So I have six points, Your Honor.

Just to reiterate the thing you were talking about before. The Final Rule doesn't cut off funding for anybody. So the harm to patients is at the end of the chain of causation that I don't think either plaintiff has carried the burden of showing actually exists because it requires assuming that Title X sub-recipients from Essential Access will forego Title X funding and cut off services to patients rather than comply with the Final Rule.

THE COURT: Well, I mean, again, you talk about inferences that can be drawn just because the new rule doesn't cut people off per se.

But if it imposes certain burdens which are perceived by some as being unethical, ineffective and potentially misleading or impedes their ability to carry out what they understand their medical obligations and ethical obligations to be, it's not hard to predict some people may say no thanks.

MR. BURNHAM: That needs to be substantiated though, Your Honor, by evidence. And I think the declaration -- one of

the declarations that Ms. Ybarra quoted said the recipient might consider leaving the program.

There was -- the only one I can remember them saying would definitely leave and therefore close was Fresno. Although I don't want to put words in Ms. Ybarra's mouth. I'm sure she will tell me if there are others that I missed.

But, you know, so you have to assume that there is a large number of sub-recipients, a non-negligible number, that will affirmatively leave and refuse to accept federal funding.

You also have to assume, which I don't think they have shown, because it is their burden, that there is not going to be other Title X recipients or existing Title X recipients that can expand that are able to help fill the gap left by the recipients who say, you know what? Rather than comply with the Final Rule, we're going to leave this space all together.

THE COURT: And do you have any evidence of that? I know you say they have the burden, but I'm asking you: Do you have any evidence of waiting in the wings, filling in the gap based on experience?

MR. BURNHAM: I mean, there is a long discussion, Your Honor, of this issue in the preamble to the Final Rule. There are 300,000, I think it was, comments before HHS before it issued the Final Rule. HSS has considered all of that and made a formal determination on behalf of the agency that this -- the Final Rule actually will likely lead to increased care.

THE COURT: I understand that determination has been made. I'm asking you again: Is there anything specific that the agency relied on in reaching that conclusion?

MR. BURNHAM: The 300,000 comments that were submitted to the agency, Your Honor.

I don't have a comment at my fingertips about California that I can give Your Honor and say here is affirmative proof that these five organizations or ten organizations will fill the gap that plaintiffs say will come to open if the Final Rule is allowed to go into place.

But, again, I just -- I think it's intuitive, Your Honor. Absent strong countervailing evidence that people will come, accept the federal funding in order to provide medical care to the women that currently receive it in compliance with the Final Rule. I just think it's totally counterintuitive and not carried -- they have not substantiated it with the evidence they have filed, that the entire program will end.

THE COURT: I'm not sure how intuitive that is in certain rural parts of California where it's very hard to find any doctor at all or any licensed medical person for miles and miles and miles or who are able to serve, for instance, a largely non-English speaking population. It's not quite so easy that, you know, somebody will just step into the breach.

MR. BURNHAM: Two points on that, Your Honor. I know that they suggest that. I'm not aware of a declaration

actually providing the example Your Honor has suggested in a specific and factual concrete way.

Second, you know, even if there -- now this is more of a merits point, but I think it goes into irreparable harm. Even if there are as-applied circumstances where the Final Rule could be problematic, like the hypothetical Your Honor just gave, I think that's a question for an as-applied challenge.

The plaintiffs have brought a facial challenge to the Final Rule and all of its applications and that I think is a distinction that needs to be drawn.

If I could, Your Honor, I just have three other points on other forms of irreparable harm that have been suggested.

The diversion of resources point. I don't think diversion of resources in a federal grant program can ever be irreparable harm, and that's for two reasons.

First, it's monetary.

Second, we're only talking about resources that would be expended in order to continue to be eligible for more money from the federal government. So we're not talking about a direct regulation on doctors, on anybody that requires them to affirmatively expend money. We're just talking about money that would be expended to retain eligibility, to receive money from the federal government. And I'm not aware of any case that would suggest requiring applicants for federal grants to do things in order to apply for those grants is irreparable

harm. So I think that takes that completely off the table.

On the point that the attorney from California made -- I forget your name -- about the state regulations and minimum standards of care, I think that's just a preemption point. So if the state is saying that because the rule would preempt some countervailing -- some contrary state regulation, I don't think that could ever be irreparable harm. I mean, that would mean that in any case in which the federal government has preempted a state rule, that preemption is itself irreparable harm.

Because, remember, that point was made on behalf of the state, not on behalf of an individual plaintiff, not on behalf of a medical provider. The state does not suffer irreparable harm just because some requirement that it has in its statutes has been preempted by a federal rule.

It also hasn't been preempted because, again, this is a federal grant program.

THE COURT: We're not -- I'm not talking about preemption. I think what they are talking about is a kind of harm they would suffer as a sovereign if this -- whether by way of preemption, whether by way of other supremacy principles, whatever it is, that the State's inability to carry out a particular program or regulation, in the end it may be legal, may not be legal. But the question is: Is that a harm that's cognizable for purposes of determining whether or not there is irreparable injury?

MR. BURNHAM: And the answer is no, Your Honor. Because whenever a federal law or a federal rule preempts a state rule, that means the state is unable to carry out its program. That is not irreparable harm or every preemption case where a state law is being preempted by federal law would be --

THE COURT: If there is a challenge, for instance, to a preemption claim and there is a debate about whether that law is preempted or not and before you adjudicate that, you're at the preliminary injunction stage, I would think a state or locality might be able to say: This is the harm to the sovereign interest we're going to suffer if this preemption argument -- you know, if we are to be preempted and we would like the Court to enjoin this attempt at preemption while we litigate.

That doesn't mean -- at the end of the day one side is going to lose one side is going to win, but that does not mean that there is not a cognizable interest that could constitute irreparable injury in the calculus of whether a preliminary injunction should issue.

MR. BURNHAM: So, Your Honor, I agree that a state could say that. I just don't think that's -- I mean, that is not an established principle that I'm aware of; that the harm to the state of not being able to enforce -- I think the example that counsel gave was a requirement that patients be referred for a long-term long-acting IUD.

The state's inability to enforce that rule against Title X grant recipients I don't think is irreparable harm. I mean, that's just a frustration of something that the state wants to do but the federal government has said in the narrow context -- and, by the way, it is a very narrow context -- of this federal grant program you can't. I'm not aware of any authority that that constitutes irreparable harm.

Now, the state has a similar flavor of this, which is that because the rule will apply to women who live in California, that will impose other costs on the state. But I think that's just another way of sort of bringing in *parens patriae* concepts that in our judgment are not enough even for standing, much less for irreparable harm.

My fifth point would be -- and I would like to just, if I could, Your Honor, you know, in weighing the harms, you know, there is a countervailing harm. I think this goes more to balance of equities than irreparable harm, but I would like to read Your Honor a quote from *Rust*, if I may.

That is, quote:

> "The Government may make a value judgment favoring child birth over abortion and implement that judgment by the allocation of public funds" -- I'm skipping a little bit -- "by, quote, subsidizing family planning services which will lead to conception and childbirth and declining to promote or encourage

abortion."

That's at Pages 192 to 193 of *Rust*. So one of the things the Supreme Court pointed out in *Rust* was that the Government has strong countervailing interests here. It is, after all, a federal grant program.

And so Congress, in creating the program, had a political compromise at the time that said none of the money the federal government is going to spend in this program can be used for programs where abortion is a method of family planning.

So in weighing the equities and comparing the harms it's important that that is a self-evident harm. I don't think there is any question that that harm exists to the Government's interest in the program in this case. And that is something that weighs against the points that plaintiffs have made today.

THE COURT: Well, that does sort of presume you win on the merits because one could argue that there are countervailing federal interests, such as the interest in non-directive counseling under the Appropriations Act or the various provisions that have been cited under the ACA -- we will get into that in a moment -- or a compliance with the Administrative Procedures Act.

So you can always assume that you're right -- you are right on the merits and, therefore, you have a paramount interest, but I'm not sure how that's helpful analytically at this early stage of preliminary injunction.

MR. BURNHAM: But I think it's helpful --

THE COURT: You know, the merits does not -- your one party's assumption about the merits does not necessarily give them the irreparable harm that sort of obtains with that merits analysis.

MR. BURNHAM: Well, I guess I have two responses, Your Honor.

First, if they can't show irreparable harm, the inquiry is over and they can't get a preliminary injunction. So that's where my first -- I forget if it was four or five points.

Then on the equities, even if I'm wrong on the merits, I'm still right about the balance of the equities. Because what *Rust versus Sullivan* was saying is that the Government has a legitimate interest in promoting childbirth over abortion.

So I may -- you may grant the preliminary injunction because of the other factors, but that point goes to the equities regardless of whether the agency violated the APA or the other provisions that Your Honor has said because that is a legitimate Government interest that the Supreme Court recognized in *Rust versus Sullivan*.

So I respectfully think that that is still something the Court needs to weigh. Although, as you say, the merits are most of the action here, and I'm happy to discuss that when Your Honor is ready.

THE COURT: All right. Why don't you respond both --

I'll let you respond both on the question -- if you have anything more to add on irreparable injury, and particularly to the point -- to the extent that you are arguing that there will be widespread dislocation. If there is any other evidence to support that, other than sort of some anecdotal evidence.

And, two, the balance of hardship questions, particularly in light of the Government's acknowledged interest in *Rust versus Sullivan* in expressing its policy preference towards birth as opposed to termination of birth.

MS. YBARRA: Yes, Your Honor.

On the first question, your first question, Mr. Burnham, I think, stated inaccurately that there is nothing in the record suggesting that clinics will actually flee the Title X program in large numbers should the rule be enacted. I've got numerous cites for Your Honor here, and I know the record is voluminous, I will direct you to them.

