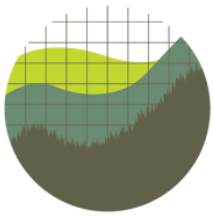

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

July 31, 2017

VIA ELECTRONIC SUBMISSION

Attn: Office of Population Affairs, U.S. Department of Health and Human Services

CC: Neomi Rao, Administrator, Office of Information and Regulatory Affairs

Re: Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (June 1, 2018); "Family Planning" – Docket No. HHS-OS-2018-0008

The Institute for Policy Integrity at New York University School of Law[1] ("Policy Integrity") respectfully submits the following comments to the Department of Health and Human Services ("HHS" or "the Department") on the proposed rule "Compliance With Statutory Program Integrity Requirements" ("Proposed Rule"),[2] which would revise implementing regulations for Title X of the Public Health Service Act ("Title X"). Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

Title X provides federal grants to family planning programs that "offer a broad range of acceptable and effective family planning methods and services."[3] Though existing regulations already sufficiently implement statutory limits on directly using federal grants to fund abortion services,[4] the Proposed Rule now seeks to encumber entities that provide both Title X-eligible programs and abortion-related services with additional restrictions. Among restrictions, the Proposed Rule would require these entities to maintain separate facilities and finances for any abortion-related programs (the "separation requirement").[5]

Our comments focus on serious errors and oversights in the Department's analysis of the Proposed Rule's costs and benefits. Specifically, we note the following:

- HHS misstates and misapplies the standard for conducting a regulatory impact analysis under Executive Order 12,866.
- HHS ignores the Proposed Rule's potentially substantial indirect costs—most notably, the health consequences stemming from patients' reduced access to healthcare services.
- HHS fails to assess the distributional impacts of the Proposed Rule.

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[1] No part of this document purports to present New York University School of Law's views, if any.

[2] HHS, Compliance With Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 (June 1, 2018) (hereinafter "Proposed Rule").

[3] PHS Act § 1001(a) (codified at 42 U.S.C. § 300(a)).

[4] PHS Act § 1008.

[5] Proposed Rule, 83 Fed. Reg. at 25,519.

I. The Department Is Required under Executive Order 12,866 to Carefully Weigh Both Costs and Benefits, Using Quantitative Data Whenever Possible

The Proposed Rule misstates and misapplies the standards of Executive Order 12,866. HHS mistakenly writes that, under that Executive Order's requirement for agencies to assess impacts in order to maximize net benefits, a regulatory impact analysis must be prepared *only* "for major rules with economically significant effects ($100 million or more in any 1 year)."[6] Because the agency concludes that the Proposed Rule will not pass "the $100 million threshold,"[7] HHS then performs only a limited impact analysis that relies on unsubstantiated guesses about direct costs and benefits and ignores significant indirect costs.[8]

In fact, Executive Order 12,866 requires a data-driven analysis of costs and benefits for an agency's proposed rule and all reasonable alternatives—quantified to the full extent feasible—whenever that proposed rule qualifies as a "significant regulatory action within the scope of section 3(f)(1)."[9] Section 3(f)(1) includes not just the $100 million threshold but also all actions "likely to . . . **adversely affect in a material way** the economy, a sector of the economy, productivity, competition, jobs, the environment, **public health or safety**, or State, local, or tribal governments or communities."[10] HHS has not explained why the Proposed Rule does not meet this criterion. In fact, as we explain below, the rule will very likely result in significant adverse health effects. The impacts of those significant adverse health effects—if properly studied and monetized—might have pushed total regulatory impacts above the $100 million threshold. But regardless of the threshold, the material adverse health effects by themselves are sufficient to qualify the Proposed Rule as significant and trigger the Executive Order's requirements for a quantitative analysis, supported by data, of all important costs and benefits.

Additionally, an action that "[m]aterially alter[s] the budgetary impact of entitlements, **grants**, user fees, or loan programs **or the rights and obligations of recipients** thereof," also qualifies as significant,[11] and such rules also require a complete "assessment of the potential costs and benefits."[12] The Proposed Rule directly affects grantmaking to family planning programs and the rights and obligations of Title X recipients. Furthermore, the Proposed Rule is a drastic, material change from the Title X policies now in effect, and many existing programs rely on funding that the Proposed Rule puts in jeopardy.

Yet despite the Executive Order's instructions for an agency to assess costs and benefits, to "base its decisions on the **best reasonably obtainable scientific, technical, economic, and other information**," and to propose a regulation "only upon a reasoned determination

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[6] Proposed Rule, 83 Fed. Reg. at 25,522.

[7] *Id*.

[8] See *infra* on how HHS falls short of Executive Order 12,866's instructions to consider all adverse regulatory effects and base decisions on the best obtainable data.

