July 30, 2018

To:
Family Planning, U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 716G
200 Independence Avenue SW, Washington, DC 20201

Subject: Family Planning — Comment on RIN 0937-ZA00, "Compliance with Statutory Program Integrity Requirements"

On May 17, 2018, the Office of Information and Regulatory Affairs (OIRA) received RIN 0937-ZA00, "Compliance with Statutory Program Integrity Requirements" (the "proposed rule"),[1] a proposed rule submitted by the Department of Health and Human Services (HHS or "Department"), Office of the Assistant Secretary for Health (OASH), Office of Population Affairs (OPA) or "HHS/OASH/OPA" to revise the Code of Federal Regulations, Title 42, Part 59 pertaining to Title X of the Public Health Service Act ("PHS Act"), 42 U.S.C. §300 *et seq.* With this proposed rule, HHS/OASH/OPA aims to "ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning."[2] On June 1, 2018, RIN 0937-ZA00 was published in the Federal Register as a proposed rule and HHS/OASH/OPA invited stakeholders to submit comments.

The Population Research Institute (PRI) is grateful for the opportunity to submit a comment to HHS/OASH/OPA on RIN 0937-ZA00 (Docket No. HHS–OS–2018–0008), "Compliance with Statutory Program Integrity Requirements." PRI is a non-profit non-governmental organization that promotes respect for human rights in the context of population and family planning issues and in population assistance programming and policy. PRI does not receive funding from the U.S. Government.

PRI strongly supports HHS/OASH/OPA's proposed rule, expect where PRI makes recommendations in Part III of this Comment for steps HHS/OASH/OPA should take to ensure that Title X programming properly complies with statutory requirements under the PHS Act and other federal statutes. PRI also makes several general recommendations in Part IV of this Comment on key elements in the current proposed rule that should be included in the Department's final rule. PRI asks that HHS/OASH/OPA adopt the proposed rule as a final rule verbatim as it was published in the Federal Register on June 1, 2018 (83 Fed. Reg. 25529-25533) except where changes are recommended in Part III of this Comment.

Part I: Definitions for the Purposes of This Comment

[1] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 et seq. (Jun. 1, 2018) (proposed rule to be codified at 42 C.F.R. pt. 59).

[2] *Ibid.* at 25,502.

Recipient means any entity that would be defined under §59.2 of the proposed rule (RIN 0937-ZA00) as a "grantee" or "subrecipient," i.e. any recipient or subrecipient of a grant or contract under 42 U.S.C. §300 *et seq.*

Part II: Proposed Rule to Title X Regulations Should Be Adopted as Published in 83 Fed. Reg. 25529-25533

HHS/OASH/OPA has the authority to make regulations for grants and contracts authorized through Title X of the PHS Act "as the Secretary may promulgate."[3] As noted by HHS/OASH/OPA,[4] the Supreme Court ruled in *Encino Motorcars, LLC v. Navarro*, 579 U.S. __ (2016) that federal agencies need only provide a reasoned explanation for a rule change, which HHS/OASH/OPA has already provided.[5]

The language of §§59.13, 59.14, 59.15, 59.16 and the definitions for "family planning," "grantee," and "project/program" in §59.2 in the proposed rule are not substantially different from the language adopted by the Department in §§59.2 and 59.7-59.10 at 42 C.F.R. Part 59 on February 2, 1988.[6] As noted by HHS/OASH/OPA, the Supreme Court upheld the Department's regulations on Title X at 42 C.F.R. Part 59 (1989 ed.), including §§59.7-59.10, on both statutory and constitutional grounds[7] in its decision in *Rust v. Sullivan*, 500 U.S. 173 (1991). Thus, it is entirely unnecessary for HHS/OASH/OPA to, in any way, modify or lessen the restrictions outlined in §§59.13-59.16 of the proposed rule in pursuit of the Department's obligation to ensure statutory compliance with sec. 1008 of the PHS Act.

The Supreme Court made clear in its decision in *Maher v. Roe*, 432 U.S. 464, 474 (1977) that the government may "make a value judgment favoring childbirth over abortion, and to implement that judgment by the allocation of public funds."[8] In *Harris v. McRae*, 448 U.S. 297, 325 (1980), the Supreme Court found that the government's interest in prohibiting public funds from being used to fund abortion was "rationally related to the legitimate governmental objective of protecting potential life."[9] As the Supreme Court found in *Harris v. McRae*, denying public funding for abortion is by no means contrary to the Court's precedent in *Roe v. Wade*, 410 U.S. 113 (1973) because preventing the use of public funds to pay for abortion "places no governmental obstacle in the path of a woman who chooses to terminate her

[3] Public Health Service Act, sec. 1006, 42 U.S.C. § 300a–4(a).

[4] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502, 25,505 (Jun. 1, 2018).

[5] *Ibid.*

[6] Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion Is a Method of Family Planning; Standard Compliance for Family Planning Services Projects, 53 Fed. Reg. 2,922, 2,944–2,946 (Feb. 2, 1988) (final rules codified at 42 C.F.R. pt. 59).

[7] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502, 25,503 (Jun. 1, 2018).

[8] Maher v. Roe, 432 U.S. 464, 474 (1977).

[9] Harris v. McRae, 448 U.S. 297, 325 (1980).

pregnancy."[10] Thus, the government is free to prohibit public funding for abortion in a government health program and need not prove a "compelling interest" in order to do so.[11]

In *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989), the Supreme Court reasoned that the government need not restrict a ban on funding for abortion simply to direct funding for the abortion procedure but the government may also choose to deny funding for auxiliary means through which abortion is provided, including denying public funding for facilities or personnel that provide abortion services.[12] The Court also found that the government need not participate in facilitating women's access to abortion, declaring, "the State need not commit any resources to facilitating abortions."[13] Thus, HHS/OASH/OPA is within its rights to assure that Title X funds are not used in public programs that facilitate abortions.

In *Rust v. Sullivan*, the Supreme Court held that the Department's regulations at 42 C.F.R. Part 59 (1989 ed.) were not contrary to Title X recipients' or applying entities' First Amendment rights. The Court maintained that the proposition that the government, when subsidizing a particular viewpoint, "must subsidize analogous counterpart rights" had been "soundly rejected" by the Court.[14] The Court rejected the notion that 42 C.F.R. Part 59 (1989 ed.) sought to "discriminate invidiously"[15] against the excise of free speech, stating that the Department's regulations were found to simply be "a prohibition on a project grantee or its employees from engaging in activities outside of its scope."[16] Rather, the Court found, the Department was "simply insisting that public funds be spent for the purposes for which they were authorized."[17]

HHS/OASH/OPA is thus within its authority to promulgate §§59.2 and 59.13-59.16.

HHS/OASH/OPA is also within its authority to remove §59.3(b) from the current regulations as no provision of the PHS Act or any other relevant federal law requires the Department to adopt this

[10] Harris v. McRae, 448 U.S. 297, 315 (1980).

[11] *See* Maher v. Roe, 432 U.S. 464, 477 (1977): "a State is not required to show a compelling interest for its policy choice to favor normal childbirth."

