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Thank you for the chance to provide comments on OIRA’s review of the scheduled rulemaking on Section 1557 of the Affordable Care Act (ACA), “Nondiscrimination in Health Programs and Activities,” by the Department of Health and Human Services (HHS).

Regulatory intervention is not required here for many reasons. Among these are that there is no evidence that the proposed modification of the Affordable Care Act’s pre-existing non-discrimination provisions is necessary, there has been no meaningful economic analysis of what the costs of the rule’s modifications might be, and there is no evidence that HHS has considered the impact of the proposed rule on intersecting and conflicting federal law. We are especially troubled by its potential conflict with freedom of conscience—and the Religious Freedom Restoration Act in particular—as well as its overly broad and expansive scope over insurance plans.

Of course, draft language for the proposed regulation is not yet available. Given the stated priorities of the administration, however, we assume the new rule will be similar in language and scope to the rule on Section 1557 finalized on May 18, 2016, under President Obama, and rescinded on June 19, 2020, under President Trump. Many of the problems with the 2016 Rule were resolved in the 2020 Rule, and we are concerned that any new rulemaking will reintroduce problems with the 2016 Rule.

In particular, we expect the new rule to reinterpret discrimination on the basis of sex to include “sexual orientation” and “gender identity.” In our comments, we will reference the text of 2016 Rule, based on the presumption that the new proposed rule will be similar.

If our presumption proves correct, then we believe the new rule would create serious conflicts of conscience for many organizations, hospitals, physicians, and other individuals involved in health care. By prohibiting differential treatment on the basis of “gender identity” in health

services, the regulation would penalize medical professionals and health care organizations that, as a matter of faith, moral conviction, or professional medical judgment, believe that maleness and femaleness are biological realities to be respected and affirmed, not altered or treated as diseases.

We also anticipate that the proposed regulation would create special privileges based on gender identity. And this, in turn, will lead to unreasonable and costly litigation for physicians, hospitals, insurers, and others involved in health care. It would effectively require controversial procedures, such as “gender-reassignment” surgery, that respected medical professionals argue have not been proven to be effective in treating serious mental health conditions. Rather than respect the diversity of opinions on sensitive and controversial health care issues, the proposed regulation would endorse and enforce one side of the debate and trample on the freedom of conscience of many in the medical community.

Every individual should be treated with dignity and respect, especially when he or she is in need of medical care. Most physicians, nurses, other health care professionals, and health care organizations joined the field of medicine precisely because they believe in the inherent dignity and value of every human life and have a strong desire to heal and help individuals achieve their full potential. However, we are concerned that the proposed regulation would interfere with the doctor-patient relationship and would advance bad public policy.

Problems with Redefining “Sex” to Include Gender Identity and Possibly Sexual Orientation

Section 1557 of the Affordable Care Act states:

[A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title 1 (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.¹

1. 42 U.S.C. § 18116(a).

Section 1557 guarantees that no individual can be denied benefits in a health program that is either federally run or federally funded because of their membership in well-established, empirically-discernible categories of civil rights law, including race, color, national origin, sex, age, or disability.² As passed by Congress, Section 1557 of the ACA does not create special privileges for new classes of people. Nor does it require insurers and physicians to cover or provide specific procedures or treatments. We are concerned that under new rulemaking, the Department would interpret Section 1557 as if it does create special privileges for new classes of people, defined in ways that are highly controversial and not empirically discernible.

We presume that the Department’s proposed regulation will redefine discrimination on the basis of “sex” to include “sex stereotyping,” “gender identity,” and “termination of pregnancy,” among other things.³ Specifically, the proposed regulation would consider “discrimination” based on sex stereotypes to include “expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct (individuals who identify as neither, both, or as a combination of male and female genders).”⁴

In the proposed version of the 2016 Rule, the Department noted that “as a matter of policy, we support banning discrimination in health programs and activities not only on the bases identified previously, but also on the basis of sexual orientation.” The Department requested comment “on the best way of ensuring that this rule includes the most robust set of protections supported by the courts on an ongoing basis.”

The Department considered any explicit or categorical exclusions of coverage for “gender transition” treatment as “unlawful on its face.”⁵ Although the Department claimed that the proposed regulations would not “affirmatively require”⁶ coverage of such treatment, this claim was undercut by the Department’s more concrete statements on the matter:

In evaluating whether it is discriminatory to deny or limit a request for coverage of a particular service for an individual seeking the service as part of transition

2. 80 Federal Register 54218 (proposed September 8, 2015).