The McKinney declaration, where it's asserted that the West Side Family Health Center will not be able to accept Title X funding if the new rule is implemented. That's not conditional. That's not wavering.

And all of the declarations that we've submitted from sub-recipients take that same position.

The declaration, the Forer declaration at Paragraph 39 -- this is Elizabeth Forer -- makes a similar assertion.

"If the rule is implemented the sub-recipient

will be forced to forego Title X funding."

THE COURT: Do these declarations go on to say what impact that will have on that particular grantee in terms of its operations?

MS. YBARRA: Absolutely, Your Honor. All of the -- all of our declarants detail the effects that this loss, if any, will have on their patient populations, which are often quite vulnerable.

I also -- I won't read from them all, but I direct Your Honor, to Dr. Marshall's declaration at Paragraph 28 where she describes having to stop the Teen Outreach Clinic that is operated at CommuniCare, her organization.

The Wilburn declaration at Paragraph 21 discussing reduced access to care by virtue of having to forego Title X funds.

And, additionally, I want to address the -- the hypothetical that you engaged in with Mr. Burnham because it's not a hypothetical. The question of if we have reduced access to care, especially in rural parts of the country or the state, how is that going to present a greater impediment to women and low income individuals in those areas?

And I direct Your Honor to Paragraph 49 of the Tosh declaration where Ms. Tosh walks through exactly that scenario. There are over ten counties in California where women lack access to the most effective forms of contraception. Rural women in those areas have less access to healthcare and are

going to be greatly affected by the implementation of this rule.

MS. RICH: And may I add, in terms of perverse consequences from the Final Rule, our expert testimony, which was primarily the Brindis declaration and the Kost declaration show through evidence that is not rebutted that the Final Rule is going to decrease access to contraception; that decreased access to contraception increases the likelihood of unintended pregnancies, and that the unintended pregnancies often lead to abortions.

And so there is evidence in the record going -- when it comes to balancing whatever the Government's purported interest in life to the other interests here, that, in fact, the Final Rule is going to have perverse consequences, and they have not rebutted that.

THE COURT: All right. We've got limited time here. I would like to -- thank you. I would like to get to some of the merits questions.

Starting with the Appropriations Act, the directive, I take it, that has appeared in each of the Appropriations Acts since -- was it 1996, that says all pregnancy counseling shall be non-directive. And the critical issue seems to me is what is counseling?

As I understand the Government's argument that the Final Rule complies is not inconsistent with the Appropriations Act

because it allows for non-directive counseling. It's the referrals that one could argue is not non-directive, fairly directive or certainly not neutral.

The Act, of course -- the Appropriations Act says that -- says "counseling." It doesn't say "counseling and referral." If it said "referral," it would be -- I wouldn't have to struggle with this issue.

What's the strongest argument that "counseling" includes "referral"?

MS. RICH: I'll give you two. First, is that the comments on the rule suggested that every major medical association that practices family planning considers appropriate referrals to be part of non-directive counseling. And that includes the defendant's own Quality Family Planning Guidelines, which were adopted in consultation with the Centers of Disease Control and the American Medical Association and other major medical providers, who all consider that providing an appropriate referral is part of the act of providing options counseling.

Second, is looking at the text of the Final Rule itself, because in many other places the government acknowledges that referrals are part of the act of options counseling. It's just that they want to carve out abortion referrals. But in other places -- and I believe we cited this in our reply brief -- when they talk about adoption counseling, they will say

"adoption counseling, comma, including referrals."

THE COURT: And I think you did mention the Quality Family Planning Guidelines as an example of that.

What about the PSHA itself? There is reference to another section. I'm not sure if it's in Title X per se, but it's that Section 254C6A1.

MS. RICH: Uh-huh.

THE COURT: That -- I think it's about adoption services, but it refers to adopting information referrals to --

"Providers are supposed to provide adoption information referrals to pregnant women on an equal basis with all other courses of action included in non-directive counseling of pregnant women."

MS. RICH: Correct.

THE COURT: Now, that's not -- that's not actually Title X, is it? I think it's a section that immediately precedes Title X, but it's in the Act.

Is there anywhere else in that Act, which is sort of the grandparent of all these, that uses the term "non-directive counseling"? Do you know? Is that the only place where it's mentioned?

MS. RICH: I'm not aware of any other place there, but the Public Health Services Act does require that all services must be voluntary. And I think the concept of voluntariness is one of the roots of the non-directive

counseling concept.

The idea is that -- of non-directive counseling is if a patient comes in and they say either "I want to choose an abortion" or if they say, you know, "I don't believe in abortion, don't tell me about it," either way the provider is expected to respect their wishes. That's what non-directive counseling means.

And providing an appropriate referral for whatever the circumstance is just part of good medical practice.

THE COURT: Is there something -- I understand that there are comments that were filed about counseling where that includes referral. Is there something -- is there an industry manual? Is there an industry bible or something --

MS. RICH: The Quality Family Planning Guidelines themselves which were adopted by HHS is probably the closest you're going to find to a bible. I believe Dr. Brindis describes it as the gold standard or standard of care for family planning practitioners.

THE COURT: When was that adopted?

MS. RICH: Well, it has been developed for many years and it is not a break in practice, but it was formally adopted by HHS in 2014 into it's guidance for all Title X providers.

THE COURT: All right. What's the Government's response?

MR. BURNHAM: Well, your Honor, I think there is a

pretty fundamental difference that you can see in the U.S. Code between counseling and referrals.

So I have a couple points, but let me start with the basic legal point, which is that there is no -- you know, the presumption against implied repeals is strong and it's particularly strong in an appropriations statute.

So I think what the Court has to --

THE COURT: Except there is an argument here. Let's talk about that. You made that point in your brief, but the come-back is this is not a repeal.

MR. BURNHAM: Yes. Absolutely. That was going to be my very next sentence, Your Honor. I don't think it's a repeal at all. I think what the Court has to do is read Section 1008 and the appropriations rider together. All right? So read the two provisions in harmony.

And then even when Congress added the appropriations rider, Congress knew what Section 1008 meant because the Supreme Court of the United States had said what it meant, and it meant that you could do all the things that the Final Rule is doing as relevant here.

THE COURT: Presumably it also understood what the then post 1988 guidelines or guidance were. To the extent that there were some change in repeal in 1993, presumably Congress was aware of that.

MR. BURNHAM: Yes.

THE COURT: Right.

MR. BURNHAM: But if Congress wanted to require that, Congress would have said so in a way that was explicit.

THE COURT: They wanted to do what?

MR. BURNHAM: They wanted to -- imagine if Congress wanted to codify the 1993 regulation, which is essentially the regulation that has just been replaced by the Final Rule. It wanted to codify a regulation that allowed abortion referrals and required abortion counseling, which I think is what plaintiffs are basically saying.

They are basically saying the non-directive rider codifies the post *Rust* regulation and makes illegal the regulation that *Rust* approved. I think that's their fundamental argument.

And what I'm saying is that that's just not -- that is totally not supported by either what's in the appropriations rider itself or the immediately preceding history because in 1993 Congress actually enacted -- I'm sorry, not 1993. In 1992 Congress actually passed legislation to overturn *Rust versus Sullivan* and do exactly what plaintiffs are saying the appropriations rider did. The problem for plaintiffs is that the president vetoed the legislation and so it never became law.

But in that legislation, which is at -- the easiest cite to find is probably 1992 Westlaw 86830. This is cited in the preamble at Page 7716. Congress said:

"Non-directive pregnancy counseling is the meaningful presentation of options where the physician or advanced practice provider is not suggesting or advising one option over another."

That says nothing about referrals.

And then, indeed, in that legislation they also had a concept called "pregnancy management options" -- that's a term of art; that's a quote -- which included, quote:

"Non-directive counseling and referrals on topics including, quote, termination of pregnancy."

None of that language appears in the non-directive appropriations rider.

And, indeed, the non-directive appropriations rider itself even underscores that they are not trying to disturb Section 1008 by saying that no Title X money can go for abortion.

And so to get to the heart of the matter, I think reading the two provisions together it's pretty clear that the rider is not meant to change the meaning of 1008, constrain the meaning of 1008, or overturn ***Rust versus Sullivan*** at all. But even if it were, the Final Rule allows non-directive counseling about abortion.

So a patient that comes into a Title X recipient under the Final Rule and asks questions about abortion can receive a full -- all the counseling that the doctor thinks is necessary to give the patient an understanding of how the procedure

works, the medical risks, the cost, the benefit, the recovery time, everything. There is no limitation on the doctor's ability to provide non-directive abortion counseling.

The only limitation comes after that when the patient asks for a referral, which is not medical information. It's factual information about where to go and obtain the procedure.

THE COURT: Well, I understand it and you see these as two separate things, counseling and referral.

What do I do with the fact that the PHSA itself, the only time it mentions non-directive counseling under Section 256(c), appeared to encompass within that term referrals as well as providing information.

MR. BURNHAM: A couple things, Your Honor.

THE COURT: That's Congress speaking at that point.

MR. BU RN: That is a, like, sideways reference to the two things. It's not meant to define non-directive counseling or define referrals.

So I think --

THE COURT: Well, it's some indication at the time it passed at least the PHSA what it meant by non-directive counseling.

MR. BURNHAM: Well, I don't --

THE COURT: Hold on.

That it assumed that it encompassed both, as I read it, and yet -- and there has been no other reference. I don't know

if there is another statute that uses the term "non-directive counseling" other than in the Appropriations Act, which then came about some years later.

MR. BURNHAM: Well, there is the statute that failed, Your Honor. And so it's not as though we have to guess at what Congress would have said had it wanted to overturn section -- the instruction in 1008.