[12] *See* Webster v. Reproductive Health Svcs., 492 U.S. 490, 510 (1989): "Having held that the State's refusal to fund abortions does not violate Roe v. Wade, it strains logic to reach a contrary result for the use of public facilities and employees. If the State may "make a value judgment favoring childbirth over abortion and . . . implement that judgment by the allocation of public funds," Maher, supra, at 432 U. S. 474, surely it may do so through the allocation of other public resources, such as hospitals and medical staff."

[13] Webster v. Reproductive Health Svcs., 492 U.S. 490, 511 (1989).

[14] Rust v. Sullivan, 500 U.S. 173, 194 (1991).

[15] Rust v. Sullivan, 500 U.S. 173, 192 (1991) (quoting Regan v. Taxation With Representation, 461 U.S. 540, 548 (1983), quoting Cammarano v. United States, 358 U.S. 498, 513 (1959), quoting Speiser v. Randall, 357 U.S. 513, 519 (1958), quoting American Communications Assn. v. Douds, 339 U.S. 382, 402 (1950)).

[16] Rust v. Sullivan, 500 U.S. 173, 194 (1991).

[17] Rust v. Sullivan, 500 U.S. 173, 196 (1991).

interpretation. Removing §59.3(b) would reduce confusion in implementing Title X regulations as the paragraph has been invalidated by Congress[18] and has no force or effect in any event.

It would seem that HHS/OASH/OPA is also within its authority to promulgate §§59.11 and 59.17. While these sections were not a part of the Department's 42 C.F.R. Part 59 (1989 ed.) upheld by the Supreme Court in *Rust v. Sullivan*, these sections merely require Title X projects to comply with State and local laws.

It would also seem that HHS/OASH/OPA has the authority to promulgate §59.18. Ensuring the appropriate use of funds, including by prohibiting Title X recipients from expending Title X funds for infrastructure costs in support of a recipient's abortion business, is necessary for the Secretary to ensure that Title X funds are not comingled with or used in support of expenditures for prohibited abortion-related activities. This is necessary to ensure statutory compliance with sec. 1008 of the PHS Act. Furthermore, the requirements set forth in §59.18 are necessary to ensure that the Secretary is able to effectively implement the maintenance of physical and financial separation between Title X services and prohibited abortion-related activities as would be required under §59.15 if the proposed rule is adopted. In *Rust v. Sullivan*, the Supreme Court upheld the Department's regulation requiring physical and financial separation as "program integrity requirements" necessary to enforce the Secretary's interpretation of the sec. 1008. The Court found that the program integrity requirements "are based on a permissible construction of the statute, and are not inconsistent with Congressional intent"[19] and the Court deferred to the Secretary's judgement in implementing this rule.[20]

Therefore, HHS/OASH/OPA should adopt the proposed rule verbatim as it was published in the Federal Register on June 1, 2018 (83 Fed. Reg. 25529-25533), except the sections of the proposed rule as noted in Part III of this Comment below.

Part III: Recommended Changes to the Proposed Rule

A. Require Title X Projects to Maintain Organizational Separation, in Addition to Physical and Financial Separation, Between Title X Services and Prohibited Abortion-Related Activities

In order to maintain the objective programming integrity of Title X projects in compliance with the requirements and purpose of sec. 1008 of the PHS Act, it is necessary that HHS/OASH/OPA require complete separation between Title X services and any activities that directly, or indirectly, support or facilitate access to abortion as a method of family planning.[21] Title X funds cannot be used in programs where abortion is promoted or supported as a family planning option and thus it is essential that Title X projects are clearly distinct from organizations that engage in prohibited abortion-related activities. In order to ensure statutory compliance with sec. 1008 of the PHS Act, HHS/OASH/OPA must implement

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[18] *See* Providing for congressional disapproval under chapter 8 of title 5, United States Code, of the final rule submitted by Secretary of Health and Human Services relating to compliance with title X requirements by project recipients in selecting subrecipients, Pub. L. No. 115-23, 131 Stat. 89 (2017).

[19] Rust v. Sullivan, 500 U.S. 173, 188 (1991).

[20] Rust v. Sullivan, 500 U.S. 173, 190 (1991).

[21] *See* 83 Fed Reg. 25,502, 25,505.

effective policies to ensure that Title X projects do not support abortion by any means. To this end, the HHS/OASH/OPA is correct in requiring projects to maintain complete physical and financial separation between Title X services and abortion-related activities.

However, mere physical and financial separation is not enough to ensure program integrity. Even with physical and financial separation, Title X recipients are still able to engage in prohibited abortion-related activities under the same organization name, the same logo and operate under the same organization headquarters as parts of the organization involved with providing a Title X project. This could serve as a point of confusion for some clients who may not be familiar with the fine print of how HHS regulates its Title X program. Clients may also not have the time or ability to make the careful distinction between a) 'Title X recipients when they are operating in their capacity as part of a Title X program, not offering abortion services' and b) 'Title X recipients when they are operating in their private organizational capacity, offering abortion services.' Clients may be misled into believing that a Title X recipient, which is part of a Title X program at one location, must also be a Title X project participant at other locations. It is conceivable under this arrangement that potential clients would mistakenly seek Title X services at recipients' locations not participating in a Title X project. This will complicate service delivery for potential clients as they may be forced to pay out of pocket for services they assumed would be discounted through a government program or they may have to face being turned away from services. On the other hand, they may also be unexpectedly confronted with abortion counseling at non-Title X locations which they would not have been required to endure had the clinic been under the purview of a Title X project.

Moreover, Title X recipients that engage in prohibited abortion-related activities are currently allowed to include both abortion and Title X services under the same tax return. This arrangement may reduce an organization's accounting costs and tax burden by allowing them to pool together both abortion and Title X services revenue for tax purposes. In doing so, the Government is providing organizations that perform or promote abortion with special tax treatment that would not seem to be afforded to them under a correct interpretation of sec. 1008 of the PHS Act.

Thus, it is necessary that HHS/OASH/OPA amend its proposed rule to require Title X projects to maintain "complete physical, financial, and organizational separation" between Title X services and prohibited abortion activities. HHS/OASH/OPA should require that Title X recipients that wish to engage in prohibited abortion-related activities must establish an organization completely legally distinct from the grantee (or subrecipient) in which to engage in such activities. HHS/OASH/OPA should require that the Title X recipient may only engage in prohibited abortion-related activities through a legally distinct, organization that is also maintains physical and financial separation from Title X programming.

HHS/OASH/OPA is fully within its rights to require organizational separation. The Supreme Court in *Chevron U.S.A. Inc. v. Natural Resource Defense Council, Inc.*, 467 U. S. 837 (1984), found that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer" and that the federal agency should thereby be given deference when interpreting statues within its mandate.[22] HHS/OASH/OPA is within its rights to interpret sec. 1008 of the PHS Act according to the plain language of the text and in accordance with Congressional intent on the matter. The plain language of sec. 1008 of the PHS does not preclude an interpretation that Title X projects must maintain organizational separation, and there is nothing to indicate that Congressional intent would be opposed to this arrangement when allocating Title X funds.