[9] Exec. Order 12,866 § 6(a)(3)(C).

[10] *Id.* at § 3(f)(1)

[11] *Id.* at § 3(f)(3).

[12] *Id.* at § 6(a)(3)(B).

that the benefits of the intended regulation justify its costs,"[13] HHS has fallen well short of these common-sense standards for rational decisionmaking. For example, HHS offers no supporting data or explanation for its estimates of the costs of complying with the proposed physical and financial separation requirements.[14] HHS offers no basis for its central estimate of how many sites and grantees will require an evaluation, how many hours the evaluations will take, or how much complying with the physical separation requirement will cost. Furthermore, while the proposed regulation adds a number of additional criteria for determining financial separation, including separate personnel and separate recordkeeping systems,[15] the agency's assessment of costs fails to estimate the burden of these additional compliance factors, including the cost of hiring additional personnel to staff the physically and financially separate service sites.[16]

HHS similarly offers no supporting data or explanation for its claims of estimated benefits, including claims about increasing patient access to family planning services, protecting patients from victimization, and respecting providers' "conscience."[17] HHS's limited assessment of alternatives also likely overlooks reasonable regulatory options that might better maximize net benefits, and the agency fails to consider the actual change in costs and benefits for even the few alternatives it does identify: for example, dismissing the "signage" alternative by concluding that "signage is often not read," without any analysis or supporting data about the ability of signage to mitigate any alleged public confusion over the scope of Title X services[18]—indeed, without any analysis or supporting data on the existence of that alleged confusion.[19]

Most irrationally, though, HHS fails to consider the proposed rule's significant indirect health costs and distributional effects, as described in the next two sections.

II. HHS Fails to Consider the Proposed Rule's Indirect but Significant Costs, including Lost Access to Healthcare and Negative Health Effects for Women

A rational cost-benefit analysis considers both the direct *and* indirect effects of a proposed rule. To that end, Executive Order 12,866 requires agencies to consider not just the "direct cost . . . to businesses and others in complying with the regulation," but also "any adverse effects" the rule might have on "the efficient functioning of the economy, private markets . . . health, safety, and the natural environment."[20] Longstanding guidance on regulatory impact analysis from the White House Office of Management and Budget similarly instructs agencies to "look beyond the direct benefits and direct costs of [their]

[13] *Id.* at § 1(b)(6)-(7).
[14] Proposed Rule, 83 Fed. Reg. at 25,525.
[15] *Id.* at 25,532.
[16] *Id.* at 25,525.
[17] *Id.* at 25,525-26.
[18] *Id.* at 25,526-27.
[19] *Id.* at 25,507 (concluding that HHS "believes that such potential co-mingling and confusion is evidence that the 2000 Regulations neither adequately reflect nor further the text and purpose of section 1008," without providing any evidence of the alleged "public confusion over the scope of Title X services"); *see id.* (seemingly admitting that HHS does not know whether the confusion is "actual or potential").
[20] E.O. 12,866 § 6(a)(3)(C)(ii).

rulemaking and consider any important ancillary benefits and countervailing risks."[21] The Supreme Court, too, has made clear that "'cost' includes more than the expense of complying with regulations" and that "any disadvantage could be termed a cost."[22]

Despite HHS's clear obligation to consider indirect consequences, the limited cost-benefit analysis for the Proposed Rule assesses only some direct costs and ignores the ways in which the Proposed Rule is likely to reduce patients' access to healthcare.

Title X provides the nation's only public funding for contraception and reproductive healthcare. Thanks to Title X, these critical—and sometimes lifesaving—services are made affordable to millions of women.[23] However, in the Proposed Rule, HHS does not acknowledge the costs of limiting Title X funding and eligibility. HHS considers compliance costs from the rule, including learning the rule's requirements, training, assurance submissions, documentation of compliance, and monitoring and enforcement, as well as some direct costs of the separation requirement,[24] but it does not explore the very probably impacts the Proposed Rule will have on women.

To understand these costs, it is useful to understand what a world with the Proposed Rule in effect could look like, as there are a number of foreseeable scenarios where these Title X revisions impose meaningful costs on women. The Proposed Rule requires entities that both receive Title X funding and provide abortion services to now maintain separate facilities and finances for these different programs, a requirement which would undoubtedly increase their expenses. Affected entities may choose to respond to the rule in a handful of ways:

(1) Affected entities may choose to comply with the rule and incur the additional costs of the separation requirement;
(2) Affected entities may choose to continue to provide abortion services and forego Title X funding;
(3) Affected entities may cease to provide abortion services or abortion counseling; or
(4) Affected entities may close due to the requirements of the Proposed Rule.