3. Ibid.

4. Ibid.

5. Any “covered entity shall not,” among other things, “[c]ategorically or automatically exclude from coverage, or limit coverage for, all health services related to gender transition” or “[o]therwise deny or limit coverage, or deny a claim, for specific health services related to gender transition if such denial or limitation results in discrimination against a transgender individual.” Ibid., 54190 and 54220.

6. Ibid., 54190.

related care, OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, a health plan or State Medicaid agency denies a claim for coverage of a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the plan's coverage of hysterectomies under other circumstances.⁷

A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to perform the procedure on transgender individuals in the same manner it provides the procedure for other individuals.⁸

Under these guidelines, if a covered physician administered treatments or performed surgeries that *could* further gender transitions, that physician would *have to* provide them for gender transitions on the same terms, and insurance had to cover it, regardless of the independent medical judgment of the physician.⁹ Furthermore, the Department proposed no religious accommodation or exemption to its gender identity mandate or any other aspect of its proposed regulations.

Thus, the regulation, once finalized, would have forced many physicians, hospitals, and other health care providers to participate in "gender-reassignment" surgeries and treatments, even if it violated their religious beliefs or their best medical judgment. Moreover, because it applied so broadly, the regulation proposed could also force employers, individuals, and taxpayers to fund coverage for such procedures even if doing so conflicted with their sincere beliefs. However, those conflicts were averted by the revisions made in the subsequent 2020 Rule.

Scope and Impact of the Proposed Regulation

Again, judging from the 2016 Rule, the proposed regulation would apply to any "health programs or activities any part of which receives Federal financial assistance administered by

7. Ibid.

8. Ibid., 54204.

9. According to the Department, "if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender person." Ibid., 54205. However, all existing patients must be treated in a "nondiscriminatory" manner, and it was unclear whether a physician could stop taking new patients in response to the regulations or if the Department would consider that illegal discrimination as well.

HHS” as well as any health programs or activities administered by HHS or those established under Title I of the ACA, including federally facilitated and state-based insurance exchanges.¹⁰

This includes any “hospital, health clinic, group health plan, health insurance issuer, physician’s practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity” that receives HHS funds.¹¹

The proposed regulation would therefore apply to:

- Approximately 133,000 health care facilities;
- “[A]lmost all practicing physicians in the United States...because they accept some form of Federal remuneration or reimbursement”;
- All state Medicaid programs; and
- All the businesses and activities of a private insurer if any of its businesses receive any federal financial assistance either directly (such as a through a Medicaid managed care contract) or indirectly (through subsidies provided to its customers as is the case with Medicare Advantage and exchange plans). However, the 2020 Rule narrowed the scope of application to insurers (as discussed later).¹²

Because the federal government now extensively subsidizes both medical care and health insurance coverage it would be nearly impossible for medical professionals to work free from these regulations.

The Office for Civil Rights in the Department would enforce Section 1557 by conducting compliance reviews and investigating complaints. If it concludes that a covered entity has violated Section 1557, the entity may be stripped of its federal funding. Additionally, the Department would interpret “enforcement mechanisms” to include private rights of action, meaning individuals who feel that they have been discriminated against based on their gender identity may sue for damages in federal court.¹³

Reasonable Judgments About Biology Are Not “Discriminatory”

Many people reasonably believe that maleness and femaleness are objective, biological realities that are integral to who we are as human beings. On the basis of religious teachings, moral

10. *Ibid.*, 54173.

11. *Ibid.*, 54216.

12. *Ibid.*, 54174–54175 and 54195

13. *Ibid.*, 54192.

reasoning, scientific evidence, and medical experience, many have strong grounds to hold that one's sex is an immutable characteristic that should be respected, not rejected or treated as a disease.¹⁴ Accordingly, many involved in providing medical care and those enrolled in health insurance plans have serious objections to participating in or paying for sex-reassignment surgeries or gender transitions. Yet the regulations would label these kinds of reasonable beliefs as “discriminatory” and seek to forbid them from being followed in the coverage or provision of health care services.