[22] Chevron U.S.A. Inc. v. Natural Resource Defense Council, Inc., 467 U. S. 837, 844 (1984).

In *Rust v. Sullivan*, 500 U.S. 173, the Court upheld the HHS' "program integrity requirements" under the Title X rule introduced on February 2, 1988 which maintained, as the current proposed rule does, that Title X projects must maintain physical and financial separation. The Court found that the program integrity requirement did not conflict with Congressional intent and stated that it "defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition."[23] Requiring organizational separation would only add a discrete and logical extension of the program integrity requirements upheld in *Rust v. Sullivan*.

Requiring organizational separation would not impose "unconstitutional conditions" on the recipient because it would not "deny a benefit"[24] to an organization that wishes to engage in abortion-related activities. The recipient organization would be free to engage in those activities simply by establishing a separate organization for that purpose. In *FCC v. League of Women Voters of California*, 468 U.S. 364 (1984), the Court ruled that it was impermissible for the Government to require television and radio stations recipient of government grants to refrain from all editorializing. However, the Court also reasoned in that case that had the Government allowed grantees to "establish *affiliate' organizations which could then use the station's facilities to editorialize with nonfederal funds, such a statutory mechanism would plainly be valid.*"[25] Thus, the Government can clearly require organizational separation when making grants, just so long as it does not prevent grantees from establishing a separate organization in which to engage in these activities. The Title X regulations create no such boundary in establishing separate organizations and thus would be able to require organizational separation when making Title X grants and contracts.

In *Reagan v. Taxation With Representation*, 461 U.S. 540 (1983), the Court found that requiring a 501(c)(3) organization to establish a separate 501(c)(4) organization in order to engage in lobbying activities does not in any way create a substantial burden on an organization's First Amendment right to free speech. According to the Court, "The IRS apparently requires only that the two groups be separately incorporated and keep records adequate to show that tax-deductible contributions are not used to pay for lobbying. This is not unduly burdensome."[26] Similarly, requiring a 501(c)(3) organization or any other organization to simply establish another 501(c)(3) (or another organization) in order to engage in abortion-related activities would not unduly burden a Title X recipient. Requiring organizations to maintain physical and financial separation in a Title X project in most cases would impose a greater burden on a Title X recipient than a requirement for organizational separation would. The Supreme Court upheld the Department's more burdensome requirement for maintaining physical and financial separation and thus, there should be no reason that a requirement for organizational separation would not be upheld on similar grounds. Requiring organizational separation would not unduly burden Title X recipients as some Title X recipients already maintain organization separation for tax purposes. Take, for example, the Planned Parenthood Federation of America (PPFA) which maintains a 501(c)(3) organization for qualifying activities and maintains a separately organized 501(c)(4) through which it engages in lobbying activities. A number of PPFA's affiliates also maintain separate 501(c)(3) and 501(c)(4) organizations.

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[23] Rust v. Sullivan, 500 U.S. 173, 190 (1991).

[24] Perry v. Sindermann, 408 U.S. 593, 597 (1972); *see also* Rust v. Sullivan, 500 U.S. 173 (1991).

[25] Rust v. Sullivan, 500 U.S. 173, 197 (1991) (quoting FCC v. League of Women Voters of California, 468 U.S. 364, 400 (1984).

[26] Regan v. Taxation With Representation, 461 U.S. 540, 544 (1983).

In *Rust v. Sullivan*, the Court upheld the "program integrity requirements" of the Government's Title X regulation in-part because "The Title X *grantee* can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds."[27] Requiring that a Title X project maintain organizational separation would not fundamentally change the situation: Title X recipients would be free to continue providing abortion-related services so long as it conducts those activities with an organization separate and independent from the organization participating in a Title X project.

HHS/OASH/OPA should require that Title X projects maintain "complete physical, financial, and organizational separation" between Title X projects and prohibited abortion-related activities.

B. Remove the Allowance for Passive Abortion Referral in §59.14

§59.14 in the proposed rule would prohibit Title X projects from performing, promoting, referring for, or supporting abortion as a method of family planning. §59.14 also prohibits the project from taking any other affirmative action to assist the patient or client in having an abortion. These provisions are absolutely crucial to ensuring that public funds for Title X are not "used in programs where abortion is a method of family planning."[28]

The act of providing abortion referrals inextricably links the provider with the prohibited abortion activity. An abortion referral—regardless of whether it is provided to the client after the client specifically requests it or not—provides the client with resources that directly assist the client in obtaining an abortion.

§59.14(a) of the proposed rule as written allows a medical doctor in a Title X project to:

> "provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is currently pregnant clearly states that she has already decided to have an abortion. This list is only to be provided to a woman who, of her own accord, makes such a request."[29]

But providing a patient who clearly states her intention to have an abortion with a list of services providers of which "some…also provide abortion" is not substantially different from providing a direct abortion referral and this activity can be carried out with the same intent as providing a typical abortion referral. Providing a list which includes abortion providers is a form of passive referral not substantially different from providing a direct referral. The act of providing a list of abortion providers necessarily facilitates the abortion by providing the client with resources necessary to obtain an abortion.

There is also nothing under the proposed rule as it is currently written to prevent a doctor from providing this list more frequently than what would be necessary. The Consolidated Appropriations Act, 2018 (Pub.

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[27] Rust v. Sullivan, 500 U.S. 173, 196 (1991).

[28] Public Health Service Act, sec. 1008, 42 U.S.C. §300a-6.

[29] 83 Fed. Reg. 25,502, 25,531.

L. 115-141) prohibits any funds appropriated under Division K of that Act to be expended for abortions except in cases of a "woman [who] suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed."[30] In the same spirit, HHS/OASH/OPA should not require doctors in a Title X project to provide abortion referrals (passive or otherwise) except in the case of a medical emergency in which the pregnancy is the cause of a life-endangering physical condition. There is nothing in the PHS Act or elsewhere preventing HHS/OASH/OPA from interpreting sec. 1008 of the PHS Act in this way and Congressional intent would not seem to contradict this interpretation. HHS/OASH/OPA describes its own proposed rule as one in which "Title X projects would not directly *or indirectly encourage or promote abortion* as a method of family planning through the manner in which referrals are made" (emphasis added).[31] It is unclear, then, why HHS/OASH/OPA has created a specific exemption (that is to say, a "loophole") for Title X recipients to provide passive abortion referrals when a pregnant woman asks for one.

HHS/OASH/OPA attempts to justify allowing Title X doctors to provide lists to their patients that include abortion providers by citing the provision of the Consolidated Appropriations Act, 2018 which states that "all pregnancy counseling shall be nondirective" when using Title X funds.[32] HHS/OASH/OPA argues that, because of this, "a doctor would be permitted to provide nondirective counseling on abortion" and, more still, that, because of this provision, a doctor *should* be permitted to "provide nondirective counseling on abortion."[33]

However, HHS/OASH/OPA is mistaken in its interpretation of Pub. L. 115–141. Pub. L. 115–141 *does* stipulate that all "pregnancy counseling" funded with Title X appropriations "shall be nondirective," but it by no means requires that Title X appropriations be used to provide "nondirective" "pregnancy counseling" in the first place. HHS/OASH/OPA is just as free not to use Title X appropriations for any "pregnancy counseling" at all. In fact, HHS/OASH/OPA's definition of "family planning" in §59.2 indicates that HHS/OASH/OPA has chosen to interpret "family planning" to *exclude* pregnancy counseling or services of any kind. Indeed, §59.2 in the proposed rule states "Family planning does not include postconception care (including obstetric or prenatal care)."[34] Family planning services provided by a Title X project do not provide postconceptional services and therefore, by definition, cannot include abortion services, including "nondirective counseling on abortion." There is no need then for HHS/OASH/OPA to make an exemption for abortion referrals in cases where a pregnant woman who has decided to have an abortion asks where such services may be obtained.