THE COURT: Well, perhaps that was done at a time while -- I don't remember whether *Rust* was pending when that bill was drafted, but there was a clear dispute, perhaps a need to enunciate more clearly, what was encompassed.

By 1996, some four years later, it had already been the practice of HHS to have -- to require sort of non-directive counseling and referral. So, therefore, there was -- one could argue there was less of a need to draw that careful distinction in its nomenclature.

MR. BURNHAM: I suppose, Your Honor, but we're talking about a regulation that went to the Supreme Court that Congress attempted to overturn in the face of a presidential veto where the provision that we were relying on was something that was passed in an appropriations bill.

And so I think that --

THE COURT: Four years before.

MR. BURNHAM: Four years later.

THE COURT: Four years later?

MR. BURNHAM: After Congress had seen legislation fail --

THE COURT: But the failed legislation was in 1992.

MR. BURNHAM: Yes.

THE COURT: So how much inference you can draw from what Congress in 1996 intended when it was enacting an Appropriations Act and using a term which was different from its proposed legislation in 1992 and different again from its use of that nomenclature at the time of the PHSA.

MR. BURNHAM: I disagree, I guess, Your Honor, with the point about the PHSA, because the language is pretty oblique about the distinguishing between referrals and counseling.

All that act says is that doctors should be able to provide adoption referrals in the course of their non-directive counseling, which I don't think tells you a lot about whether Congress thinks the terms are distinguished.

As far as the -- one other point I wanted --

THE COURT: If you read that literally that means that referral is part of non-directive counseling. Included in. Included in.

So they thought it was included at the time.

MR. BURNHAM: Your Honor, I think that is a very -- I think that is a disproportionate amount of weight to put on a reference that is then being brought into this case through the

1996 appropriations rider --

THE COURT: I'm just looking for every instance when Congress used that term. Now, admittedly it was a different Congress. It was in 2000 --

MR. BURNHAM: Right. So Congress, I think, Your Honor, in legislation that it passed rejecting completely the conflation of counseling and referrals. Whereas, the PHSA includes, like, a sideways reference to the two that seems to kind of conflate them, but doesn't purport to define either. Whereas, in the failed legislation it actually defined the term "non-directive pregnancy counseling" in a way that clearly excluded referrals.

One other point about the 2014 guidelines. My understanding is those say they proposed non-directive counseling and then say, quote:

"Every effort should be made to expedite and follow through on all referrals."

And so there is even a distinction in those guidelines which, of course, don't have the force of law anyway, between counseling and referrals.

The only other point I think that is really important here, Your Honor. It's not me that thinks the 1996 appropriations rider does a lot of work. It's the plaintiffs. Because the plaintiffs are suggesting that simply by saying counseling -- which, by the way, doesn't even require to be

provided. It just says that if there is counseling, it must be non-directive.

The plaintiffs are saying that line overturned *Rust versus Sullivan* and accomplished what the failed legislation of 1992 failed to accomplish.

THE COURT: Well, I don't think there they are saying it overturns *Rust*. *Rust* said one permissible interpretation of the Title X is to allow for restrictive -- restrictions on counseling, restrictions on referral, separation.

Because of the ambiguity of the act itself, the ambiguity of the legislative intent, which it acknowledged, that this was one -- and because there was some basis -- based on the GAO study and the Office of Inspector General study, that there was a basis, a reasonable basis to interpret it that way.

So it's not overturning *Rust versus Sullivan*. It is saying, well, granted that was one reasonable interpretation, but this legislation now restricts the range of interpretation.

MR. BURNHAM: So, your Honor, I don't mean -- fine. Maybe it's not it overturns *Rust versus Sullivan*, but it takes the construction that *Rust* blessed off the table in a way that Congress had tried unsuccessfully to do four years earlier.

The only other point I would make about this, Your Honor, you know, as I've said, the Final Rule allows fully non-directive counseling. So as I understand the argument -- I'm not actually sure what the argument is precisely. I guess

it's both; that the prohibition on abortion referrals somehow renders the antecedent counseling to be directive. But I'm not sure how that could be because the counseling --

THE COURT: I think the argument --

(Simultaneous crosstalk.)

THE COURT: I think, as I understand it, that counseling encompasses referral. And to the extent that the referral process has now been biased in one direction, counseling, broadly construed, is no longer --

MR. BURNHAM: And I'm not aware of anything to support that understanding of counseling. Because even if we were under the 1988 regulation, which forbade abortion counseling, I have not seen anything that suggests in order to be non-directive, counseling has to be comprehensive, which is what they are really saying.

I think what the argument really is, it's two -- there's two steps where I think their argument fails.

The first is the conflation of referral with counseling, which I don't think has any basis in the U.S. Code or in the history of this regulation.

And the second is the idea that when you take one topic out of the counseling, that renders the counseling directive.

I'm not aware of any authority for that proposition in law and I don't know that there is anything to suggest that that's what Congress thought I was doing.

Because after all, Section 1008 says that abortion -- no money can go to a program where abortion is a method of family planning, and that provision is still on the books, and I don't think any of us think the fact that it's been repealed, that under plaintiff's construction of the appropriations rider, the doctor could promote abortion. That could be the doctor's primary advised method of family planning in a Title X program, as long as the --

THE COURT: I don't think so. It has to be non-directive.

MR. BURNHAM: That's what I was going to say, as long as the counseling is non-directive. But the doctor could present an abortion as a perfectly acceptable, wonderful method of family planning, which I think would be very hard to square with Section 1008. As long as it's non-directive. I agree with Your Honor, it has to be non-directive.

But that does an awful lot of work for this appropriations rider that makes an oblique reference to non-directive counseling.

THE COURT: Well, I'm not sure I understand that -- the last point. It seems to me a non-sequitur.

The critical question seems to me -- I don't have too much of a problem whether -- if the restrictions on referral are deemed part of, quote, counseling within the meaning of the Appropriations Act, that this was -- this is a directive rather

than non-directive. At least there is a good argument for that.

That critical question is: Is this counseling? Can you have non-directive counseling and directive referral? Because that's what it is basically. The referral process is fairly direct.

MR. BURNHAM: There's two pieces to that. And so I think Your Honor could say -- I'm not disagreeing with pretty much anything that Your Honor just said.

The only thing I would quibble with is I think you could say that the prenatal -- the mandatory prenatal referral, if referral is counseling, directive. I don't disagree.

I do disagree that saying you cannot provide an abortion referral makes the entire thing a directive. Because that's the point I was trying to make, perhaps inartfully, is that by taking one thing off the table and saying that you can't provide counseling on this topic.

Another example would be one that plaintiffs object to, which is that the Final Rule allows counseling on things that are outside FDA approval, things that are not -- I forget the exact term.

THE COURT: Maybe we're jumping ahead a little bit, but part of the concern is that part of the Final Rule that says, number one, abortion providers can't constitute a majority of the list upon -- for the referral list and, perhaps

more importantly, those who provide those services cannot be identified.

So you have to submit a list that -- that does not identify which, of course, arguably obfuscates the end goal that a particular patient may be seeking and, therefore, you know, to make it difficult for that option.

I don't think there is a -- is there a similar requirement that those who provide prenatal services cannot be identified?

MR. BURNHAM: I don't believe -- so if I could just finish the -- the only point I wanted to make, Your Honor, before this question, and then I'll -- I'm happy to answer that question. The answer, the short answer to your question is no, I don't think so.

Although, I mean, it's hard to imagine because the list will have some number of providers and if you only identified the prenatal ones and not the abortion ones, it would have the same effect. I mean, it's hard to imagine how this would actually work.

But the point I was trying to make is that under the preceding rule there are certain forms of counseling that aren't allowed in Title X also, and I don't think anyone thinks that that makes the counseling directive.

The point I'm trying to make is just that when you take one topic, one way of responding to pregnancy out of the equation, that doesn't render what's left directive. And I

think that's true whether counseling and referrals are the same thing or whether they are not.

And so even if they are the same thing Your Honor thinks that the terms are, you know, intertwined or interchangeable, I think then the only thing that would be problematic under that analysis would be the requirement of prenatal referrals.

As far as the list goes, I mean, I think the list just follows from the restriction on referrals. I mean, once the restriction on referrals is allowed, if it is allowed, then the list is just an implementation of that.

And just to give a sense of what I think Section 1008 means, in addition to its breadth on its face, the way Representative Diegel described this legislation when it was passed in 1970 was, quote:

> "The committee members clearly intend that abortion is not to be encouraged or promoted in any way through this legislation."

So I think, you know, if HHS is right, that a permissible construction of 1008, as *Rust* says it is, is one in which abortion referrals aren't allowed, then the list is clearly allowed as well. Because to do the list in a way that, you know, singles out the abortion providers or is weighted toward abortion providers would just violate the same principle.

So I think -- my point is that I think the referral requirement or the referral prohibition and the list rise and

fall together. I don't think there is a delta between those two things.

THE COURT: All right. Let me hear the response.

MS. RICH: Sure. I think I want to back up by suggesting that it is the Court's obligation to read the non-directive mandate and the original language of Title X together in a way that is most harmonious.

And thankfully we have a long record of agency practice that does exactly that; that says that, indeed, the non-directive mandate includes referrals and all other parts that are normally part of counseling.

And Congress didn't just pass this appropriations rider once in 1996. It has been part of the Title X Appropriations Act for every single year since then, for the last 27 years.

And agency policy in general has been very consistent, with the exception of the 1988 regulations and then the current Final Rule, that counseling is indeed -- that referrals are indeed part of the act of providing options counseling.

And, again, I'd like to go -- point Your Honor to the text of the Final Rule itself, which concedes in other contexts that providing appropriate referrals is part of, is included in the act of providing counseling.

So I think that really the burden is on defendants here to explain why non-directive counseling --

THE COURT: What's your response to the fact that

when Congress wanted to spell it out more expressly, like in its attempted legislation in 1992, it did, but didn't do so here.