Gender identity and sexual orientation, unlike race or sex, can vary, are self-reported, and entirely self-defined characteristics independent of the body. Government should not grant special privileges on such bases when legal recognition of a group as a “protected class” is, with few exceptions, reserved for groups with objectively identifiable immutable characteristics.¹⁵

The Department nevertheless argues that Section 1557's uncontroversial bar on “sex discrimination” should be redefined controversially to cover gender identity and possibly sexual orientation.¹⁶ But differential treatment based on actions related to gender identity or sexual orientation does not constitute “sex” discrimination under a plain reading of Section 1557. Indeed, there is no evidence that Congress departed from the common, objective definition of sex when drafting Section 1557. Absent clear congressional authorization, then, the Department would not be justified in replacing the commonsense understanding of sex as a permanent reality grounded in biology with *its* view that sex is something merely “assigned at birth” and that a person's gender may actually be “neither, both, or a combination of male and female,” regardless of biology, and based solely on one's subjective “internal sense of gender.”¹⁷

Under such a radical redefinition of “sex,” a person or covered entity that in conscience and good faith declines to participate in “gender transition” treatments could face unwarranted litigation

14. Ryan T. Anderson, “Sexual Orientation and Gender Identity (SOGI) Laws Threaten Freedom,” Heritage Foundation Backgrounder No. 3082, November 30, 2015, <http://www.heritage.org/research/reports/2015/11/sexual-orientation-and-gender-identity-sogi-laws-threatenfreedom>; Ryan T. Anderson, “Sexual Orientation and Gender Identity Are Not Like Race: Why ENDA Is Bad Policy,” The Witherspoon Institute, Public Discourse, March 18, 2015, <http://www.thepublicdiscourse.com/2015/03/14649/> (accessed October 27, 2015); John Finnis, “Law, Morality, and ‘Sexual Orientation,’” in *Human Rights and Common Good: The Collected Essays of John Finnis*, Vol. 3 (New York: Oxford University Press, 2011), pp. 335–336.

15. Anderson, “Sexual Orientation and Gender Identity (SOGI) Laws Threaten Freedom”; Ryan T. Anderson, “ENDA Threatens Fundamental Civil Liberties,” Heritage Foundation *Backgrounder* No. 2857, November 1, 2013, <http://www.heritage.org/research/reports/2013/11/enda-threatens-fundamental-civil-liberties>; and Anderson, “Sexual Orientation and Gender Identity Are Not Like Race.”

16. See 80 FR 54176–54177.

17. *Ibid.*, 54174 and 51477

and liability.¹⁸ Because decisions about medical procedures, treatments, and insurance coverage made in line with reasonable medical, moral, and religious beliefs about biology and the best interests of the patient are nothing like invidious sex discrimination, they should not be treated by the federal government as such.

The Unsettled Question of Proper Treatment of Gender Dysphoria

Serious concerns raised by respected physicians about the propriety of “gender-reassignment” operations should give the Department pause before forcing individuals, physicians, hospitals, and insurers to participate in or cover such procedures. There are a variety of reasonable medical opinions about the best treatment for gender dysphoria—a deep-seated desire to appear and be treated as a member of the opposite sex. Permanently altering, resecting, or amputating well-functioning organs of the human body is a controversial form of treatment. Indeed, several European countries who adopted such treatments early, including the UK, Sweden, and Finland, are now urging caution. This would be an inopportune time for the federal government to not take a side in these debates through unaccountable agency action and then coercively impose that judgment on all medical professionals.

Paul McHugh, MD, University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine and former Psychiatrist-in-Chief at Johns Hopkins University Hospital, has written extensively about the serious medical and psychological questions surrounding sex-reassignment surgery. When Dr. McHugh arrived at Johns Hopkins in the 1970s, the hospital had become one of the leading centers for sex-reassignment surgery in the country. Yet few follow-up studies were being conducted with patients receiving sex-reassignment operations as treatment for gender identity disorder (now called gender dysphoria in the *Diagnostic and Statistical Manual of Mental Disorders*). McHugh encouraged Jon Meyer, who was a colleague, psychiatrist, and psychoanalyst, to conduct research on the psychological well-being of patients after sex-reassignment surgery to see if the procedure led to any improvements. The results, as McHugh describes them, left much to be desired:

[Meyer] found that most of the patients he tracked down some years after their surgery were contented with what they had done and that only a few regretted it. But in every other respect, they were little changed in their psychological condition. They had much the same problems with relationships, work, and emotions as before. The hope that they would emerge now from their emotional difficulties to flourish psychologically had not been fulfilled. We saw the results as demonstrating that just as these men enjoyed cross-dressing as women before

18. Ibid., 54220.

the operation so they enjoyed cross-living after it. But they were no better in their psychological integration or any easier to live with.¹⁹

