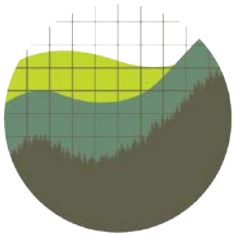

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

August 13, 2019

Department of Health and Human Services

Attn: Office of Civil Rights

Re: Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846 (proposed June 14, 2019)

Docket ID: HHS-OCR-2019-0007

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 proposed revisions to implementing regulations for Section 1557 of the Patient Protection and Affordable Care Act ("Proposed Rule").[2] 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.

Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in any health program or activity that receives Federal funds or that is administered by an executive agency.[3] In a 2016 rulemaking ("2016 Rule"), HHS defined discrimination "on the basis of sex," to include, among other things, discrimination on the basis of sex stereotyping, gender identity, and termination of pregnancy.[4] The 2016 Rule also required that "significant publications and communications" from covered healthcare entities be accompanied by a notice that the entity did not discriminate and multi-language "taglines" informing recipients of available language assistance services.[5] HHS now proposes to eliminate the 2016 Rule's definition of "on the basis of sex" as well as its notice and tagline requirements.

Our comments focus on two serious flaws in the Regulatory Impact Analysis ("RIA") for the Proposed Rule:

- HHS ignores the Proposed Rule's potentially substantial costs to patients (in the form of forgone benefits from the 2016 Rule). Specifically, HHS fails to assess adverse health consequences that could result from some patient populations' reduced access to healthcare under the Proposed Rule relative to the 2016 Rule.

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

[2] 84 Fed. Reg. 27,846 (proposed June 14, 2019).

[3] *Id.* at 27,847 (citing 42 U.S.C. § 18116)

[4] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375, 31,387 (May 18, 2016).

[5] *Id.* at 31,395-403.

- HHS fails to support its claims regarding the Proposed Rule's intangible benefits.

I. HHS fails to consider the Proposed Rule's costs to patients

The 2016 Rule was expected to increase access to healthcare coverage and services for women, transgender individuals, and patients with limited English proficiency. By repealing key provisions of the 2016 Rule, the Proposed Rule can thus be expected to *reduce* access to care for these patient populations. Yet HHS does not account for this reduction in access—and its negative health consequences—when assessing the Proposed Rule's costs.

HHS's failure to consider health costs violates Executive Order 12,866, which instructs agencies to consider not just "direct cost . . . to businesses and others in complying with the regulation," but also "any adverse effects" a rule might have on "the efficient functioning of the economy, private markets . . . health, safety, and the natural environment."[6] The Office of Management and Budget's longstanding guidance document on regulatory impact analysis, Circular A-4, similarly directs agencies to "look beyond the direct benefits and direct costs of [their] rulemaking and consider any important ancillary [i.e., indirect] benefits and countervailing risks."[7]

By ignoring health costs, HHS also violates its obligation under the Administrative Procedure Act ("APA") to engage in reasoned decisionmaking. A regulation is arbitrary and capricious under the APA if the issuing agency fails to "examine the relevant data" or "consider an important aspect of the problem."[8] As the Supreme Court explained in *Michigan v. EPA*, "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate," and costs "include[] more than the expense of complying with regulations"; instead, "any disadvantage could be termed a cost."[9] Accordingly, federal courts have repeatedly struck down rules that, like the Proposed Rule, fail to consider potentially significant indirect costs.[10]

Finally, when agencies repeal or revise existing rules, the APA requires them to provide a "reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy."[11] Here, HHS offers no explanation for disregarding its previous

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[6] Exec. Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[7] Office of Mgmt. & Budget, Circular A-4 on Regulatory Analysis 26 (2003) [hereinafter Circular A-4].

[8] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted).

[9] *Michigan v. EPA*, 135 S. Ct. 2699, 2707–08 (2015); *see also Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732–33 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) ("As a general rule, the costs of an agency's action are a relevant factor that the agency must consider before deciding whether to act.").

[10] *See, e.g., Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin.*, 956 F.2d 321, 326-27 (D.C. Cir. 1992) (remanding fuel-efficiency rule due to agency's failure to consider indirect safety costs); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1225 (5th Cir. 1991) (striking down rule for failure to consider indirect safety effects of substituting asbestos-free car brakes); *see also Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (when agency relies on a cost-benefit analysis to support its rulemaking, "a serious flaw undermining that analysis can render the rule unreasonable").

[11] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009); *see also Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) ("[E]ven when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation.").

findings on the 2016 Rule's health benefits—benefits that will be forgone if the Proposed Rule is finalized.