MS. RICH: I think it's totally normal that an appropriations rider will be a little bit shorter and more simple than a stand-alone bill. That seems -- the 1992 failed legislation doesn't seem to me to be very relevant here. Everyone -- and, as I said, there is longstanding practice that shows that referrals are part of non-directive counseling.

I think that if Defendant's position were taken, then the non-directive mandate itself would really be meaningless. And it's not the Court's job to find -- it's the Court's job to find meaning and harmony with all of the acts of Congress, not to consider one of them sort of superfluous.

THE COURT: So what are the main things that make -- if you include referrals, make counseling non-directive in contravention of the Appropriations Act?

MS. RICH: So in the Final Rule --

THE COURT: Yeah.

MS. RICH: -- they make counseling non-directive?

Well, the fact that there is a ban on abortion referrals. The fact that there is mandated referrals for prenatal care, even for a woman who says that she doesn't want to continue with her pregnancy. If a doctor is forced to tell her that she -- that here you should be referred to prenatal care, that

is not non-directive counseling.

The fact that providers are forbidden from identifying the most high quality, affordable or convenient providers of abortion on their sort of non-referral referral list.

I would add to some of the things that Your Honor mentioned earlier, one particularly pernicious aspect of the Final Rule is that Title X providers cannot include on their list anyone who -- any provider who doesn't provide comprehensive primary care. That means that if the most affordable, most convenient, highest quality abortion provider happens to be a specialized women's health clinic like Planned Parenthood, they cannot be on that list. They can't even have a brochure in their waiting room for Planned Parenthood. And as our evidence has shown, that means in many cases that actually is the only convenient, affordable, high quality option for abortion services.

And then there is the fact that Title X providers are actually allowed to, in the face of a woman who says that she doesn't intend to continue her pregnancy, the Final Rule allows those providers to give her a list that doesn't include any abortion providers. It's as if you're sending low income women who are needing to make a very time sensitive medical decision on a scavenger hunt and saying, "Here is a map." And, in fact, you've given them a faulty map that doesn't identify the places where they need to go in order to be able to exercise their

choice.

None of this is consistent with the concept of non-directive counseling.

THE COURT: Well, let me ask you about the comprehensive primary care requirement. That applies to all providers regardless of whether it's prenatal care or abortion?

MS. RICH: Right. When providing this -- I'm sort of calling it the non-referral referral list, I'm not quite sure what to call it -- they are only allowed to include providers who offer comprehensive primary care. So not a specialty clinic.

THE COURT: In either direction.

MS. RICH: In either direction.

THE COURT: So, but your argument, as a practical matter, those who will be impacted disproportionally will be specialized providers that provide abortion services. They are more prevalent, for instance, than those who provide prenatal care who are not comprehensive primary care providers?

MS. RICH: Correct. Yeah.

THE COURT: Is there some evidence in the record of that?

MS. RICH: I believe the Tosh declaration and the Kost declaration will both show that there are quite a number of places, especially in more rural parts of California, where the only available abortion provider is a specialized clinic.

MS. YBARRA: Your Honor, if I could just add to Ms. Rich's argument there.

Mr. Burnham, during his argument, articulated a number of things that he and the Government, I guess, now contend a doctor can discuss with a patient concerning abortion and detailing certain aspects of care surrounding abortion, stopping short at referral.

There is no basis for that in the rule whatsoever. The rule paid lip service to allowing non-directive abortion counseling, but the other parameters of the rule gut any meaningful interpretation of what that -- that might mean.

The Government repeatedly cites in its brief, its opposition brief, a single interpretive example at 59.14(e)(5) arguing that counseling is non-directive and doesn't run afoul of the Appropriations Act because this one example provides the road map. But there is no example for how a doctor is supposed to discuss abortion with a patient, even stopping short of a referral, in the rule.

What Mr. Burnham just articulated was made up from whole cloth, as far as we can tell.

THE COURT: Well, what is it in -- you say that the rest of the rule undermines the, quote, lip service, close quote. What's an example of -- besides the referral, what's a restriction?

MS. YBARRA: The restrictions are the prohibition on

promoting or encouraging abortion in any way; referral, promotion, encouragement. There are -- that prohibition is repeated through the rule.

And it's -- the rule does not explain how a doctor is supposed to --

THE COURT: So presenting supposedly neutral, unbiased options that include abortion might run afoul -- might be deemed to be promoting or encouraging abortion?

MS. YBARRA: Yes, Your Honor.

The only example that the Government gives in its opposition brief is saying that a doctor discussing recovery time with a patient, recovery time for a medical abortion, wouldn't run afoul of that provision. But there is no basis for that in the rule. The rule paints the prohibition in much broader strokes.

MR. BURNHAM: Your Honor, if I may?

I would submit that promotion and encouragement of abortion is directive. So that's just prohibited by the requirement that counseling be non-directive.

THE COURT: So what's an example besides explaining to a patient what the recovery time for an abortion might be? What's another example that would be within the safe harbor?

MR. BURNHAM: Anything that's non-directive.

THE COURT: Can you have give an example? If somebody comes and wants to know about their options and is

tending towards terminating pregnancy, what can a doctor say?

MR. BURNHAM: The doctor can provide all the medical information that's relevant to that decision. The only thing the doctor can't do is say, "Here is a referral for someone who can perform the abortion."

The doctor can say that the reason why he or she cannot provide the referral is because Title X won't allow him or hire.

So one of their arguments that they make in a variety of flavors is that this requires doctors to lie or suggest to patients that abortion is bad or immoral or something like that on. Not at all. The doctor --

THE COURT: Well, the doctor gives, for instance, an assessment of risk of birth versus abortion --

MR. BURNHAM: Yes, and it --

THE COURT: -- and it happens that there is a -- if it happens, there is a lower risk if one chooses to terminate rather than carrying through to term, that would not -- that doctor could say that and not run afoul of the Final Rule?

MR. BURNHAM: I mean, in general. I guess, the specifics could always matter, but I would think about promotion and encouragement as the opposite, as sort of the flip side of the non-directive coin; right?

So as long as the doctor is not being directive -- because the regulation clearly authorizes non-directive counseling --

then I think we're in okay shape.

There is one point, Your Honor, that I apologize for not making the last time we were speaking. We talked for awhile about the 1993 regulation on the books when Congress first enacted the appropriations rider. I actually forgot there is a quote in there that makes very clear that everyone understood counseling and referrals to be distinct concepts. And this is at -- shoot. It's at 58 Federal Rule 7464.

Again, that's 58 --

THE COURT: 74?

MR. BURNHAM: -64, Your Honor. And here is the quote, if you will allow, indulge me:

"Title X projects would be required in the event of an unplanned pregnancy and where the patient requests such action to provide non-directive counseling to the patient on all options relating to her pregnancy, including abortion, and to refer her for abortion if that is the option she selects."

So I think you have a -- that's a pretty good example of the two concepts being treated as sequential things that happened one after the other.

MS. YBARRA: Your Honor, could I briefly address this point that we're in okay shape as long as the doctor is being non-directive?

THE COURT: Briefly, but I'd like you to address this

question because there are -- I think I have found various places in the -- various regulations where the term "counseling" and "abortion" are used separately. That occurs in the -- under the 1998 rule. It occurs to a certain extent under the 2000 rule.

MS. YBARRA: I will be very brief. I would like to disabuse the Court of any notion that as long as a doctor is not being directive, we're in okay shape.

I direct the Court's attention to 59.16 example (b)(1), which provides that merely making a brochure -- having a brochure sitting out on a table in a Title X project and the brochure discusses abortion, that would be violative of the rules.

That has nothing to do with a doctor providing specific advice to a patient, but that is under HHS's interpretation of their own rules encouraging abortion or activity that encourages abortion.

MR. BURNHAM: Your Honor, I don't think having advertisements out in the waiting room has anything to do with counseling at all. And so I'm not sure what that has to do with --

THE COURT: I guess it begs the question if in the course of the counseling the doctor hands a brochure that describes the process of abortion -- you know, I don't know what the brochure says, but if he hands out a brochure, it's

not a referral.

MR. BURNHAM: This is a very specific prohibition. It prohibits:

"Brochures advertising a clinic that provides abortions where such brochures are available in any fashion."

So this is talking about promotional materials or whatever, informational materials about a place where abortions are performed, not medical materials explaining how, you know, abortion works and all of that.

THE COURT: So having a brochure that just explained the medical process would not violate Title X?

MR. BURNHAM: Your Honor, I don't have a direct -- I don't have an answer for you on that. I can tell you that non-directive --

THE COURT: If you don't have a direct answer, I'm not sure who would.

MR. BURNHAM: Well, Your Honor, in the course of non-directive counseling, if part of non-directive counseling -- I just don't know what all goes into non-directive counseling in every circumstance.

What I'm telling you is the rule allows non-directive counseling and that the promotion or encouragement language is just juxtaposed against that.

THE COURT: But that's part of the question. How do

you juxtapose that? How do you resolve it? That's why I asked the question.

MR. BURNHAM: If it's directive, it promotes or encourages.

THE COURT: Okay. So if a doctor has a brochure, and you often see these, like --

MR. BURNHAM: If that is normal -- if that is part of how non-directive counseling normally works, I don't think it would -- it would not be a problem.

THE COURT: How does one determine what is part of normal non-directive counseling?

MR. BURNHAM: I think that's what we're here doing.

THE COURT: We can barely find that term. It's been used twice by Congress, as far as I can see, through the history of Congress.

MR. BURNHAM: I just -- you know, I'm happy to confirm with HHS and get back to you.

