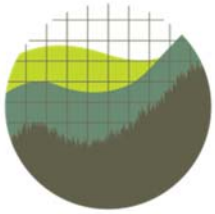

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

March 27, 2018

VIA ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services

Attn: Office for Civil Rights

Re: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (Jan. 26, 2018); RIN 0945-ZA03

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] respectfully submits the following comments to the Department of Health and Human Services ("HHS" or "the Department") regarding its proposed rule on statutory conscience protections in health care ("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.

Our comments focus, first, on HHS's failure to provide a reasoned explanation for disregarding relevant prior findings and, second, on serious errors and oversights in the Department's Regulatory Impact Analysis for the Proposed Rule. Specifically, we note the following:

- HHS disregards, without explanation, concerns that it raised in its 2011 rulemaking on conscience protections ("2011 Rule"), such as the possibility that an overly broad conscience protections rule would interfere with patients' ability to offer informed consent and the possibility that an overly broad rule would lead providers to believe—mistakenly—that statutory conscience protections allow them to discriminate against certain types of patients.
- HHS's Regulatory Impact Analysis ignores the Proposed Rule's potentially substantial indirect costs, such as reduced access to health care for patients and increased personnel expenses for providers.
- The Regulatory Impact Analysis fails to assess the distributional impacts of the Proposed Rule.
- The Regulatory Impact Analysis underestimates the number of entities covered by the Proposed Rule's assurance and certification requirement and, as a result, understates the Proposed Rule's direct compliance costs.

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[1] This document does not purport to present New York University School of Law's views, if any.

[2] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) (hereinafter "Proposed Rule").

I. HHS Fails to Provide a Reasoned Explanation for Disregarding Findings It Made in the 2011 Rule.

This is not HHS's first rulemaking on conscience protections. In 2008, the Department finalized a regulation ("2008 Rule") that, among other things, purported to clarify the scope of conscience protections under the Church Amendments, Section 245 of the Public Health Service Act, and the Weldon Amendment by expansively defining certain statutory terms.[3] HHS subsequently rescinded all of the 2008 Rule's definitions in the 2011 Rule, citing concerns about their potential to (1) compromise patients' ability to offer informed consent, (2) cause confusion about the scope of statutory protections, and (3) inadvertently encourage providers to discriminate against certain categories of patients.[4]

When an agency amends, suspends, or repeals a rule, the agency must provide "a reasoned explanation . . . for disregarding facts or circumstances that underlay or were engendered by the prior policy."[5] Underlying the 2011 Rule was a conclusion by HHS that expansive definitions of statutory terms would compromise patients' ability to offer informed consent and foster confusion and discrimination. Accordingly, before it can adopt the Proposed Rule, which defines statutory terms even more broadly than the 2008 Rule did, the Department must acknowledge its prior concerns about expansive definitions and explain either why those concerns are not implicated by the definitions proposed here or why the Proposed Rule is justified despite those concerns. In the absence of such an explanation, the Proposed Rule is arbitrary and capricious.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Compromise Patients' Ability to Provide Informed Consent

When it rescinded the majority of the 2008 Rule in 2011, HHS did so, in part, to "clarify any mistaken belief that [the 2008 Rule] altered the scope of information that must be provided to a patient by their provider in order to fulfill informed consent requirements."[6] The 2011

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[3] Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,073 (Dec. 19, 2008) (hereinafter "2008 Rule").

[4] Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9973-74 (Feb. 23, 2011) (hereinafter "2011 Rule").

[5] *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 516 (2009).

[6] 2011 Rule, 76 Fed. Reg. at 9973.

Rule emphasized that making a patient aware of all available health care options is "crucial to the provision of quality health care services."[7]

The Proposed Rule is likely to limit patients' awareness of their health care options to an even greater extent than the 2008 Rule would have.[8] For example, the Proposed Rule suggests that a provider has no obligation to offer patients a disclaimer regarding health care procedures to which the provider has a religious or moral objection.[9] In other words, providers need not warn patients that they are not being informed of all available treatment options. And yet HHS fails even to acknowledge its 2011 finding that a conscience protections rule could not properly "alter[ ] the scope of information that must be provided to a patient,"[10] much less explain why the Department no longer holds that view.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Cause Confusion About the Scope of Statutory Protections

The 2011 Rule highlighted commenters' concern that the definitions in the 2008 Rule "were far broader than scope of the federal provider conscience statutes."[11] In rescinding those definitions, the Department noted its agreement that the definitions "may have caused confusion regarding the scope" of statutory protections.[12]

Definitions included in the Proposed Rule are even broader than those adopted in 2008. For example, whereas the 2008 Rule interpreted statutory protections against "assist[ing] in in the performance" of an objectionable procedure to encompass any action with a "reasonable" connection to that procedure,[13] the Proposed Rule requires only an "articulable" connection to the procedure.[14] But the Proposed Rule nevertheless fails to acknowledge HHS's prior finding as to the potential for broad definitions to cause confusion. Nor does the Department explain why the Proposed Rule is justified in spite of this potential for confusion.