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[21] Office of Mgmt. & Budget, Circular A-4 (2003), https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

[22] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015); *see also Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.,* 956 F.2d 321, 326-27 (D.C. Cir. 1992) (striking down fuel-efficiency rule for failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (holding that EPA was required to consider the indirect safety effects of substitute options for car brakes when banning asbestos-based brakes under the Toxic Substances Control Act).

[23] Proposed Rule, 83 Fed. Reg. at 25,523 ("These entities operated at 3,898 service sites, and provided services to 4,007,552 people."); Adam Sonfield, Kinsey Hasstedt, Rachel Benson Gold. Guttmacher Institute. *Moving Forward: Family Planning in an Era of Health Reform*. (Mar. 2014); C.I. Fowler et al., *Family Planning Annual Report: 2010 National Summary,* Research Triangle Park, NC: RTI International, 2011, http://www.hhs.gov/opa/pdfs/fpar-2010-national-summary.pdf. (According to the Guttmacher Institute, in 2010, Title X supported 4,100 family planning providers throughout all 50 states and Washington, D.C., delivering family planning care to more than 4.7 million women.).

[24] Proposed Rule, 83 Fed. Reg. at 25,522

In the first two of these scenarios, it is likely that family planning and reproductive health services become costlier for women: either their care providers, as affected entities, raise costs to meet the requirements of the Proposed Rule (e.g., to establish new facilities and hire new staff) or affected entities raise costs because they have chosen to not comply and therefore lost federal funding. Some compliance requirements may also make it more difficult for women to access care at these service sites: for example, if sites change their phone numbers, e-mail addresses, websites, and entrances in order to comply,[25] women may quite literally have difficulty finding and accessing care even at service sites previously familiar to them. In the third response scenario listed above, women lose access to legal, safe, and affordable abortion. In the final scenario above, women must go elsewhere to receive the reproductive healthcare and family planning services that they have come to rely on. In all scenarios, the end result is that some women will lose access to some critical healthcare services, and that loss of access will result in a number of very real health, financial, physical, and psychological consequences for women and their families.

The Proposed Rule Will Increase Women's Transaction Costs for Receiving Care

As we explain above, the Proposed Rule is likely to reduce the availability and consumption of medical services, negatively affecting patient health and wellbeing. The Proposed Rule does not consider the burden of having to seek out new providers that meet women's particular reproductive health or family planning needs, nor does HHS consider that some women—due to geographic circumstances and constraints on their finances and time—may no longer have access to adequate healthcare services if current Title X recipients limit services or shut down as a result of the Proposed Rule.

A patient no longer able to access affordable family planning services at a preferred location must incur the cost of seeking out an alternative provider. Assuming patients typically choose the most convenient healthcare provider available, a second-choice provider is by definition almost always farther away, lower quality, or otherwise costlier than the first. Traveling farther away to a second-choice provider, for example, the patient loses time and money spent on transportation, and may be required to request time off from work or pay for childcare services. For some patients, these costs may be insurmountable.

The resulting loss of healthcare services imposes a variety of costs—financial, physical, and psychological—on patients and their families.

The Proposed Rule Will Lead to Adverse Health Consequences and Health Costs

Lack of access not only comes with real financial costs to women, but also a number of indirect health costs. Some patients who lose access or ease of access to family planning services may be too discouraged to seek out alternative sources of healthcare services. These patients may eschew treatment altogether, leading to negative health

[25] Proposed Rule, 83 Fed. Reg. at 25,532 (listing such separations as factors for determining compliance).

consequences.[26] Many Title X recipients, like Planned Parenthood, provide preventative care services, including HIV and STI screenings and well-woman exams, in addition to contraception and family planning services. Some women who no longer have access to such providers will be forced to forego these essential health services altogether; others will lose time and money seeking out alternate providers. Research from the Guttmacher Policy Institute shows that when Title X recipient programs close, almost half of the patients dependent on those services lose their only access to health care.[27] To the extent that the Proposed Rule materially limits access to legal and safe abortion, HHS also fails to consider the costs for women who are forced to consider or rely on illegal and possibly unsafe abortion or travel far distances to receive such care.[28]

The Proposed Rule Has Social and Economic Costs for Women, Too

There are other indirect social and economic costs from the Proposed Rule as well. Many Title X recipients provide contraception as one of their health care services. In a 2012 rulemaking regarding religious exemptions from contraception coverage requirements under the Affordable Care Act, HHS explained that access to contraception has significant benefits for women:

> Researchers have shown that access to contraception improves the social and economic status of women. Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force . . . . The [federal government] aim[s] to reduce these disparities by providing women broad access to preventive services, including contraceptive services.[29]

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[26] For more information on adverse health consequences from reduced STI screenings, for example, *see* Michelle Andrews, *Trump's Redirection of Family Planning Funds Could Undercut STD Fight*, National Public Radio (June 12, 2018), https://www.npr.org/sections/health-shots/2018/06/12/618902785/trumps-redirection-of-family-planning-funds-could-undercut-std-fight.; Laura Bassett, *Indiana Shut Down Its Rural Planned Parenthood Clinics and Got an HIV Outbreak*, Huffington Post (March 31, 2015), https://www.huffingtonpost.com/2015/03/31/indiana-planned-parenthood_n_6977232.html.