Rather, a client who is pregnant and clearly states that she has decided to have an abortion and of her own accord requests where abortion services can be obtained should be informed by the Title X recipient that the Title X project does not offer abortion services and does not provide abortion referrals. Recognizing the doctor's duty to protect patient health and safety, the doctor may, however, of his or her own accord and in his or her professional judgement, refer the patient qualified, comprehensive health service providers that do not provide abortion. They may also offer the patient a list of licensed, qualified,

[30] Consolidated Appropriations Act, 2018, Div. H, Title V, sec. 507(a), Pub. L. No. 115-141, 132 Stat. 348, 764 (2018).

[31] 83 Fed. Reg. 25,502, 25,518.

[32] Consolidated Appropriations Act, 2018, Pub. L. No. 115–141, 132 Stat. 716-17 (2018).

[33] 83 Fed. Reg. 25,502, 25,507.

[34] 83 Fed. Reg. 25,502, 25,529.

comprehensive health service providers, none of which offer abortion services, the same list that the Title X recipient would have provided to any other client under the proposed rule. It is important that Title X service providers be able to provide their clients with referrals to comprehensive health care service providers that do not provide abortion, even without their clients requesting a referral. Doctors have a duty to protect the health and safety of their patients and must be permitted to refer women to prenatal, obstetric, mental health care services, relationship counseling, and other health care services as necessary and appropriate. Pregnancy can cause serious health issues for some women and can, for some women, aggravate underlying health issues that can pose a risk to her health or life. HHS/OASH/OPA is correct in its assessment that:

> "it is not the intent of the proposed regulatory provision at § 59.14 to restrict the ability of health professionals to communicate to a patient any information they discover in the course of physical examination or otherwise about her medical condition, such as a condition that might make her extant pregnancy high risk. Nor would the provision preclude a health professional from disclosing to the woman any physical findings he or she has made regarding her condition and communicating his or her assessment of the urgency of her need for treatment or action, consistent with the exercise of his or her professional judgment, although the treatment or action might fall outside the parameters of the Title X program."[35]

Pregnancy can also be a stressful time for some women, and doctors should be free to provide women with referrals to health services as appropriate which at the same time do not provide abortion or abortion counseling. Pregnancy is also a particularly vulnerable time for the health and development of the unborn child. It is necessary that doctors be free to operate on their professional judgement in referring pregnant women to licensed, qualified, and comprehensive health services as appropriate to promote the health, well-being, and safety of both the client and her unborn child, just so long as Title X service providers, when offering such referrals, do not provide pregnant women with referrals to service providers that provide abortion. Allowing doctors to provide referrals to service providers which actively perform services that terminate the life of the unborn child is contrary to the doctor's duty to protect the health of both the mother and the unborn child and it is contrary to the government's legitimate interest in choosing to promote childbirth over abortion.

If no such licensed, qualified, comprehensive health service providers are located within proximity of the Title X service provider, it is still imperative that the Title X doctor be able to provide the client with access to health services to protect the health and safety of both the client and her unborn child. If no licensed, qualified, comprehensive health service providers that do not offer abortion services are located in proximity to the Title X service provider (within a 100-mile radius of the Title X service facility), the doctor may then (and only then) provide the client with a list of licensed, qualified, comprehensive health service providers (some of which also provide abortion, in addition to comprehensive prenatal care). This list should not identify which providers provide abortion and all of the providers listed should be licensed and qualified to provide wholistic comprehensive health care services (i.e. should be licensed and qualified to provide prenatal and obstetric care).

Thus, the following language should be removed from §59.14(a):

> "If asked, a medical doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care), but only if a woman who is currently pregnant clearly states that she has already

[35] 83 Fed. Reg. 25,502, 25,518.

> decided to have an abortion. This list is only to be provided to a woman who, of her own accord, makes such a request. The list shall not identify the providers who perform abortion as such."[36]

The following language should be removed from §59.14(c):

> "Recognizing, however, the duty of a physician to promote patient safety, a doctor may, if asked, provide a list of licensed, qualified, comprehensive health service providers (some of which also provide abortion, in addition to comprehensive prenatal care). Such information related to abortion is permitted only if a woman who is currently pregnant clearly states that she has already decided to have an abortion";[37]

and replaced with the following (in §59.14(c)):

> "Recognizing, however, the duty of a physician to promote patient safety, a doctor, in exercising his or her professional judgement to protect patient health and safety, may refer the patient to a licensed, qualified, comprehensive health service provider so long as the health service provider does not provide abortion as a method of family planning, abortion counseling, or services that facilitate in obtaining an abortion. A doctor may, in exercising his or her professional judgement, provide the patient with a list of licensed, qualified, comprehensive health service providers, none of which provide abortion as a method of family planning, abortion counseling, or services that facilitate in obtaining an abortion. A doctor may provide a patient with this list even if the patient is pregnant and has clearly stated that she has already decided to have an abortion.
> If there are no licensed, qualified, comprehensive health service providers within a 100-mile radius of the facility where the patient is receiving Title X services, a doctor may provide a list of licensed, qualified, comprehensive health service providers (some, but not all, of which also provide abortion, in addition to comprehensive prenatal care). This list shall not identify the providers who perform abortion as such. However, if the patient under these circumstances, is a pregnant woman who has clearly stated that she has decided to have an abortion and asks where abortion services can be obtained, the doctor, in the interest of protecting the life of the unborn child, shall be prohibited from providing the patient with a list which includes service providers that provide abortion as such and the doctor shall be prohibited from referring a patient under these circumstances to a provider that provides abortion, abortion counseling, or services that facilitate in obtaining an abortion. The doctor, however, in the interest of the patient's health and safety, may choose to provide a patient under these circumstances with a list of comprehensive health service providers that do not provide abortion, abortion counseling, or services that facilitate in obtaining an abortion, even if these providers are located further than 100 miles from the facility where the patient is receiving Title X services.
> Nothing in this section should be construed as prohibiting a Title X project from referring the client immediately to an appropriate provider of emergency medical services in cases in which emergency care is required."

[36] 83 Fed. Reg. 25,502, 25,531.

[37] *Ibid*.

C. Expand the List of Enumerated Prohibited Activities that Promote Abortion to Ensure Statutory Compliance with 42 U.S.C. §300a–6

In §59.16, the proposed rule enumerates several prohibited abortion-related activities that would qualify as encouraging, promoting, or advocating abortion as a method of family planning. However, the list of prohibited activities in §59.16 is rather short and fails to encompass many activities that should be considered active promotion of abortion under HHS/OASH/OPA's understanding of the term.