I think if doctors were giving non-directive counseling -- which is what they are doing right now under the prior rule and have been since Title X has been cited. If part of non-directive counseling is providing written information, there's nothing in the Final Rule that changes that because the Final Rule is very clear that non-directive counseling about abortion is allowed. It says it explicitly in the regulation and then it juxtaposes that with promotion or encouragement.

The only time it talks about literature is a prohibition on literature advertising abortion clinics, which I think is part and parcel with the prohibition on abortion referrals.

One other document that we have been talking about some is the CDC Quality Family Planning Guidelines. I have to figure out what page this is.

Let me read you the quote and I'll come back to the citation in a second. When it talks about counseling, it says:

> "Options counseling shall be provided in accordance with recommendations from professional medical associations."

And then two paragraphs later it talks about:

> "Referral to appropriate providers of follow-up care should be made at the request of the client as needed."

Then it says the part I read earlier, when is:

> "Every effort should be made to expedite and follow through on all referrals."

So that, that guidance itself juxtaposes the two concepts. And so I just think that's pretty clear from both the regulatory backdrop when Congress enacted the rider, which I quoted to Your Honor a little while ago. It's clear from just the common plain meaning of the word "counseling" versus the word "referral."

I think it's just evident that the 1996 appropriations

rider wasn't meant to say that Title X projects have to always and forever, at least as long as the rider existed, allow referrals for abortion.

MS. RICH: And I would comment on that, that none of the examples that defense counsel just cited involve a juxtaposition of counseling and referrals. They all suggest that they are part of the same act.

And, in fact, that is consistent with the 2000 regulations and is consistent with medical practice generally.

THE COURT: All right. Let's talk about the ACA. We need to move on here. The waiver argument. The waiver issue.

It's undisputed that no party expressly raised Section 1554 subsections one through six in their comments.

There is some suggestion that some arguments that are analogous to 1554, some of its subsections about -- some concerns about ethics, some concerns about effectiveness of delivery and barriers may have been raised, but nobody raised, including any of the parties here, conflict with the ACA.

MS. YBARRA: Your Honor, I start from a different premise, which we discuss in our reply brief.

The *Sierra Club* case cited at the -- California's reply at page six, it's also cited in ours, holds that:

"The waiver rule does not apply to preclude argument where the scope of the agency's power to act is concerned."

And that is the case that we have here. And that's because an agency has an independent obligation to examine its own authority and not promulgate implementing regulations in a way that exceed its scope.

THE COURT: I understand that. Judge White of this court so ruled, citing the D.C. Circuit's decision in *RDC versus EPA*.

But as far as I know, that line of reasoning, which would sort of excuse the otherwise exhaustion kind of doctrine, has not been adopted by the Ninth Circuit, unless you can tell me otherwise.

Is there some Ninth Circuit authority that embraced this theory?

MS. YBARRA: No, Your Honor. I've not seen the Ninth Circuit take that up, but it is still good law.

THE COURT: Where else -- any other circuit besides the D.C. Circuit sort of employing that kind of language?

MS. YBARRA: Not that I'm aware of, Your Honor. The D.C. Circuit is it, and Judge White here in this Court.

But separate and apart from that, the comments that the plaintiffs submitted in their supplemental submissions yesterday, they run the gamut of discussing both the ACA generally, which is raised by several commentators -- commenters, including the State of California itself in a meeting days before the Final Rule was issued between the

Office of Management and Budget and the Attorney Generals from several states.

In addition to those general comments raising concerns about compliance with the ACA, commenters raised specific concerns addressing each one of the six prohibitions of 1554 and how the rule violates it.

The commenters are not required to use the magic words and cite Section 1554. And the *National Parks* case makes that clear.

> "The comments are quite detailed and on point and are sufficient to put the agency on notice that there is a compliance issue in this regard. Public is not under any obligation to cite the specific legal provision to the agency, however."

That's *National Parks* at Page 1065.

The Court said:

> "The public need only raise the issue with sufficient clarity to put the agency on notice that the issue has been raised."

The Government certainly has been on notice about 1554 and potential problems it poses here. They raised 1554 themselves in concurrent rule making. Specifically, rule making regarding exemption from the ACA's contraceptive coverage mandate, where they specifically discuss Section 1554 repeatedly in a Final Rule announced in November of 2018.

Essential Access has also separately raised 1554 in response to HHS rule making years ago in 2011, soon after the ACA was enacted.

So there is no question that 1554 and the concerns raised substantively in those six provisions have been -- the Government has been made aware of those concerns and has had an opportunity to address them.

THE COURT: With respect to the first subsection of 1554 that creates any unreasonable barrier to the ability of individuals to obtain appropriate medical care, which comments -- although not citing 1554, if you just tell me in the record briefly -- are most on point, you think gave HHS the requisite notice?

MS. RICH: Well, I would direct Your Honor to our supplemental position from yesterday.

But I think that the entire concept of creating, for instance, these non-referral referrals lists that actively create barriers, I think that the American Medical Association and the American Public Health Association comments all speak to this.

Just a sec. Let me get out my copy of our supplemental brief.

(Brief pause.)

MS. YBARRA: Your Honor, I would say I think our briefs track in the pagination. Plaintiff's supplemental brief

at Page 2, Paragraph 6, which is the Exhibit H to the Rich declaration. The Multistate Attorneys General letter at Pages 4 and 6 is specifically on point. Plaintiffs submit that all of the comments cited in our supplemental briefs address this issue.

THE COURT: All right. Let me hear from the Government in response.

MR. BURNHAM: I guess my big picture response is that saying to a decision maker -- and I will use the analogy of District Court and the Court of Appeals -- that something violates the Affordable Care Act or is intentioned with the Affordable Care Act is obviously quite different from saying here is a provision in that many hundred of page law that we think you're about to do is violate.

THE COURT: What about the converse? That is, you raise the substantive argument, but you don't label it.

MR. BURNHAM: No, Your Honor. Because -- not here because these are not the same argument.

So what they are pointing to were places where somebody said, hey, this would create a barrier to healthcare, which is a normative claim about why the rule might be a bad idea. That's completely different.

So to take the example that was just cited. It says:

"The proposed rule seeks to create barriers to access to women's healthcare including abortion.

These Government imposed barriers to the physician/patient relationship interfere with the provision of medical care and will impede public health."

That's a policy argument for why this rule is a bad idea. That's a completely different thing from saying that this is also prohibited by Section 1554 of the Affordable Care Act.

Just like if we came to Your Honor or the plaintiffs came to Your Honor and said strike down the Final Rule because it creates barriers to access to women's healthcare and you didn't. Then they went to the Ninth Circuit and they said, see, the lower court missed 1554 and you should reverse on that basis. I think the Ninth Circuit would say that that was clearly waived. And this is totally analogous to that because it's the exact same legal rule and it exists for the exact same reason.

THE COURT: So the fact that it is now claimed to be a violation of the statute would have been of significance to the agency.

MR. BURNHAM: Oh, yes. The whole point of the rule is to channel those kinds of arguments into the rule making so that we don't have to come here; right? So that the agency doesn't go through an entire rule making, issue a Final Rule. Then we have to go to court, and then the argument is made, you know, the silver bullet argument that the agency didn't see

that says the whole rule is invalid.

I do think -- and we can talk about the merits in a minute -- that the reason nobody raised is because it clearly doesn't apply.

But I would like to, if I could, just talk about the *Sierra Club* case for just a second?

THE COURT: Yeah.

MR. BURNHAM: There's two distinctions from that case. The first is that the Court at Page 1060 found, quote, the record replete with comments from other stakeholders who objected, end quote, on the same basis that was being pressed in the litigation.

Now, we're not saying that Essential Access in California can't make this argument because they didn't raise it. We're saying they can't make it because nobody raised it in the 2- or 300,000 comments that were submitted to the agency. I think that's a pretty fundamental distinction.

And then the second distinction -- and I don't have the opinion in front of me. I read it this morning. So I don't want to quibble about this. I want to caveat my quibble with the acknowledgment that I could be remembering it wrong.

But Ms. Ybarra described the exception to the rule as one involving the scope of the agency's power to act. I don't think that was quite right. I think the quibbling -- what the opinion was saying is the agency's fundamental power to act at

all. And the agency's power to act at all is obviously a very different thing from the scope of its power to act.

And here I don't think anyone disputes that HHS has the authority to issue regulations in general implementing Section 1008. That comes from 42 U.S.C. 300(a)(4).

So I caveat that by saying I don't have the opinion in front of me, but the way I recall it is it's about fundamental authority, not about scope. Maybe Your Honor has it. But that's my recollection of the case.

THE COURT: All right. Let's get to the merits for a second here. We're running out of time.

What about the fact that 1554 does not address funding? It addresses the -- any regulations that erect barriers to healthcare or impede communications, et cetera, et cetera.

Why doesn't that run into the exact same kind of argument that was addressed and pretty much rejected, admittedly on a Constitutional basis, in *Rust*?

And that is, the decision of the Government to fund and not fund does not constitute a barrier. Does not constitute, for instance, a violation of a woman's right to choose because if the Government decides to fund or not fund, the person is in no worse position than if there were no funding at all. I mean, there is no accesses available outside the funding process.

So why wouldn't Section 1554, all of its subdivisions --

and I understand the arguments why the Final Rule might be inconsistent or arguably inconsistent with those. Why don't we run into this overarching problem that it doesn't reach the funding statute per the reasoning of *Rust*?

MS. RICH: I think because what the statute does, what Congress intended here, which in Section 1554 is to constrain HHS's rule making ability in such a way. And it's not about what is or isn't funded. It's is HHS creating regulations that themselves introduce new barriers over and above the decisions that Congress makes to fund or not fund certain activities.

And so what -- it is indeed very important that we're talking about interpreting a statute here rather than -- it would be, I think, a mistake to just import *Rust*'s Constitutional discussion into this statutory scheme. But here we see that Congress has said not -- not intending to repeal Section 1008, there is -- we're not arguing that's what Section 1554 does.