A. HHS fails to consider costs that will result from repealing the 2016 Rule's definition of "on the basis of sex"

Among the reasonably foreseeable health costs that HHS fails to consider are those that will result from eliminating the 2016 Rule's definition of "on the basis of sex." In its Regulatory Impact Analysis for the 2016 Rule ("2016 RIA"), HHS determined that the 2016 Rule's interpretation of sex discrimination would prompt "changes in behavior by covered entities" and that these behavioral changes would generate benefits, primarily for women and transgender individuals, including a "reduction in the number of individuals who are uninsured" and a "reduction in health disparities" due to "more people receiving adequate health care, regardless of their sex, including gender identity."[12] In reaching this conclusion, the Department explained that "despite the [Affordable Care Act] improving access to health services and health insurance, many women and transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities."[13]

For transgender individuals, the 2016 RIA identified three barriers to care that the 2016 Rule would address: refusal of treatment due to provider bias, the absence of gender identity from covered entities' nondiscrimination policies, and difficulty obtaining insurance coverage.[14] HHS cited evidence that transgender individuals who face these barriers "often postpone or do not seek needed health care, which may lead to negative health consequences."[15] In this way, discrimination against transgender individuals in healthcare settings "exacerbates health disparities experienced by the LGBT population, including: higher rates of mental health issues, including depression and suicide attempts; higher risk of HIV/AIDS; higher use of tobacco and other drugs; and higher risk of certain cancers, such as breast cancer."[16] By preventing discrimination, the 2016 Rule was expected to mitigate some of these harms.

To further support its conclusion that the 2016 Rule's interpretation of sex discrimination would improve the health of women and transgender individuals, the 2016 RIA "look[ed] to a State of California economic impact assessment of State practices prohibiting gender discrimination in health care."[17] As benefits of the California policy, that assessment cited reduced violence against affected individuals (i.e., those protected by the anti-discrimination provisions), reduced depression and suicide attempts, and declines in substance abuse.[18]

By repealing the 2016 Rule's definition of "on the basis of sex," HHS will forgo the benefits described above. In other words, relative to a world in which the 2016 Rule remains in place, the

[12] 81 Fed. Reg. at 31,460-61.

[13] *Id.* at 31,460.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

Proposed Rule can be expected to *reduce* women and transgender individuals' access to health coverage and care and *increase* health disparities. Yet nowhere in the RIA for the Proposed Rule does the Department assess these health costs. Instead, the RIA includes only two passing references to the potential health effects of adopting a narrower interpretation of sex discrimination.

In its first reference to health effects, HHS claims that it "lacks the data necessary to estimate the number of individuals who benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive these benefits as a consequence of the rule."[19] However, an agency's uncertainty about the precise magnitude of a regulatory effect does not justify assigning that effect no weight in the agency's cost-benefit analysis.[20] While there may be "a range of values" for the costs to patients of rescinding the 2016 Rule's interpretation of sex discrimination, the value "is certainly not zero."[21] Thus, the costs must be "accounted for in the agency's analysis."[22] Even if HHS cannot fully quantify and monetize them, it must at least consider potential health effects in qualitative terms, as it did in the 2016 Rule.[23]

HHS's second reference to health costs is a request for "comment and documentation of cases where . . . persons would not have received treatments or procedures related to gender identity or termination of pregnancy, but for the [2016] Rule's gender identity and termination of pregnancy provisions."[24] As an initial matter, HHS's framing of this request reflects an inappropriately cramped view of the health effects of the 2016 Rule. As the 2016 RIA makes clear, allowing discrimination against transgender individuals affects those individuals' access to healthcare *generally*, not just their access to treatments or procedures related to gender identity.[25]

Furthermore, HHS cannot discharge its responsibility to assess health costs simply by requesting comment on the issue. While commenters can supply useful information to inform an agency's analysis, the agency bears the ultimate burden of supplying "a satisfactory explanation for its action," including due consideration of "relevant factors" like cost.[26] If HHS believes it lacks sufficient information on the health benefits of the 2016 Rule for women and transgender individuals (and thus the costs of the Proposed Rule for those groups), it should conduct its own

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[19] 84 Fed. Reg. at 27,876.

[20] *See Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1190, 1200 (9th Cir. 2008) (finding agency reasoning arbitrary and capricious where agency argued that benefits of carbon dioxide reductions were "too uncertain to support their explicit valuation and inclusion" in a regulatory cost-benefit analysis).

[21] *Id.* at 1200.

[22] *Id.*

[23] Circular A-4 at 27 ("If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects . . . .").

[24] 84 Fed. Reg. at 27,886.

[25] *See* 81 Fed. Reg. at 31,460.