While the proposed rule states that a project may not "encourage, promote or advocate abortion,"[38] it is important, for the sake of clarity, that HHS/OASH/OPA enumerate the widest possible range of activities that would be prohibited under the new Title X regulations. This is important for Title X recipients so they have a clear understanding of which activities they may engage in and which they may not engage in. This will prevent confusion and frustration on the part of Title X recipients which may have a good-faith intention to comply with the HHS/OASH/OPA's rule but may be unclear on how to do so. This is also important for aiding the Secretary in ensuring grantee compliance with §§59.14–59.16.

The following are our recommendations for expanding the list of enumerated prohibited activities that promote abortion to ensure statutory compliance with sec. 1008 of the PHS Act:

1. Change §59.16(a)(4) from "Paying dues" to "Providing financial or material support"

§59.16(a)(4) restricts a Title X project from "Paying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning."[39] This is in line with sec. 1008 of the PHS Act which states that no Title X funds shall be used "in programs where abortion is a method of family planning."[40] In order to maintain programming integrity, it is essential that Title X projects are restricted from providing financial support to organizations that engage in the very same abortion-related activities prohibited for Title X projects.

However, the paying of dues are not the only means organizations have at their disposal to financially or materially support another organization engaged in abortion-related activities. Organizations may also engage in other means of supporting partnering organizations including providing grants or funding apart from dues, or providing training, technical assistance, consultation services, or in-kind contributions. If a Title X project provides such assistance to another organization that "as a more than insignificant part of its activities, advocates abortion as a method of family planning,"[41] providing such assistance with Title X funds would necessarily involve the project in promoting abortion.

A Title X project which, for example, engages in providing training on how to perform abortions or which provides training on effective tactics for lobbying for abortion would clearly compromise the integrity of the Title X program. Similarly, a Title X project which provides technical assistance to an abortion provider by providing service statistics on the clinic's monthly volume of abortion clients or

[38] 83 Fed. Reg. 25,502, 25,532.

[39] *Ibid.*

[40] Public Health Service Act, sec. 1008, 42 U.S.C. § 300a–6.

[41] 83 Fed. Reg. 25,502, 25,532.

provides computing systems for tracking abortion equipment inventory would clearly be contrary to the intent and purpose of sec. 1008 of the PHS Act.

There is no reason why HHS/OASH/OPA should restrict its prohibition merely to "Paying dues" to groups or organizations that advocate for abortion. HHS/OASH/OPA should remove the term "Paying dues" from §59.16(a)(4) of the proposed rule and should instead replace this term with "Providing financial or material support." HHS/OASH/OPA should then define "financial or material support" as:

> "the transfer of funds made available under this award or the transfer goods or services financed with such funds, including any tangible or intangible item provided under this Title including but not limited to any training, service, technical advice, in-kind donations, in-kind service, or any item of real property."[42]

2. Prohibit Title X Projects from Providing Abortion Supplies or Equipment

The HHS/OASH/OPA's proposed rule makes it sufficiently clear that performing, promoting, referring for, advocating for, and lobbying for abortion are prohibited abortion-related activities under the Department's interpretation of sec. 1008 of the PHS Act. However, nowhere in the proposed rule is it mentioned that a Title X project is prohibited from providing abortion supplies or equipment.

In the field of foreign assistance programming, some non-governmental organizations recipient of U.S. Government assistance may not preform abortion themselves but are nevertheless actively engaged in procuring abortion supplies such as abortion-inducing drugs. It is possible that Title X projects, under the proposed rule, as currently written, would likewise be able to provide abortion equipment and supplies so long as they do not "perform," "promote," or "refer for" abortion. This is contrary to the text and purpose of sec. 1008. If a Title X project were to provide abortion supplies or equipment, it would necessarily implicate the Title X project in promoting abortion. HHS/OASH/OPA should amend the list of prohibited abortion-related actions in §59.16 as follows:

> "Providing, paying for, transporting, selling, procuring, storing, manufacturing, or distributing supplies and equipment intended to be used for the purpose of inducing abortions as a method of family planning;"

3. Prohibit Title X Projects from Providing Abortion-Inducing Drugs

In the same vein, HHS/OASH/OPA should explicitly prohibit Title X projects from providing abortion-inducing drugs—including mifepristone, misoprostol, and oxytocin—with the intention that they will be used for the purposes of inducing abortion.

In the context of a Title X project which only provides family planning services, there are no circumstances where mifepristone would be necessary to carry out Title X services. Mifepristone has no

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[42] Language here borrowed from U.S. Agency for Int'l Dev. (USAID), Protecting Life in Global Health Assistance, RAA29, STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS, ¶(a)(pt. II)(6)(iv), ADS 303maa, 83 (partial revision: Jun. 7, 2018); *and* Foreign Assistance Act of 1961, § 634(b)(1), Pub. L. No. 87-195, 75 Stat. 424, et seq. (codified as amended at 22 U.S.C. § 2394(b)). While these definitions pertain to definitions of foreign assistance, they can readily be adapted, with slight modifications, for the purposes of the Department's regulations on Title X.

on-label indicated purpose other than to induce an early-term abortion. Mifepristone should never be provided, stored, or distributed through a Title X project.

Misoprostol and oxytocin are uterotonic medications used in the treatment of postpartum hemorrhage and inducing labor, the former typically used primarily only in low-income countries in areas where access to more effective cold-chain medications are scarce. But since Title X projects do not provide postconceptional services, there is no need for the use of uterotonics for this purpose in any event. Furthermore, misoprostol is not registered in the United States for this indication.
Misoprostol can also be used to help prevent gastric ulcers in patients who are susceptible to developing ulcers when taking NSAIDs (i.e. aspirin, ibuprofen, naproxen, etc.). Prevention of gastric ulcers is the only indication for which misoprostol is registered in the United States.

Some OB/GYNs and other physicians that provide family planning services may use misoprostol when inserting an IUD because they may believe that it makes insertion procedure easier for the physician or less painful for the patient. However, the evidence on this is mixed. While some studies have shown that misoprostol may reduce pain or insertion difficulty for some,[43,44] a majority of studies have shown that misoprostol neither makes IUD insertion easier, nor does it appear to reduce patient pain.[45,46] In fact, some studies have shown that misoprostol is actually associated with higher reported patient-perceived pain[47] and pre-insertion side effects[48,49] over the placebo. Misoprostol also does not appear to decrease patient side effects or increase patient satisfaction or acceptability of the IUD insertion procedure compared to patients given diclofenac alone.[50]

The World Health Organization (WHO) recommends the use of misoprostol alone for early-term medical abortion where mifepristone is not available. The WHO maintains well-defined recommendations for

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[43] Lotke PS, Tiwari A, Nuño VL. Inserting intrauterine devices in nulliparous women: is misoprostol beneficial? A registered clinical trial. *Am J Clin Exp Obstet Gynecol*. 2013;1(1):62-8.