What we are saying, that Section 1554 has introduced significant new guidance to the agency about their rule making capacity, and certainly HHS had an independent obligation to understand the limits on its rule making and to act within that legal authority.

THE COURT: Well, if you look through the ACA, and 1554 is codified in Section 18114, you go back a couple of

sections to 18116, there is an example there where there is a prohibition, for instance, on discrimination under any health program or activity, any part of which have is receiving federal financial assistance.

Now, maybe they want to make sure that reached Title X recipients, Title VI recipients, et cetera, et cetera. But one could argue that when Congress in enacting the ACA had funding, was trying to regulate sort of the way a funding program or touch upon how a funding program operates it did so expressly, but here it didn't say anything. It just says no regulation that creates an unreasonable barrier.

MS. RICH: Uh-huh. Uh-huh. You know, and which I don't think, to me, suggests that it's a general prohibition and a general new requirement that limits HHS's rule making ability.

You know, I think the 1557 provision, Congress clearly wanted it to include not just -- you know, have a non-discrimination mandate that applied, not just to HHS's activities, but to all of the recipients of federal funds. That's all of Medicaid and all of Medicare. So it was explicit in how it did that. And Section 1554 is clearly directed at the agency's rule making authority and making -- putting some limits on that.

THE COURT: Response?

MR. BURNHAM: So, your Honor, I mean, you've

identified what was going to be my principal argument, which is that there is a fundamental difference between direct regulation of people and limitations on how the Government will spend its own money. And that animated much of *Rust*.

I think that same distinction disposes of the plaintiff's First Amendment claim, which I actually think is definitely squarely foreclosed by *Rust*.

And what this statute is talking about is the direct regulation of physicians through the Affordable Care Act. It's not talking about limitations on when the Government will spend money in programs like Title X. I think that's particularly clear, given the Court's obligation to read this in harmony with Section 1008. Because, again, there is nothing in here that talks about 1008. There is nothing in here that talks about Title X or talks about funding. It just talks about what regulations HHS cannot promulgate directly regulating physicians.

So I don't dispute that this statute was intended to limit HHS's regulatory authority. What I dispute is that this statute is then say something about HHS's regulatory authority implementing a Congressional mandate about Section 1008, about how Congress is willing to have the Government's money spent in a program like Title X.

And so I think for both of those reasons there is just nothing to this argument, which I suspect is why nobody raised

it during the notice and comment process.

THE COURT: Well, let me ask the state. Part of the reasoning in *Rust* is that a doctor's ability to provide and a women's right to receive information and services outside the context of a Title X project remain unfettered, quote/unquote. And, therefore, the fact that there was sort of defunding of one option under Title X kind of left the rest of the world as it was and, therefore, there was still unfettered access.

Do you think there is a distinction here? Are you making an argument that it is not the case that such access remains, quote, unfettered under the Final Rule in this day and age?

MS. RICH: Yeah. It's clear, I think, that their access is not unfettered under the Final Rule.

I think it's important to note that, you know, *Rust* was saying that there was one -- you know, one interpretation that was permissible at that time, but since then Congress has changed the law. Congress has changed the law with the non-directive mandate. It changed the law with 1554.

So I just don't think *Rust* -- the holdings in *Rust* apply the same way.

THE COURT: To the extent -- what I'm getting at, to the extent that *Rust* is rejection of the right to choose, Constitutional right, was based on the fact that that Constitutional right remained accessible with or without Title X. That was the assumption that Justice Rehnquist makes.

Are you making an argument that currently in the face of the Final Rule and under whatever circumstances there are today that absent Title X funding there is no unfettered access?

MS. RICH: We're not bringing an undue burden claim in this case.

THE COURT: I understand that. That's why I'm analogizing this, in order to establish an unreasonable barrier to the ability.

Other than the defunding, for instance, and the closure of Title X or scaling down the Title X clinics, is there an unreasonable barrier to the ability of individuals to obtain appropriate medical care in the absence of -- in the aftermath of Title X?

MS. RICH: I absolutely think that it's an unreasonable barrier and that Congress has now prohibited those kind of barriers in the context of -- that are created by the Government in the context of Title X and any other Government program.

THE COURT: What if Congress just simply defunded or drastically cut all Title X monies by 90 percent? Would that violate the ACA?

MS. RICH: No, I don't think so, Your Honor.

THE COURT: Why wouldn't it? If suddenly all clinics not on a choice --

MS. RICH: That would be a situation that would be

more similar to what the Government is describing right now, where Congress can decide to appropriate or not appropriate money.

What we're addressing our 1554 complaint to is not funding or lack of funding. It's the regulations that deliberately create new barriers through the gag rule. Through the separation rule that doesn't allow collocation.

THE COURT: Well, essentially it's an unequal burdening. Isn't that your argument?

I mean, if they did it across the board and made, you know, certain restrictions apply equally to both options or, as I say, drastically cut funding which equally affected both kinds of providers, would that violate 1554? And if not, it sounds like you're arguing really it's almost like discrimination, the erection of special barriers for one option and not the other.

MS. RICH: Yeah. Well, as your Honor may have noticed, we have brought an equal protection claim in our Complaint and we're looking forward to litigating that, but that's not the basis for our P.I. motion.

THE COURT: That's what I'm trying to understand, the 1554 argument.

1554 talks about sort of absolutes on a -- you know, the ability to access healthcare not on an equal basis relative to somebody else, but just the ability to not have an unreasonable

barrier to access.

MS. RICH: I think it's very important that 1554 is directed at the agency's rule making ability. It's not directed at, you know, funding decisions. It's directed at their ability to issue regulations, which is exactly what they were doing here in the Final Rule.

MS. YBARRA: I completely agree, your Honor. 1554 by its terms narrows the authority of the secretary of HHS specifically.

To Your Honor's -- I have one more point I wanted to add. The current regulations won't just result in the exodus and flight from the Title X program that we have been talking about. They will do that. But in addition, the rule requiring mandatory prenatal care referrals creates a barrier to access to timely care for a pregnant woman who might otherwise wish to terminate her pregnancy. And Dr. Marshall's declaration goes through that in detail, describing how that might harm such a woman.

THE COURT: Well, so is there an argument that in a way women would be better off not having to go through this sort of charade and illusion of going to a provider and then being referred to an option that is of no use and no interest to her and that precious time is being wasted.

MS. YBARRA: Yes, Your Honor. That is absolutely the case and that is absolutely the situation described in

Paragraph 22 of Dr. Marshall's declaration, where she details a potential patient who comes to the clinic and has reasons, independent reasons for not wishing to start a family at that point even though she's pregnant, and then the run-around that she would have to endure, and the delays in access to the care that she seeks by having to go through this charade, as I think you aptly put it, of being referred to a prenatal care provider.

THE COURT: What about -- you also have the appropriations argument with respect to the counseling and the referral, but with respect to the separation of facilities, obviously, the Appropriations Act does not -- that's not a basis to challenge the separation of facilities.

So you have the ACA and that's where you have to rely on sort of the effect of --

MS. RICH: So there is the timeliness and there is the creation of a barrier, I think both of which are directly implicated by the separation requirement.

THE COURT: All right. Anything to add, counsel?

MR. BURNHAM: So a couple things.

One thing I would be remiss if I didn't point out. So one of the things that plaintiffs, I know, believe strongly is that prenatal care is unnecessary for women seeking to terminate their pregnancy. I would point out that HHS made a recent determination that prenatal care is always necessary until the

pregnancy is over.

And so I do think that's part of what the Court has to consider in assessing the requirement that referrals be given for prenatal care because until the termination happens HHS is determined, and HHS is an expert in this area, that prenatal care is medically indicated.

THE COURT: Even for someone who wants an immediate abortion?

MR. BURNHAM: I mean, that's what it says at Final Rule 7748.

THE COURT: I know it says that, but what's the medical evidence that supports that?

MR. BURNHAM: Well, I guess there is a question about what "immediacy" means, Your Honor. So I think it just depends.

HHS's point, I believe, is that prenatal care is always something for the woman, as well as for the unborn child, that is medically required until the pregnancy is over. So I just wanted to point that out. That's in the preamble and that's that.

On the point we were just discussing about ***Rust*** and the point you were making about why 1554 -- you weren't making the point, but the question you were asking about why 1554 might not apply. The Supreme Court's more recent decision in ***Legal Services Corporation versus Velazquez***, which is cited in

California's brief, I think underscores the point that your questions were suggesting.

And I'll just give you a quick quote, Your Honor. There they were contrasting legal representation from the relationship in Title X, and they say:

> "This is in stark contrast to *Rust*. There a patient could receive the approved Title X family planning counseling funded by the Government and later could consult with an affiliate or independent organization to receive abortion counseling."

And that's at 531 to 533. That's at Page 547, 2001.

I think the point that *Rust* made and the *Legal Services Corporation* case makes about the First Amendment is equally applicable to 1554 because when the Government is providing a service, which is family planning services that the Government is paying for, limitations on the conditions in which the Government will provide the service are not themselves barriers to care; right? Because as your Honor I think noted, the Government could always just pull the program back.

So I'm not questioning that 1554 is a limitation on the secretary's regulatory authority. What I'm questioning is that it's a limitation on the secretary's regulatory authority in this very narrow, very specific context.

THE COURT: I wonder, though, whether there is certain aspects of the Final Rule here that create a kind of

impediment that perhaps didn't exist or wasn't talked about much in *Rust*. And that is, for instance, requiring somebody to go through -- be referred to prenatal care or -- and I forget whether the ban on referrals was as expressed in 1988 regulations.