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[7] *Id.*

[8] Proposed Rule, 83 Fed. Reg. at 3924.

[9] *See id.* at 3894-95 (defining "referral or refer for" to include "disclaimers," and noting that referral was not defined in the 2008 Rule).

[10] 2011 Rule, 76 Fed. Reg. at 9973.

[11] *Id.*

[12] *Id.*

[13] 2008 Rule, 73 Fed. Reg. at 78,097.

[14] Proposed Rule, 83 Fed. Reg. at 78,090-91.

HHS Disregards Its Prior Findings on the Potential for Expansive Definitions to Encourage Discrimination Against Categories of Patients

HHS's 2011 decision to rescind the definitions in the 2008 Rule was also motivated by concern that the definitions would lead providers to believe, incorrectly, that statutory protections extended not just to refusals to perform particular procedures, but also to refusals to care for particular types of patients. As the Department explained in the 2011 Rule, statutory conscience protections "were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable."[15] But the Department agreed with commenters that the 2008 Rule could nevertheless give the impression that "Federal statutory conscience protections allow providers to refuse to treat entire groups of people based on religious or moral beliefs."[16] As a result, HHS feared that the 2008 Rule could reduce access to "a wide range of medical services, including care for sexual assault victims, provision of HIV/AIDS treatment, and emergency services."[17]

Again, the definitions in the Proposed Rule are even broader than those that caused the Department concern in 2011 and are thus likely to give rise to the same harmful misimpressions about the scope of statutory conscience protections. But the Department neither acknowledges its prior concerns regarding the inadvertent encouragement of discrimination nor explains why proceeding with the Proposed Rule is reasonable despite those concerns.

II. HHS Fails to Consider the Proposed Rule's Indirect Costs

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 "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."[18] 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] rulemaking and consider any important

[15] 2011 Rule, 76 Fed. Reg. at 9973-74.

[16] *Id.* at 9973.

[17] *Id.* at 9974.

[18] E.O. 12,866 § 6(a)(3)(C)(ii).

ancillary benefits and countervailing risks."[19] 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."[20]

Despite HHS's clear obligation to consider indirect consequences, the Regulatory Impact Analysis for the Proposed Rule assesses only direct compliance costs and ignores the ways in which the Proposed Rule is likely to reduce patients' access to health care and increase providers' personnel expenses.

HHS Fails to Consider Costs to Patients from the Express Denial of Medical Services

For a variety of reasons, the Proposed Rule is likely to reduce the availability and consumption of medical services, negatively affecting patient health and wellbeing. As discussed in Section I of these comments, the Proposed Rule's expansive definitions of statutory terms are likely to lead some providers to adopt a much broader interpretation of statutory conscience protections than Congress intended. This, in turn, will increase the frequency with which patients are denied care due to a provider's religious or moral objections. Such denials can impose a variety of costs—financial, physical, and psychological—on patients.

At minimum, a patient denied care must incur the cost of seeking out an alternative provider. Assuming patients typically choose the most convenient healthcare provider available, a second-choice provider may be farther away than the first. Traveling farther away, 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.

Furthermore, some patients who are denied care may be too discouraged to seek out alternative sources of healthcare services. These patients may eschew treatment altogether, leading to negative health consequences.

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

[20] *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).

Finally, the Proposed Rule may discourage some patients from seeking medical services in the first place, simply because they *fear* being rejected by a provider. This assumption is reciprocal to the Department's assumption that some potential healthcare providers are currently (absent the Proposed Rule) discouraged from entering the profession because they fear they will be discriminated against for their religious and moral convictions.[21]

HHS Fails to Consider Costs to Patients from the Undisclosed Denial of Medical Services

The Proposed Rule's likely health costs extend beyond patients who are (or who fear that they will be) expressly denied care. As explained in Section I of these comments, the Proposed Rule encourages providers not merely to refuse to provide referrals for procedures or services to which they object, but also to refuse to warn patients that the provider is declining to recommend such treatments. A patient who does not realize she is being denied information about a particular health care option might choose an alternative that is less beneficial to her health or wellbeing.[22]

HHS Fails to Consider Indirect Personnel Costs for Providers

In addition to imposing health costs on patients, the Proposed Rule may indirectly increase personnel costs for some health care entities. For example, if the Proposed Rule causes support staff at a given health care facility to decline to perform services that they previously performed (or to decline to treat patients whom they previously treated), the facility will need to pay for additional labor to meet the same level of demand.

[21] Proposed Rule, 83 Fed. Reg. at 3916.