Seeing little to no positive impact on the psychological health of transgender adults, McHugh could not justify continuing to surgically alter or remove healthy and fully functioning organs at the patients' requests. McHugh concluded that Johns Hopkins's practice of sex-reassignment surgeries, instead of helping patients, "was fundamentally cooperating with a mental illness" and the hospital stopped prescribing and performing the procedure.²⁰

Concurring with the observations made at Johns Hopkins, a 2011 long-term study of individuals who underwent sex-reassignment surgery documented sustained mental hardships of transgender-identifying individuals. Conducted over a 30-year period in Sweden, the study found that 10 years to 30 years after sex-reassignment surgery "the most striking result was the high mortality rate," due in significant part to post-operative transgender individuals having suicide rates nearly 20 times higher than their peers.²¹

McHugh addressed the question of proper treatment in the context of civil rights:

[P]olicy makers and the media are doing no favors either to the public or the transgendered by treating their confusions as a right in need of defending rather than as a mental disorder that deserves understanding, treatment and prevention.

* * *

Claiming that this is [a] civil-rights matter and encouraging surgical intervention is in reality to collaborate with and promote a mental disorder.²²

The proposed version of the 2016 Rule made no mention of the professionals who argue that there are serious medical and psychological concerns surrounding sex-reassignment surgery and gender-transition treatments.²³ There are now even more prominent critics of the strict "gender-

19. Paul R. McHugh, "Surgical Sex," *First Things*, November 2004, <http://www.firstthings.com/article/2004/11/surgical-sex>

20. *Ibid.*

21. Cecilia Dhejne et al., "Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden," *PLOS ONE*, Vol. 6, No. 2 (February 2011), <http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0016885&representation=PDF> (accessed October 27, 2015).

22. Paul McHugh, "Transgender Surgery Isn't the Solution," *The Wall Street Journal*, June 12, 2014, <http://www.wsj.com/articles/paul-mchugh-transgender-surgery-isnt-the-solution-1402615120>

23. 80 FR 54189–54190. Indeed, the only medical evidence cited in the preamble to the proposed regulation was a citation to an HHS Departmental Appeals Board decision to invalidate Medicare's previous

affirming approach. Thus, it would be negligent for a rule issued in 2022 to ignore these scientifically-grounded criticisms.

We are concerned that the proposed regulation will have serious effects on the practice of medicine, freedom of conscience, and choice in health care coverage. The 2016 Rule appeared to operate on the presumption that the question of gender-reassignment surgery is settled when respected physicians and researchers believe it is not the proper treatment for gender dysphoria. Whether or not one agrees with Dr. McHugh and other medical professionals' concerns about such procedures, they should retain the freedom to practice medicine according to their best judgments without governmental penalty.

Forcing Physicians to Act Against Their Medical Judgment and Insurance to Pay for It

The proposed regulations would disregard reasonable medical decisions and instead open medical professionals to extensive litigation and potential liability if they decline to participate in a transgender-identified individual's demands for a "sex change."

In 2016, the Department explained how a hypothetical gynecologist's office would be required to change its policy under the proposed regulations to "provide a medically necessary hysterectomy for a transgender man...in the same manner it provides the procedure for other individuals."²⁴ What constitutes a "medically necessary" procedure was not defined.

However, in a preceding section of the preamble of the 2016 Proposed Rule, the Department suggested that health insurance plans could be forced to cover procedures involved in sex-reassignment surgeries provided at least one medical professional deems the procedure "medically necessary" to treat gender dysphoria. The Department explained:

If, for example, a health plan or State Medicaid agency denies a claim for coverage of a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the plan's coverage of hysterectomies under other circumstances. OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.²⁵

Without further clarification, such regulatory language could force gynecologists who perform hysterectomies for some purposes, such as to treat uterine or ovarian cancer, to perform the

exclusion of sex reassignment coverage, which in turn cites the opinion of only one medical group that advances transgender surgeries.

24. *Ibid.*, 54204.

25. *Ibid.*, 54190.

surgery for gender-reassignment purposes as long as the patient has a referral from a psychologist. Gynecologists who decline to perform hysterectomies in such cases because of conscientious objections or because they judge them medically inappropriate could nevertheless face litigation under the proposed regulations, as would insurers that decline to pay for the procedures.

Similarly, physicians or insurers who regularly prescribe or cover hormones for some purposes, such as to treat conditions associated with aging in men and women, could face liability under the proposed regulation if they refuse to provide or pay for such hormones for gender-transition reasons.