MR. BURNHAM: Oh, yes, your Honor. The 1988 regulations prohibited both referring and counseling on abortion and, also, required, quote:

"Once a client served by a Title X project is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services by providing -- by furnishing a list of available providers that promote the welfare of mother and unborn child."

And that's at 53 Federal Register 2945.

THE COURT: All right. So then the question would be raised: How is this more severe? How is this more an impediment than what was upheld in *Rust*?

MS. YBARRA: That's an incomplete quote that counsel just read, Your Honor.

The 1988 regulations stated that requirement and/or that the patient should be referred to social services. And they left that decision to the discretion of the doctor and her sound medical judgment.

THE COURT: Whereas, here it's mandated.

MS. YBARRA: Correct.

THE COURT: All right. Let's move on to the last -- I know there are constitutional claims, but the one I want to address is the APA claim here.

And the question, one question is whether or not this falls into the category of where a more detailed justification, quote/unquote, from the agency is required because the new policy -- it's a new policy, it's a changed policy -- rests on factual findings that contradict those which underlie its prior policy or the prior policy engenders serious reliance interests that must be taken into account.

What are the -- under which or both of those prongs are you asserting that -- I assume you're asserting the more detailed justification standard applies. And I'd like your explanation and what in the record supports one or two of those bases which underpin that higher degree of scrutiny?

MS. YBARRA: Your Honor, we've detailed this argument, citing to *State Farm* specifically.

It's -- after decades of entrenched practice, it's insufficient for the agency to point back to *Rust* and the Supreme Court's reasoning in *Rust* in 1991 that, the point you made earlier, with one permissible reading of Section 1008.

But *Rust* upheld the 1988 regulations based on 1982 reports from the General Accounting Office and the Inspector General. Those reports are now 37 years old. They are undeniably stale.

And they are inapplicable to the landscape today. They concerned entirely different regulations than those the department seeks to rescind here, which have been in effect from 2000 until -- and are still in effect and will be until May 2nd.

So those reports cannot -- those reports that were relied on in *Rust* to justify the changes, the 1988 regulations worked, can't address the regulatory regime in place for the last 20 years.

And Congress has required an agency to make a record of rule making and for the agency to make findings under the APA that are supported by substantial evidence. And the defendants have not done so here.

They cite two documents. One is the -- the only record evidence they cite is a 2014 study finding abortions are increasingly performed at non-specialty clinics and reports of isolated instances where Title X funded centers overbilled Medicaid. Neither of those reflects a real problem regarding the misuse of Title X funds that would justify the extraordinary change that defendants propose to make with these regulations.

To the contrary, what is in the record, it shows that the OPA engages in strict oversight of Title X grantees, including plaintiff Essential Access Health, to guard against fund misuse regarding program reviews, monitoring on-site visits, data

collection, audits. These are detailed in the Rabinovitz declaration at Paragraphs 16 to 18.

Essential Access Health itself monitors compliance by sub-recipients with the program rules by collecting data, doing on-site visits and evaluations.

And OPA itself said in 2017:

"Family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that those funds are not used for prohibited activities such as abortion."

So where there is such a drastic departure from the prior rule, the agency must give a reasoned explanation for the change. But the department, the agency has not given any here. Like I said, the only record evidence they cite are the two -- the study I just mentioned and the isolated instances of Medicaid abuse, but neither of those reflect a real problem.

THE COURT: Well, let me ask you. What I was asking is a more specific question, and that is: Is the new policy, does it rest on factual findings that contradict those which underlay its prior policy? Are you asserting that that's the case here? And if so, what are the factual findings that contradict its prior -- that underlie the prior policy?

MS. YBARRA: I would say those -- there aren't any factual findings, Your Honor. The agency underpins the new policy on a theoretical risk of abuse.

MS. RICH: And can I add --

THE COURT: Wasn't there a determination at one point that under the prior regulations that the current rules and auditing of separation were, of facilities, adequate and working well and anything further was not needed? Was there some reference to that in some -- am I not remembering correctly?

MS. YBARRA: I'm not certain what you're referencing, Your Honor.

With regard to the 1988 regulations that were upheld in *Rust*, there was a finding based on the Inspector General report that I mentioned in the GAO --

THE COURT: I know, and that contrasts here because there is no such study like that.

I'm asking the converse question. I thought there was some reference somewhere to a finding that I thought you had argued was inconsistent with the new separation, the revision of the physical separation; that there was some analysis of that by the agency? But perhaps my memory is not correct.

So my question is: Are you asserting that there -- you're saying there was no factual findings at all. So in a way that sort of obviates that first prong.

And my second question is: Are there -- did the prior policy engender serious reliance interests that must be taken into account? What's your response to that?

MS. YBARRA: Yes, Your Honor. As to the point that you were hunting for, yes, you're correct. The department rejected a similar, nearly identical physical separation requirement in 2000, explaining that the requirement was not likely to ever result in an enforceable compliance policy that's consistent with the efficient and cost effective delivery of family planning services.

And that's cited at Page 16, Line 27 of our opening brief.

And then I believe Ms. Rich wanted to interject. Go ahead.

MS. RICH: The comment that I wanted to make is that there are factual assertions in the Final Rule along the lines of the Final Rule will not cause a decrease in access to contraception, would be one thing that the Final Rule does assert. And I guess you could call it a factual finding.

And there is substantial evidence in the administrative record that that's not true; that, in fact --

THE COURT: Well, not that it's not true. Does it contradict those which underlay the prior policy?

So, for instance, if the prior policy was based on fact X and now the new policy is based on Y, that is one reason to heighten sort of the level of review.

MS. RICH: Absolutely. So the prior policy was based on the assumption that including, for instance, specialized women's health facilities would result in increased access to

contraception.

THE COURT: So was that a finding that was expressed in the prior regulations?

MS. RICH: I'll have to double check that, Your Honor.

THE COURT: What about the reliance interest, serious reliance interest? Do you assert that here?

MS. YBARRA: Yes, Your Honor, we do. The Department has failed to consider -- which is itself a violation of the APA as arbitrary and capricious. They failed to consider the disruption its decision would cause.

And as Ms. Rich just alluded to, state without any -- without any evidence and contrary to voluminous evidence in the record by commenters about the effects that the Final Rule will have on access to quality care and reproductive services.

THE COURT: Well, what are the reliance interests then?

MS. RICH: Well, for instance, you know, Title X providers have been able to invest in single electronic health records or single -- they can have both -- or centralized administrative responsibilities that now, if they wanted to continue being a Title X provider, they would have to do separately.

So the amount of investment in administrative costs that's now going to be doubled, they might have made different

decisions about how they arranged their business --

THE COURT: What about physical facilities?

MS. RICH: And the physical facilities as well, you know.

THE COURT: Is there evidence in the record about this?

MS. RICH: There is certainly a great deal of evidence in the record about the costs associated with the separation requirement. And I think that you can impute that there is a great deal of reliance interest associated with having to undergo those costs.

THE COURT: All right. Let me ask the Government. There are several formulations of what is required of the Government. I'm sure each side will advocate the one that's most favorable to it. But it appears that one has to search the record long and hard for any, quote, evidence. What we consider -- I mean, there is suppositions. There is policy. There is the general interests of the Government in being able to pursue the policy concerns.

But unlike what was in *Rust*, which preceded the *Rust* regulations, where you had Government reports that found some serious problems, I've not seen that in this record here.

MR. BURNHAM: Right. So I think, Your Honor, if I could just take a step back. This sort of loses the forest from the trees.

This is really -- the arbitrary and capricious claims are just the statutory claims repackaged. Because if HHS is right, that it's a reasonable interpretation of Section 1008, that you can't, for example, have cross subsidization of abortion through economies of scale, then there is no question that Section 1008, as they understand it, is being violated all over the place. That's the plaintiff's whole claim.

When the plaintiffs say that the Final Rule will increase their costs, what they mean is it will remove economies of scale. Because what's happening right now is Title X programs are cross subsidizing abortion, referral -- you know, the provision of abortion and things like that by having a shared administrative apparatus, by having the various things that California's counsel was just suggesting.

So if HHS is correct on the legal point -- and I know you haven't decided that yet, but if you agree with me that HHS's construction of 1008 is a reasonable one under *Chevron*, then I think arbitrary and capricious just falls way because there is, obviously, widespread violation of the Final Rule. That's the reason we're all here in front of you today.

So another good example is abortion referrals; right? There is plenty of evidence that people are referring for abortion. That's the whole point of the lawsuit. The plaintiffs want to be able to refer for abortion. They think they have a legal entitlement to refer for abortion and think

HHS is wrong. That's a legal dispute, whether HHS is wrong. But if HHS is right about what Title -- Section 1008 reasonable can prohibit, then that factual -- I mean, you know, the factual finding is obvious. It's stipulated. It's the whole predicate of the case.

And so I think that's why if you actually look at *Rust*, the discussion of the reports is like this very small thing at the very end of the opinion. And if you look at the Second Circuit opinion that underlay *Rust*, which is a case *Massachusetts versus* -- sorry, I forget who the defendant was. Probably a federal official. 899 F.2d at Page 63. They call the reports a, quote, slim read to underlay the rule. But they upheld the rule because what was really at issue in the case -- it's not a factual record case. You know, are the polluters emitting a certain level of CO_2 into the atmosphere and did the agency so reasonably determine. It's a legal dispute.

HHS Section 1008 is best read to require all the things the Final Rule does. Nobody disputes that the things the Final Rule prohibits are happening in the real world every day right now. That's why we're in litigation.

And so I just think when you think about it like that, it's very clear that the record --

THE COURT: Well, but you -- you say it's the -- the citation by the Supreme Court to the GAO and the OIG critical reports were just kind of an afterthought at the end. I'm not

so sure when you look at that. The Court first had to find in determining whether to uphold this interpretation of Title X that the legislation and the legislative history was ambiguous enough to then allow some deference to -- to the agency.