[22] The Department solicits comment on methodologies that can be used to quantify ancillary health costs. There are a number of ways to assess such impacts, including: retrospective cohort studies (e.g., studying the conditions of women's health in the 1960's and 1970's when information on abortion was limited); cohort studies in other countries or states where abortion counseling and referral is restricted; prospective cohort studies (i.e., a pilot program testing the regulation on a subset of the population); self-report surveys administered to a sample population of women (assessing, for example, their awareness of the existence of and details of abortions procedures); estimations of the potential effects by using statistics in the current environment as indicators; or any other of a number of epidemiological and other studies that are routinely performed by public health professionals when evaluating policies that affect public health.

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.[23] In addition to failing to take the aforementioned ancillary costs into consideration, the Department has failed to consider how these costs will burden certain groups disproportionately. The Department's failure to consider such distributional impacts is particularly egregious given that it lists the promotion of "a society free from discrimination" as one of the chief benefits of the Proposed Rule.[24] HHS cannot rationally tout the Proposed Rule's potential to reduce discrimination against religious health care providers while ignoring its potential to increase discrimination against other groups.[25]

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

- 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 the counselling and referral services that the Proposed Rule covers.

- Rural Women: Increasing the incidence of health care providers refusing to provide counseling or referrals 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 refused counseling or referral services, these women may suffer greater costs when seeking alternative health care providers. The refusal 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. If refused counseling or referrals, these women may experience greater burdens to seek alternative health care providers.

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[23] E.O. 12,866 § 6(b)(5).

[24] Proposed Rule, 83 Fed. Reg. at 3903.

[25] *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (noting that "reasonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions"); *Sierra Club v. Sigler*, 695 F.2d 957, 979 (5th Cir. 1983) (an agency "cannot tip the scales . . . by promoting [an action's] possible benefits while ignoring [its] costs.").

- LGBTQ Individuals: As discussed in Section I, the Proposed Rule, like the 2008 Rule, may lead health care workers to believe they can permissibly refuse to provide any type of medical service to gay or transgender individuals (or their families) based on moral or religious objections. Such refusals would decrease the quantity and quality of health care available to that population.

- Individuals with HIV/AIDS: Similarly, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical service to individuals with HIV/AIDS. Again, such refusals would decrease the quantity and quality of health care available to that population.

- Interracial/Interfaith Families: Finally, the Proposed Rule may lead health care workers to believe that they can permissibly refuse to provide any type of medical services to interracial or interfaith families because they morally object to such relationships. As with LGBTQ patients and HIV-positive patients, this misimpression could result in reduced access to health care for interracial and interfaith families.

IV. HHS Underestimates the Number of Entities Affected by the Proposed Rule and, as a Result, Underestimates the Proposed Rule's Compliance Costs

In addition to overlooking the Proposed Rule's indirect costs, HHS also underestimates the Proposed Rule's *direct* costs. Section 88.4 of the Proposed Rule requires certain recipients of HHS funding "to submit written assurances and certifications of compliance" with statutory conscience protections.[26] In calculating compliance costs for this assurance and certification requirement, the Department estimates that the requirement would apply to between 94,279 and 152,519 individuals and entities.[27] But that estimate excludes a large number of individuals and entities that, under a plain reading of the Proposed Rule, would in fact be required to submit assurances and certifications.[28]

HHS assumes that "all physicians" will be exempt from complying with the assurance and certification requirement, either because they do not accept HHS funds or because they "meet the proposed criteria for exemption . . . in proposed § 88.4(c)(1)."[29] But § 88.4(c)(1) exempts physicians and physician offices only if they (1) participate in Medicare Part B and

[26] Proposed Rule, 83 Fed. Reg. at 3896.

[27] *Id.* at 3910.

[28] *Id*. at 3910, 3915.

[29] *Id.* at 3909-10.

(2) "are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism."[30] It is patently unreasonable for the Department to assume that this exemption encompasses every physician who receives HHS funds. Some physicians, for example, accept both Medicare *and* Medicaid funding.

HHS makes a similar error in estimating the number of individuals and entities that would be exempt from the assurance and certification requirement due to § 88.4(c)(2), which exempts recipients of funding under certain grant programs administered by the Administration for Children and Families that have a purpose unrelated to health care provision or medical research. The Department assumes that "all persons and entities that provide child and youth services . . . [and] all entities providing services for the elderly and persons with disabilities . . . would fall within this exemption."[31] As with the exemption for physicians, however, the § 88.4(c)(2) exemption is unavailable if HHS money is accepted from any other source. It seems unlikely that *no* entities that provide services for children, the elderly, or the disabled receive HHS funding from *any* source other than non-healthcare-related grant programs administered by the Administration for Children and Families.

Because it underestimates the number of entities that will be obligated to comply with the Proposed Rule's assurance and certification requirement, HHS also underestimates the Proposed Rule's total compliance costs.

Respectfully,

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[30] *Id.* at 3929.

[31] *Id.* at 3910.