Of course, without the language of the current proposed regulation, its full impact on the judgments of medical professionals is unclear. For instance, could psychologists or counselors who recommend, in their best medical judgment, that patients with gender dysphoria *affirm*, rather than reject, their sex be liable for supposed “discrimination” under the proposed regulation? Similarly, may an endocrinologist recommend that patients with gender dysphoria try hormone treatments that reinforce instead of counteract their sex without being subject to a lawsuit under the regulation? At the very least, the lack of clarity would likely invite expensive litigation on these and similar questions, and the proposed regulation could very well subordinate professional medical judgments to the rulings of Department bureaucrats or federal judges.

The Harm to Religious Liberty and Freedom of Conscience

In the preamble to the 2016 Proposed Rule, the Department acknowledged that its recommended nondiscrimination rule may conflict with religious beliefs. Although the Department said the regulation would not displace the federal Religious Freedom Restoration Act or laws and regulations protecting people from having to perform, pay for, or refer for abortion against their will, it provided no guidance as to how the proposed regulations would be limited, if at all, by those laws and regulations. Moreover, it proposed no moral or religious accommodation whatsoever. And it is unlikely that a religious exemption, even if proposed at some later date, would have adequately protected the freedom of conscience of physicians, insurers, employers, health care providers, and taxpayers given the breadth of the rule.²⁶ We anticipate that the new rule will have the same problems.

26. The Department asked for comment “on whether the regulation should include any specific exemptions” and, if so, whether any should track the exemption process for certain religious institutions found in Title IX regulations. *Ibid.*, 54173.

The practical impact of the proposed regulation could spread across the field of health care and to employers and taxpayers generally:

- **Physicians.** Doctors, gynecologists, psychologists, and counselors, among others, could be forced to participate directly in treatments or procedures in violation of their moral or religious beliefs.
- **Hospitals, health clinics, nursing homes, and other health care organizations.** The impact on many health care entities would be twofold. Like physicians, they could be forced to participate directly in procedures in violation of their moral or religious beliefs. They would also be forced to pay for coverage of the same procedures in their own employee health plans.²⁷ The proposed regulations could require health care organizations to open their bathrooms, locker rooms, and shower facilities to everyone regardless of sex or to provide “comparable” facilities, regardless of an organization’s religious beliefs on the matter.²⁸
- **Employers and individuals purchasing health insurance.** As previously noted and also discussed in more detail in a subsequent section of these comments, if the proposed regulations require private insurers that receive any enrollee subsidy on an Obamacare exchange or any other type of federal financial assistance to make all of their health insurance products comport with the gender identity mandate it would make it much more difficult (and in some cases, practically impossible) for private employers and individuals to avoid paying for coverage of sex-reassignment surgeries and treatments through their insurance plans contrary to their religious belief or moral convictions.
- **Taxpayers.** We anticipate that because the proposed regulation would apply to all insurance plans receiving taxpayer-funded subsidies on Obamacare exchanges and to all state Medicaid plans, which are funded with both state and federal tax dollars, the proposed regulation would make American taxpayers complicit in funding coverage of controversial surgeries and treatments.

Conflict with Existing Federal Right to Conscience

Health care policy, at bottom, should concern itself with the well-being of patients and providers. And a basic moral principle is at stake for health care providers: their central duty to do no harm.

27. The proposed regulation listed specific covered entities that would be required to ensure their own employee health benefits program abide by the proposed nondiscrimination policy. *Ibid.*, 54220.

28. The preamble to the proposed regulations noted, “HHS does not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex.” *Ibid.*, 54181. Presumably, if a covered entity failed to provide such “comparable facilities,” regardless of sex, it could be found in violation of the proposed regulations. Notably, the Department made no estimate of the cost to covered entities for ensuring compliance with the proposed regulations in this respect.

Our society has long recognized that medical care involves two parties—the patient and the doctor. Patients should be free to seek treatment, and doctors should be free to exercise their judgment about the right treatment for patients.

We are concerned that the proposed rule on Sec. 1557 will violate this principle. Using it, the state could force doctors to offer treatment they oppose.

As noted above, many doctors reasonably believe that to remove healthy organs, or to give young people puberty-blocking drugs, would harm their patients—whatever the subjective wishes of the patient. Healthy organs are not deadly tumors, and puberty is not a disease.