And one of the first things it does, what the Court does is says we find that the secretary amply justified his changed interpretation with a reasoned analysis, quote/unquote. That implies even with the benefit of *Chevron*, even with the benefit of an ambiguous statute, et cetera, et cetera, you have to at least have a, quote, reasoned analysis.

MR. BURNHAM: Oh, absolutely, Your Honor. And I think that's certainly the requirement.

What I'm saying is HHS's analysis is totally reasoned --

THE COURT: Well --

MR. BURNHAM: Because --

THE COURT: -- and then the very first thing that Justice Rehnquist talks about after saying "reasoned analysis" is the secretary's explanation in response, in wake of the critical reports, et cetera, et cetera.

So that was the first thing that was mentioned. And so to say that those were secondary and unimportant, I'm not convinced of that.

MR. BURNHAM: Sorry, Your Honor. I guess I don't mean to suggest -- I mean, I guess I am suggesting that they were not central to the Court's opinion. And if you read the

rest of that paragraph, I think it's fairly clear that what they are saying -- what the Court goes on to say is he also determined that the new regulations were more in keeping with the original intent of the statute, et cetera.

THE COURT: It's multi-factored. He also says just by my, quote, client experience under the prior policy -- which, I guess, assumed there must have been some record of client experience -- and supported by a shift in attitude.

So there is several ingredients. You've got an ambiguous statute. You've got a basis, an empirical basis based on some studies that were done, but also some policy concerns. The Court does not create a hierarchy. I don't know which one of those --

MR. BURNHAM: So, yes. So two things, Your Honor.

The *Chevron* question, is the statute ambiguous, is this a reasonable construction, is a purely legal question. That is a distinct analysis from the arbitrary and capricious analysis.

On the latter, I just don't know what kind of evidence we would need. I mean, the plaintiffs don't dispute that they are doing things that violate the Final Rule. That's conceded. That's the entire point of the case. All of --

THE COURT: It begs the question. That assumes that the secretary's interpretation --

MR. BURNHAM: Yes.

THE COURT: -- of Title X prevails and that's part of

what we're talking about.

MR. BURNHAM: Absolutely, Your Honor. But that -- that question, the question of whether the secretary's interpretation is a reasonable one, is a legal question and it's one that *Rust* has already resolved. Because *Rust* has already held -- and it's unusual to have a Supreme Court opinion that's directly on point, but we happen to have one here, that the secretary's construction of the statute is permissible.

There is one point I wanted to go back to. There was a suggestion that I may have misquoted the 1988 regulation, and if I did, I apologize. I think it's worth just giving Your Honor the -- the actual quotation because do think it's very important and shows the '88 regulation was more severe -- or more restrictive, I should say, than the current one.

59.8(a)(1) says very plainly:

"A Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning," full stop.

The next paragraph says:

"Because Title X funds are intended only for family planning once a client serviced by a Title X project is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services by

furnishing a list of available providers that promote the welfare of the mother and unborn child."

It then goes on to say:

"In cases in which emergency care is required, however, the Title X project should be required only to refer the client immediately to an appropriate provider of services."

The current rule has the same thing. So the current regulation allows referral for abortion if it's a medical emergency or a medical necessity. And it's clear that using it as a method of family planning does not include when it's a medical necessity.

So the regulation that the Supreme Court said in *Rust* fell within the ambit of ambiguity under Section 1008 is more restrictive than the one in front of Your Honor today.

On the evidentiary point, the arbitrary and capricious point, there is just no -- I mean, there is no dispute that there is a lot of things happening that violate Section 1008 as HHS has construed it.

THE COURT: All right. Let me ask for final comment on the plaintiff's side.

MR. BURNHAM: Can I say one more thing on reliance, Your Honor? I apologize.

THE COURT: Well, let me -- I want to get a response to this. That is, what's the relationship between whether or

not the regulation, the Final Rule, is a reasonable interpretation of Title X, perhaps under a *Chevron* deference standard, and whether or not it is arbitrary and capricious? Does the first answer determine the last?

What's the relationship between those two questions? Arbitrary and capricious versus reasonable interpretation.

MS. YBARRA: Your Honor, taking it back to *Rust*. *Rust* did not interpret definitively --

THE COURT: I understand. It upheld what it concluded was one reasonable interpretation.

Is that the inquiry here, that -- whether this is a reasonable interpretation or -- is that the same question or is it a different question than whether the regulation we're looking at here is arbitrary and capricious and non-compliant with the APA.

MS. YBARRA: I believe it's a slightly different question, Your Honor, which is has the -- has the secretary sufficiently justified the Final Rule through reasoned decision making and reasoned rule making and given adequate justifications for the drastic departures from prior practice and the prior rules.

I would like to address --

THE COURT: Mr. Burnham argues that if this is a reasonable interpretation, that kind of ends the inquiry. If this survives *Chevron*, it kind of doesn't matter whether there

was a basis, a factual basis, or was done without empirical basis and contrary to the better evidence, et cetera, et cetera.

MS. YBARRA: I think that there are perhaps two sides to the same coin. Whether or not it's a reasonable interpretation, the inquiry still is the same. The agency is required to supply a reasoned analysis for its change, for its departure from past practice, and it has not done that here.

THE COURT: Has that standard of looking at it for change applied to interpretations of statutes, a *Chevron* interpretation of statutes, as opposed to just fulfilling a statute?

MS. RICH: I think Your Honor may be raising a very important question, which is does the Final Rule -- is it a reasonable way to fulfill the purpose of Title X? The purpose of Title X is to provide effective -- a wide range of effective family planning methods.

And I think even if, you know, the abortion question were not -- you know, even if there weren't Section 1008 or you resolved it one way or another, there would still be many, many questions that are raised by the Final Rule making about whether what they are doing here is going to -- is going to promote the purposes of the Public Health Service Act.

THE COURT: That inquiry you just mentioned, is that different from the question of whether or not this is a

reasonable and valid interpretation of the Act or is that a separate legal question?

MS. RICH: It's separate from the question about the reasonable interpretation of 1008. There is definitely that. And a decision either way on that certainly would narrow the issues that were at stake, but I think there are a great number of questions about whether the Final Rule was arbitrary and capricious that we've made a very strong showing on.

THE COURT: All right.

MS. YBARRA: Your Honor, one point I need to correct the record on.

Mr. Burnham suggested that it follows from the agencies, the healthcare agencies having to spend sums to comply with the rule, that they were cross subsidizing, previously cross subsidizing abortion related services improperly, and that's not the case.

I think plaintiffs give sufficient -- or many examples of activities, non-Title X funded activities, undertaken by Essential Access Health. These are outlined in the --

THE COURT: I think his argument is that if the agencies' current interpretation is correct and the interpretation, then the activities that have been done heretofore were not consistent with the now current interpretation.

MS. YBARRA: Part of the problem, Your Honor, is that

the regulations are so unclear, they are going to have a chilling effect and shut down an whole -- Essential Access Health is not a healthcare provider. They do advocacy, training, education, activity that merely discusses abortion and pregnancy options in a pregnancy options counseling context. And those activities arguably would have them in violation of the rule and they would have to construct a mirror agency at the -- you know, exorbitant expense.

THE COURT: All right. I will give you one closing comment and we're going to conclude.

MR. BURNHAM: I will be very, very quick.

Your Honor, there is a D.C. Circuit case that talks about what I was discussing, arbitrary and capricious. *Arent versus Shalala* --

THE COURT: Which one?

MR. BURNHAM: *Arent* -- I'll give you the citation. Arent *versus Shalala*, 70 F.3d 610. That footnote six actually talks about *Rust* and makes a similar point to the one I've advanced.

On the change in circumstance, the change in position, *Rust* projected the exact same argument because it was a change in position in the '88 regs on reliance. This is a year-to-year grant program. Every grant lasts one year. Every grant -- it makes clear that it creates no reliance in terms for future years.

So I don't think there is any case -- I have not seen a case that suggests there can be reliance interests that are relevant to the APA analysis when you're talking about a prospective year-to-year grant program.

The last thing. I would be absolutely remiss if I didn't encourage Your Honor. If Your Honor disagrees with me about everything I've said so far, you should limit the injunction you grant to the State of California. I think that is presented very well in our briefs. I don't have a ton to add.

The only thing I would add is the Final Rule is severable. It's got an explicit severability requirement at 7725 of the Final Rule.

And so if Your Honor thinks, for example, that counseling and referral are the same thing and that part of it falls, the program separation requirements are identical, really identical to the ones in 1988. And I think *Rust* squarely forecloses that issue.

Unless the Court has any questions.

THE COURT: I've got lots more questions, but we're out of time. I understand there are Constitutional claims and I understand the scope of an injunction. I think you've briefed that.

So I will take everything under consideration, under submission at this point.

MS. YBARRA: Your Honor, one final brief point. If

the Court is inclined to deny a request for a preliminary injunction, plaintiffs would ask that you afford us a 30-day injunction so that we have time to seek relief from the Ninth Circuit on an emergency basis.

THE COURT: I think -- well, the Government will probably --

MR. BURNHAM: If Your Honor would like to deny the injunction...

THE COURT: Whatever I do would be stayed for some period of time.

I think whatever I do, I'm going to do what I'm going to end up doing and then I will invite either party to do what it wants to do.

MS. YBARRA: Thank you, Your Honor.

THE COURT: I can't forecast at this point.

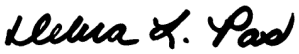
MR. BURNHAM: Thank you, Your Honor.

THE COURT: Appreciate it. Thank you for the arguments. Helpful.

(Proceedings adjourned.)

CERTIFICATE OF OFFICIAL REPORTER

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.



Debra L. Pas, CSR 11916, CRR, RMR, RPR

Thursday, May 2, 2019