[44] Scavuzzi A, Souza AS, Costa AA, Amorim MM. Misoprostol prior to inserting an intrauterine device in nulligravidas: a randomized clinical trial. *Human Reproduction*. 2013 Jun 5;28(8):2118-25.

[45] Lopez LM, Bernholc A, Zeng Y, Allen RH, Bartz D, O'Brien PA, Hubacher D. Interventions for pain with intrauterine device insertion. *Cochrane Database of Systematic Reviews*. 2015;7: CD007373. doi: 10.1002/14651858.CD007373.pub3.

[46] Swenson C, Turok DK, Ward K, Jacobson JC, Dermish A. Self-administered misoprostol or placebo before intrauterine device insertion in nulliparous women: a randomized controlled trial. *Obstetrics & Gynecology*. 2012 Aug 1;120(2):341-7.

[47] Lathrop E, Haddad L, McWhorter CP, Goedken P. Self-administration of misoprostol prior to intrauterine device insertion among nulliparous women: a randomized controlled trial. *Contraception*. 2013 Dec 1;88(6):725-9.

[48] Edelman AB, Schaefer E, Olson A, Van Houten L, Bednarek P, Leclair C, Jensen JT. Effects of prophylactic misoprostol administration prior to intrauterine device insertion in nulliparous women. Contraception. 2011 Sep 1;84(3):234-9.

[49] Lotke PS, Tiwari A, Nuño VL. Inserting intrauterine devices in nulliparous women: is misoprostol beneficial? A registered clinical trial. *Am J Clin Exp Obstet Gynecol*. 2013;1(1):62-8.

[50] Lopez LM, Bernholc A, Zeng Y, Allen RH, Bartz D, O'Brien PA, Hubacher D. Interventions for pain with intrauterine device insertion. *Cochrane Database of Systematic Reviews*. 2015;7: CD007373. doi: 10.1002/14651858.CD007373.pub3.

treatment regimens for medical abortion using misoprostol alone.[51] The WHO encourages health care workers to allow at-home use of misoprostol for abortion as the WHO claims this "can improve the privacy, convenience and acceptability of services."[52] Because misoprostol is widely available in many countries for other indications, and is sometimes even available over the counter (OTC), and because misoprostol is a relatively low-cost drug, misoprostol is routinely used to procure illegal abortions in countries where abortion is generally banned.[53] Some non-governmental organizations even encourage the use of misoprostol for these purposes.

Because there is a real risk that misoprostol can be misused for performing a medical abortion, HHS/OASH/OPA should be especially vigilant that such drugs are not being misused in Title X projects. Patients who have a susceptibility to peptic ulcers when taking NSAIDs may benefit instead by being referred to a gastroenterologist or other specialist of the gastrointestinal tract as severe peptic ulcers can, if left untreated, lead to severe and even life-threatening complications.[54] Given the evidence from academic literature that misoprostol may not improve patient or physician experience during an IUD insertion, HHS may want to weigh whether it should recommend against using misoprostol for this purpose.

4. Prohibit Title X Projects from conducting or financing biomedical research on abortion methods

HHS/OASH/OPA should explicitly prohibit Title X projects from conducting or financing biomedical research on abortion methods. Since such research would support abortion activities as a method of family planning and because such research would, in most cases, necessarily entail the performance of abortions, these activities are gravely contrary to the PHS Act, sec. 1008 prohibition on Title X funds being used in "programs where abortion is a method of family planning."[55] Title X funds should not be used for conducting research or financing research on the benefits and harms, effectiveness, acceptability, or feasibility of abortion methods.

A specific enumerated prohibition on this activity is merited and appropriate as 42 U.S.C. 300a–2 specifically grants the Secretary the authority to use funds appropriated for Title X to conduct biomedical research:

> "The Secretary may—(1)conduct, and (2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population."[56]

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[51] WORLD HEALTH ORGANIZATION, CLINICAL PRACTICE HANDBOOK FOR SAFE ABORTION (2014).

[52] WORLD HEALTH ORGANIZATION, CLINICAL PRACTICE HANDBOOK FOR SAFE ABORTION 28 (2014).

[53] WORLD HEALTH ORGANIZATION, SAFE ABORTION: TECHNICAL AND POLICY GUIDANCE FOR HEALTH SYSTEMS 46 (2nd ed. 2012).

[54] Mayo Clinic Staff, *Peptic Ulcer*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/peptic-ulcer/symptoms-causes/syc-20354223.

[55] Public Health Service Act, sec. 1008, 42 U.S.C. § 300a–6.

[56] Public Health Service Act, sec. 1004, 42 U.S.C. § 300a–2.

Per the Church Amendments (42 U.S.C. §300a–7(c)(2)), the Department is prohibited from allowing a biomedical or behavioral research grant recipients from compelling health care personnel to engage in research activities that are contrary to their religious beliefs or moral convictions. Title X recipients, thus, cannot require health care workers to conduct research on abortion as a method of family planning. However, the proposed rules do not specifically prohibit Title X projects from engaging in or financing abortion research. A plain language understanding of sec. 1008 would seem to require HHS/OASH/OPA to preclude such activities. A specific prohibition on abortion research would be beneficial in ensuring statutory compliance with sec. 1008.
In other areas of the government, federal statutes have long prohibited the use of public funds for abortion research. Since 1981, the Foreign Assistance Act has prohibited the use of U.S. foreign assistance for financing biomedical research on abortion methods.[57] There is nothing to prevent HHS/OASH/OPA from interpreting sec. 1008 of the PHS to preclude funding for abortion research. It would seem that Congressional intent to include such a prohibition in the area of foreign assistance would not, without more, preclude its application to other areas of the government, including programs implemented by HHS.

§59.16(a), or wherever appropriate in the Code of Federation Regulations, should include a prohibition on the following action:

> "Conducting or financing biomedical research which relates, in whole or in part, to methods of, or the performance of, abortion;"

5. Prohibit Title X Projects from Providing Financial or Material Support for the Purposes of Providing Abortion Services

In order to maintain statutory compliance in Title X programming, it is necessary that projects not perform or promote abortion through its activities. The proposed rule makes it clear that Title X projects may not perform, promote, refer for, lobby for, or advocate for abortion. However, the proposed rule never mentions other noteworthy and distinct activities that can be used to promote abortion such as providing training or technical assistance. As mentioned in recommendation C.1. above, it would clearly be contrary to a correct understanding of PHS Act, sec. 1008 to allow Title X projects to provide services such as training on abortion methods, training on recruiting clients for abortion services, training on providing abortion counseling, or providing technical or managerial assistance to a clinic to improve the efficiency or effectiveness of their abortion business. Some non-governmental organizations engage primarily in providing only training or technical assistance on abortion without actually performing abortion themselves. It is conceivable that Title X recipients would be able to do the same. It is necessary, therefore, that HHS/OASH/OPA list training and technical assistance in service of abortion as an enumerated prohibited action. §59.16(a) should be amended to include the following:

> "Providing financial or material support, including training, technical assistance, in-kind assistance or any other goods or services, for the purposes of making abortion available as a method of family planning;"

This enumerated item is similar to the recommendation we made in recommendation C.1. above but differs in one important respect. While recommendation C.1. prohibits a Title X project from providing financial or material support to an *organization* that "as a more than insignificant part of its activities,

[57] Foreign Assistance Act of 1961, Sec. 104(f)(3), Pub. L. No. 87-195, 75 Stat. 424, et seq. (codified as amended at 22 U.S.C. § 2151b(f)(3)).

advocates abortion,"[58] this recommendation (C.5.) prohibits a Title X project from providing financial or material support to *any* organization *for the purposes of engaging in* prohibited abortion-related activities. It is necessary that both recommendation C.1. and C.5. are enumerated as separate items so that Title X grantees are able to understand this subtle yet important distinction.