[26] *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 513, 549 (2009).

research on that question before taking any regulatory action, as recommended by Circular A-4.[27]

B. HHS fails to consider costs that will result from repealing the 2016 Rule's notice and multi-language tagline requirements

In addition to disregarding the health costs of repealing the 2016 Rule's definition of "on the basis of sex," HHS fails to give due consideration to health costs that will result from repealing the 2016 Rule's notice and multi-language tagline requirements. In the 2016 RIA, HHS found that the 2016 Rule's "provisions related to serving individuals with limited English proficiency" would "create substantial benefits to patients and providers by improving access to quality care."[28] To support this conclusion, the Department cited an Institute of Medicine report, which found that "when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance."[29] HHS noted that the Institute of Medicine report also identified other, non-health benefits from language assistance services, such as "retention of cultural information, exchange of information, greater satisfaction of care, and enhanced privacy and autonomy of individuals with limited English proficiency."[30]

In the RIA for the Proposed Rule, HHS acknowledges that repealing the 2016 Rule's notice and tagline requirements may "impose costs, such as decreasing access to, and utilization of, health care for non-English speakers by reducing their awareness of available translation services."[31] The Department claims, however, that "such impact is expected to be negligible,"[32] directly contradicting its 2016 conclusion that the notice and tagline requirements would have "substantial benefits."[33]

Furthermore, the RIA for the Proposed Rule does not mention the Institute of Medicine report cited in the 2016 RIA. Instead, HHS relies on a two-year-old assertion from a single insurer that "utilization of translation services did not appreciably rise after the [2016] Rule's imposition of notice and taglines requirements."[34] This does not constitute a "reasoned explanation" for disregarding HHS's prior findings on the substantial benefits of notice and tagline requirements for patients and providers.[35]

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[27] Circular A-4 at 39 ("When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision.").

[28] 81 Fed. Reg. at 31,459.

[29] *Id.*

[30] *Id.* The 2016 RIA noted that providers, too, would benefit from the 2016 rule, as increased use of language assistance services would enable them to "more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are understood by patients." *Id.*

[31] 84 Fed. Reg. at 27,882.

[32] *Id.*

[33] 81 Fed. Reg. at 31,459.

[34] 84 Fed. Reg. at 27,882 & n.230 (citing a claim made by Aetna representatives on May 1, 2017).

[35] *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

II. HHS does not support its claims regarding the Proposed Rule's intangible benefits

HHS attempts to justify the Proposed Rule, in part, by reference to "intangible benefits."[36] The "most important" of these, according to the Department, is that "covered entities would enjoy increased freedom to adapt their Section 1557 compliance programs to most efficiently address their particular needs."[37] But increased flexibility for regulated entities does not by itself constitute a regulatory benefit. Instead, as explained in Circular A-4, "alternatives that . . . offer increased flexibility are often more cost-effective than more prescriptive approaches."[38] Regulatory flexibility is desirable only when it allows an agency to achieve the same policy goal at a lower cost.

Here, the Proposed Rule most certainly does not achieve the goal of the 2016 Rule, which sought to prevent covered entities from operating in ways that did not adequately protect the rights of women, transgender individuals, and those with limited English proficiency. As discussed earlier, for example, one barrier to care that the 2016 RIA sought to eliminate was the failure of some covered entities to include gender identity in their nondiscrimination policies. If finalized, the Proposed Rule would offer such entities the "freedom" to resurrect that barrier to care.

Thus, HHS cannot justify the Proposed Rule merely by pointing out that it will offer covered entities freedom to adopt a greater variety of policies than they could under the 2016 Rule. Instead, the Department must explain how it expects policies adopted under the Proposed Rule to differ from policies adopted under the 2016 Rule and, further, why it believes the incremental benefits of those policy changes will outweigh their incremental costs. As the Department's own Guidelines for Regulatory Impact Analysis warn, "[i]n the absence of information, decision-makers and others may weight nonquantified effects in a manner consistent with their own (unarticulated and perhaps unconscious) beliefs, without sufficiently probing the rationale or the weighting."[39] To "counterbalance this tendency," HHS's Guidelines require "[c]lear presentation of the available evidence."[40] HHS fails to provide such a presentation in its discussion of the Proposed Rule's intangible benefits.

Respectfully submitted,

Jack Lienke, *Regulatory Policy Director*

Iliana Paul, *Policy Analyst*

[36] 84 Fed. Reg. at 27,877.

[37] *Id.*

[38] Circular A-4 at 16.

[39] HHS, Guidelines for Regulatory Impact Analysis 47 (2016).

[40] *Id.*