[27] Hasstedt, K, *Why We Cannot Afford to Undercut the Title X National Family Planning Program*, Guttmacher Policy Review Vol. 20 (2017), https://www.guttmacher.org/gpr/2017/01/why-we-cannot-afford-undercut-title-x-national-family-planning-program (For four in ten women who obtain their contraception care from a safety net family planning center that focuses on reproductive health, that provider is their only source of care); *see also* Hasstedt, K, *Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net*, Guttmacher Policy Review, Vol. 20 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2001216.pdf (26% of clients at a Planned Parenthood cite reported it was the only place they could get the services they need).

[28] For more information on the costs of restricted legal and safe abortion, *see* Planned Parenthood Federation of America, *Medical and Social Health Benefits Since Abortion Was Made Legal in the U.S.*, https://www.plannedparenthood.org/uploads/filer_public/eb/38/eb38bdf9-7ebb-4067-8758-13d28afa1d51/pp_med_soc_benefits_abortion_final_1.pdf.

[29] 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, 8,728 (Feb. 15, 2012).

Access to a full array of family planning and contraceptive services reduces the number of unintended pregnancies and gives women the tools they need to make decisions surrounding unhealthy pregnancies, which likewise can reduce socioeconomic disparities. In the proposed rule, HHS make no mention of these previously identified benefits of comprehensive family planning access; instead, the Department claims that more providers will be interested in applying for Title X funding—a claim for which it offers no support.[30]

When undertaking cost-benefit analyses, agencies are required to account for all costs of a regulatory action.[31] The Department violates this requirement by failing to acknowledge that reduced access to family planning services will result in an increase "unintended and potentially unhealthy pregnancies."[32] These unwanted pregnancies will impose costs on women by hindering their participation in the workforce and will impede the societal goal of improving the economic status of women.

HHS's failure to consider the Proposed Rule's indirect costs not only violates its obligation under Executive Order 12,866, but more generally is an irrational misrepresentation of the Proposed Rule's true impacts on women and the public. Given the agency's speculative and unsubstantiated claims about the Proposed Rule's alleged benefits to patient care, the complete inattention to these significant, negative impacts to care is particularly glaring and inconsistent.

III. HHS Fails to Consider the Proposed Rule's Distributional Impacts

Executive Order 12,866 requires agencies to "consider . . . distributive impacts" that will result from a proposed regulatory action.[33] In addition to failing to take the aforementioned indirect costs into consideration, the Department has failed to consider how these costs will burden certain groups disproportionately. This omission is particularly egregious because Title X is designed to provide affordable family planning and reproductive health services,[34] and 88% of the women who use these services are low-income, with almost two-thirds of living in poverty.[35]

Specifically, the Department should consider whether and to what extent the Proposed Rule will disproportionately burden the following subpopulations:

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[30] Proposed Rule 83 Fed. Reg. at 25,525.

[31] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (emphasizing that courts should pay attention to the "disadvantages of agency decisions"); *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1039 (D.C. Cir. 2012) (finding that the agency properly calculated the costs of amending a regulation); *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 730 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) (considering the costs of a repeal "is commonsense and settled law").

[32] *Supra* note 29.

[33] E.O. 12,866 § 6(b)(5).

[34] Proposed Rule, 83 Fed. Reg. at 25,502

[35] Christina Fowler et al, "Family Planning Annual Report: 2016 National Summary," RTI International (August 2017).
https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.

- Immigrant Women: Recent immigrants may be less well informed on the availability of reproductive health care in the U.S., and therefore in greater need of Title X services.
- Rural Women: Decreasing the number of Title X-eligible providers may create a greater problem for women who live in rural areas than for women at large, due to the increased search and travel costs associated with finding an alternative provider in rural areas.
- Low-Income Women: Women with lower incomes have fewer resources available to allocate to transportation and child care. If required to seek out alternate healthcare options, these women may suffer greater costs when seeking these alternative family planning care providers. This may even result in an insurmountable obstacle to obtaining the health service sought.
- Women of Color: Women of color disproportionately earn lower incomes and live in underserved areas. These women may experience greater burdens to seek alternative health care providers.

Conclusion

The Department has failed to provide an adequate cost-benefit analysis in explanation of the proposed Title X revisions, omitting indirect transaction costs and health costs, and the distributional effects of these costs, thereby misrepresenting the true impacts of the rule to the public.

Respectfully,

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