D. Exempt Health Care Personnel from Having to Assist or Provide Referrals for Family Planning Methods Which Violate Their Religious Beliefs or Moral Convictions

The proposed rule, as currently written, does not require Title X recipients to provide every acceptable and effective method of family planning. Title X recipients, under the proposed rule, are permitted to offer only one method or only a limited number of methods so long as the Title X project on the whole offers a broad range of family planning services.[59] Title X recipients, then, that may have a religious or moral objection to providing specific family planning methods would not be required to provide them if the current proposed rule is adopted.

However, the proposed rule fails to prevent health care personnel in a Title X project from being required to assist their employer (i.e. the Title X recipient) in providing a family planning method that would be contrary to their religious beliefs or moral convictions. Similarly, there is nothing in the proposed rule to prevent health care personnel in a Title X project from being required to refer clients for family planning methods which they are opposed to on moral or religious grounds. Moreover, the proposed rule does not mention that it would be prohibited from permitting biomedical or behavioral research grant recipients under 42 U.S.C. 300a—2 from discriminating against health care personnel that refuse to engage in family planning research contrary to their religious beliefs or moral convictions.

Per the Department's statutory requirements under the Church Amendments (42 U.S.C. 300a–7(c)(2)), Title X grants or contracts for biomedical or behavioral research cannot be used to discriminate against health care personnel on account of their refusal to perform or assist in any health care service or research activity that would violate their religious beliefs or moral convictions. Thus, health care personnel in a Title X project cannot be prohibited or penalized from refusing to engage in or to assist in biomedical research on any family planning method that would violate their religious beliefs or moral convictions. To ensure Title X projects are within statutory compliance of 42 U.S.C. 300a–7(c)(2), HHS/OASH/OPA should revise the proposed rules to exempt individuals participating in a Title X project from being required to engage in research of any kind contrary to their religious beliefs or moral convictions.

The Church Amendments also prohibits requiring any individual under a government grant or contract authorized through the PHS Act (including Title X) from performing or assisting in performing abortion or sterilization contrary to their religious beliefs or moral convictions. Grant and contract recipients are also not required to make facilities or personnel available for the performance of abortion or sterilization if these activities are prohibited by the recipient organization on religious or moral grounds.

Additionally, the Coats-Snowe Amendment (42 U.S.C. 238n) prohibits the federal government or any state or local government receiving government assistance (such as Title X, for instance) from discriminating against any health care entity on the grounds that they refuse to perform, refer for, or

[58] 83 Fed. Reg. 25,502, 25,532.

[59] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502, 25,530 (Jun. 1, 2018) (proposed rule to be codified at 42 C.F.R. pt. 59, § 59.5).

provide training for abortion or on the grounds that they refuse to even provide arrangements for these activities. Thus, Title X recipients and their employees cannot be forced to offer abortion referrals in any capacity, even to the extent that they cannot be required to provide even the means through which an abortion referral can be provided to a patient.

HHS/OASH/OPA should be aware that methods of family planning which have, in whole or in part, a postconceptional/postfertilization mechanism of action may be considered equivalent to an abortion for some researchers with moral or religious opposition to certain family planning methods.

Per the Religious Freedom Restoration Act of 1993 (RFRA) (42 U.S.C. 2000bb *et seq.*), a federal agency may not "substantially burden" a person's free exercise of religion "even if the burden results from a rule of general applicability."[60] The federal government is subject to strict scrutiny whenever attempting to abridge an individual's First Amendment right to free exercise of religion and must demonstrate both a "compelling interest" and that such an interest is advanced by the government in the "least restrictive means."[61] Individuals in a Title X program who, by exercising their right to freedom of religious practice, are opposed to assisting in or providing referrals for certain family planning methods cannot under RFRA be required to provide such assistance or referrals without the government demonstrating that doing so constitutes a "compelling interest" that is advanced by the "least restrictive means." Because the government can provide Title X clients with family planning methods apart from an individual or entity that is opposed to providing certain methods on religious grounds, the government would be hard-pressed to demonstrate that requiring Title X recipients to offer referrals or assistance for these services would be the "least restrictive means" of doing so. Indeed, the Supreme Court found in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. __ (2014) and other subsequent cases that forcing entities with religious or moral objections to comply with the Department's regulations[62] requiring employers to pay for or facilitate their employees access to contraceptive services under the authority of Sec. 2713(a)(4) of the PHS Act was a violation of RFRA. Similarly, forcing Title X recipients to offer or refer for these same services contrary to their religious beliefs would be inconsistent with federal law and Supreme Court precedent.

To ensure statutory compliance of RFRA (42 U.S.C. 2000bb *et seq.*), HHS/OASH/OPA should revise the proposed rule to explicitly exempt individuals participating in a Title X project from being required to provide referrals or assistance in providing family planning methods contrary to their religious beliefs. This would also make the Department's policy on religious and moral exemptions for health care services

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[60] Religious Freedom Restoration Act of 1993, Pub. L. No. 103-141, 107 Stat. 1488, 42 U.S.C. § 2000bb–1(a).

[61] Religious Freedom Restoration Act of 1993, Pub. L. No. 103-141, 107 Stat. 1488, 42 U.S.C. § 2000bb–1(b).

[62] *See* EMPLOYEE BENEFITS SECURITY ADMIN., U.S. DEP'T OF LABOR, FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION OF PART 36 (Jan. 9, 2017); *and* Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (Jul. 22, 2016); *and* Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318 (Jul. 14, 2015) (final rules (now repealed) codified at 45 C.F.R. pt. 147); *and* Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,092 (Aug. 27, 2014) (interim final rules (now repealed) codified at 45 C.F.R. pt. 147); *and* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (Jul. 2, 2013) (final rules (now repealed) codified at 45 C.F.R. 147); *and* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725 (Feb. 15, 2012) (final rules (now repealed) codified at 45 C.F.R. 147); *and* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 3, 2011) (interim final rules with request for comments); *and* Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726 (Jul. 19, 2010) (interim final rules with request for comments).

consistent overall as the Department has already taken a similar position with its regulations at 45 C.F.R. §§147.130-147.133.

PRI recommends the following as a template for a section to add to the current proposed rule or to add wherever appropriate in the Code of Federal Regulations:

§ XX.XX Religious and Moral Opposition to Providing Family Planning Methods and Services

(a) *Religious exemptions for individuals, grantees, and subrecipients*
(1) A Title X project, grantee, or subrecipient may not require an individual to provide, assist in, or refer for abortion, sterilization, family planning methods or services, or any health service contrary to their religious beliefs.
(2) A Title X project, grantee, or subrecipient may not terminate the employment of an individual or refuse an individual employment, promotion, or extension of staff on account of their refusal to provide, assist in, or refer for abortion, sterilization, family planning methods or services, or any health services contrary to their religious beliefs or on account of an individual holding such religious beliefs.
(3) A Title X project, grantee, or subrecipient may not require a grantee or subrecipient to perform, provide facilities for, or provide personnel for abortion, sterilization, family planning methods or services, or any health services prohibited by the entity on religious grounds.
(b) *Moral exemptions for individuals, grantees, and subrecipients*.
(1) A Title X project, grantee, or subrecipient may not require an individual to provide or assist in providing abortion or sterilization contrary to their moral convictions.
(2) A Title X project, grantee, or subrecipient may not terminate the employment of an individual or refuse an individual employment, promotion, or extension of staff on account of their refusal to provide or assist in providing abortion or sterilization contrary to their moral convictions or on account of an individual holding such moral convictions.
(3) A Title X project, grantee, or subrecipient may not require a grantee or subrecipient to perform, provide facilities for, or provide personnel for abortion or sterilization services prohibited by the entity on moral grounds.
(c) *Prohibition on discriminating against individuals opposed to activities in biomedical or behavioral research*. A Title X project that carries out biomedical or behavioral research may not require or permit a grantee or subrecipient to require any health care personnel in a Title X project to engage in health services or research activities that would be contrary to their religious beliefs or moral convictions.

Part IV: General Recommendations

With the exception of the recommended changes outlined in Part III of this Comment, the rest of the HHS/OASH/OPA's proposed rule (RIN 0937-ZA00) should be adopted as a final rule verbatim as it was published in the Federal Register on June 1, 2018 (83 Fed. Reg. 25529-25533).

A faithful plain language interpretation of sec. 1008 of the PHS Act would conclude that Title X funds must not be used in any way to perform, promote, refer for, counsel for, advocate for, advertise, lobby for, or otherwise financially or materially support abortion as a method of family planning. Title X projects must not provide funding, training, technical assistance, in-kind support, or other goods or services for the purposes of promoting abortion as a method of family planning. They also must not use Title X funds to financially or materially support other organizations which "as a more than insignificant part of its activities,"[63] promotes abortion.

In order to ensure program integrity, Title X programs must maintain "complete physical, financial, and organizational separation" between Title X projects and prohibited actions under 42 C.F.R. §§59.14 and 59.16. HHS/OASH/OPA, in ensuring compliance with sec. 1008, must ensure that there is no potential for the comingling of Title X funds with a recipient's prohibited abortion-related activities. In pursuit of this end, HHS/OASH/OPA must also ensure that fungibility concerns with Title X funds are addressed. Title X recipients must not be permitted to use common waiting rooms, entrances, staff or personnel, phone numbers, websites, or common patient records, accounting records, or file systems for both Title X services and prohibited abortion-related activities. HHS/OASH/OPA must also prohibit the use of Title X funds for building infrastructure costs in support of a Title X recipient's abortion business or other abortion-related activities.

In accordance with Sections 1001 and 1007, Title X services must be entirely voluntary and completely free from coercion. Family planning services provided through a Title X project must "not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information."[64] In agreement with Congressional intent expressed elsewhere in the area of U.S. foreign assistance policy, family planning programs funded by the government should not maintain numerical targets or quotas for the number of family planning acceptors, number of family planning acceptors for specific family planning methods.[65] They also should not maintain quotas or targets on the number of family planning acceptors from a specific demographic, age group, or suspect classification.

Minors, particularly children, should not be expected to be able to make life-changing health decisions on their own. Minors often rely on adults to help them make decisions about their health and well-being. In the absence of a parent or a guardian, the advice of an adult often carries significant weight in a minor's decision-making process. Allowing minors to access family planning services without parental or guardian involvement disproportionately favors the advice provided by the Title X recipient. Due to a minor's immaturity, this dynamic could be construed as tantamount to coercion. It is necessary, in order to maintain full compliance with Sec. 1001, that Title X projects encourage parental (or guardian as applicable) participation in a minor's decision to utilize family planning services.

HHS/OASH/OPA must also ensure that Title X projects comply with state laws for reporting cases of child abuse, child molestation, sexual abuse, rape, incest, physical intimate partner violence and human trafficking.

HHS/OASH/OPA must also ensure that the religious liberty and conscience rights of health care workers and Title X recipients are respected when making Title X awards. Requiring Title X recipients to offer sterilization services, non-directive counseling on abortion, or abortion referrals contrary to their moral or religious beliefs is inconsistent with federal law and HHS' legal obligations under the Church Amendments (42 U.S.C. 300a–7), the Coats-Snowe Amendment at 42 U.S.C. 238n(a)(1), and the Religious Freedom Restoration Act of 1993 (RFRA) (42 U.S.C. 2000bb *et seq.*).

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[63] 83 Fed. Reg. 25,502, 25,532.

[64] Public Health Service Act, sec. 1007, 22 U.S.C. § 300a-5.

[65] *See* Consolidated Appropriations Act, 2018, Pub. L. 115-141, Div. K, Title III, "Bilateral Economic Assistance," "global health programs," 132 Stat. 348, [page number unknown] (2018).

It is also imperative that if it is the intention of the government to make contraceptive coverage available to all Americans without cost or copay through their private or employee health insurance plans, it is necessary that, in statutory compliance with RFRA, that the government seeks to advance such an interest in the "least restrictive means" possible.[66] The Supreme Court found in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. __ (2014) and *Zubik v. Burwell*, 578 U.S. __ (2016) that the government was not advancing its interest in ensuring contraceptive coverage under the authorities provided by the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119, 131 (amending Sec. 2713(a)(4) of the PHS Act, as codified at 42 U.S.C. 300gg–13(a)(4))[67] for employees of organizations with religious or moral objections to providing contraceptive coverage in the "least restrictive means" available. Thus, the government must find alternate ways to advance this interest other than forcing organizations to notify the government of their intention not to pay for or facilitate access to such services. Defining "low income family" in §59.2 for the purposes of 42 C.F.R. Part 59 as "a woman... if she has health insurance coverage through an employer which does not provide the contraceptive services sought by the woman because it has a sincerely held religious or moral objection to providing such coverage"[68] would help the government to achieve its interest in providing contraceptive coverage for employees of employers that have moral or religious objections to providing such services while at the same time allowing employers to exercise their right to religious liberty and freedom of conscience.

Respectfully submitted,
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[66] *See* Religious Freedom Restoration Act of 1993, Pub. L. No. 103-141, 107 Stat. 1488, 42 U.S.C. § 2000bb–1.

[67] To see the Department's current interpretation of 42 U.S.C. § 300gg–13(a)(4), *see* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 et seq. (Oct. 13, 2017) (interim final rules codified at 45 C.F.R. pt. 147, 26 C.F.R. pt. 54, & 29 C.F.R. pt. 2590).

[68] Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502, 25,530 (Jun. 1, 2018) (proposed rule to be codified at 42 C.F.R. pt. 59, § 59.2).