Proposed Regulations May Violate Conscience Concerning Abortion

In addition to the preceding concerns, the proposed regulation may threaten the freedom of conscience of physicians, health care entities, and individuals who have religious or moral objections to abortion. For nearly four decades, the federal government has prohibited discrimination against individuals and health care providers who do not wish to pay for, cover, or perform abortions. However, the proposed regulation could prohibit discrimination in health care “on the basis of sex” further defined to include discrimination on the basis of “termination of pregnancy,” i.e., abortion.²⁹

In the preamble to the 2016 regulation, the Office for Civil Rights cited existing conscience protections for individuals, physicians, and other health care entities. Yet those conscience laws were not explicitly applied in the text of the proposed regulations, and it was unclear how the regulations would have interacted with those existing policies. It was also unclear what “discrimination” based on termination of pregnancy would look like in practice. Would it prevent any differential treatment of a woman who has had an abortion, is seeking one, or both? Would the regulation have prohibited pro-life obstetricians from declining to refer patients for abortions, or would it have required coverage and provision of abortions, as with sex-reassignment surgeries? Because of this extreme ambiguity, the proposed 2022 regulation could risk serious conflict with long-standing and widely accepted law and policies protecting conscience.³⁰

29. *Ibid.*, 54216

30. Specifically, the Church Amendments prevent the government from forcing any individual or entity receiving certain federal dollars to “perform or assist in the performance of any sterilization procedure or abortion” or make its facilities available for such procedures if doing so would violate religious or moral beliefs about abortion. 42 U.S. Code § 300a-7 et seq. Likewise, the Weldon Amendment, attached to every HHS appropriations bill since fiscal year 2004, prohibits any government receiving certain federal dollars from discriminating against health care entities (including health insurance plans) because it “does not provide, pay for, provide coverage of, or refer for abortions.” For example, see the Consolidated Appropriations Act, 2010, Public Law No. 111–117. Even

Complexities of Scope

The 2016 Rule asserted both an overbroad scope of authority and an overbroad scope of applicability, both of which were appropriately corrected in the 2020 Rule.

With respect to the scope of authority, the Department noted in its explanation of the 2020 rule:

Because the Section 1557 regulation applies only to the Department, the 2015 NPRM had reasonably sought to limit its scope to Federal financial assistance from the Department, leaving other Departments to enforce Section 1557 within their own sphere. In the 2016 Rule, however, wishing to encompass tax credits administered under Title I, the Department expanded the rule’s scope to encompass “Federal financial assistance that the Department plays a role in providing or administering.” The Department now regards this expansion as overbroad. While Section 1557 still applies to any health program or activity receiving any Federal financial assistance, this final rule prescribes enforcement only by the Department and within the Department’s jurisdiction.³¹

With respect to the scope of applicability, Section 1557 incorporates by reference title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, and the Age Discrimination Act of 1975.³² The Civil Rights Restoration Act of 1987 amended the scope of each of those statutes to specify their applicability to the entire business of a covered entity if; 1) the entity as a whole receives federal assistance, or 2) if the entity “is principally engaged in the business of providing health care,” *and* one or more of the entity’s activities receives federal assistance.³³

In the 2016 Rule, HHS interpreted the second prong of this test as applying not only to medical providers but also to health insurers. Consequently, under the 2016 Rule, the regulations would be applied to *all* of the business of an insurer that received federal assistance in connection with coverage that it provided to *some* of its customers. Thus, the scope of the 2016 Rule included any health insurance issued to customers for which there was no connection with federal

the ACA prohibits qualified health plans offered on state and federal exchanges from “discriminat[ing] against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.” Public Law 111–148 as amended by Public Law 111–152. See also U.S. Department of Health and Human Services, “Overview of Federal Statutory Health Care Provider Conscience Protections,” <http://www.hhs.gov/ocr/civilrights/faq/providerconsciencefaq.html>

31. 85 FR 37170. However, the 2020 Rule also noted that QHPs still fall under the jurisdiction of the Department since under the ACA the Department regulates their certification and their participation in the exchanges.

32. Respectively, 42 U.S.C. 2000d et seq., 20 U.S.C. 1681 et seq., and 42 U.S.C. 6101 et seq.

33. Pub. Law 100-259.

assistance, any other (non-health) lines of insurance issued by the insurer, and any other (non-insurance) business operations of the insurer, such contracts to provide administrative or consulting services to sponsors of self-insured plans.

In the 2020 Rule, HHS concluded that its previous statutory interpretation had been overbroad on the grounds that it had conflated “the business of health care” with “the business of health insurance.” In issuing the 2020 Rule, the Department explained its reasons for concluding that “the business of health insurance” is distinct and different from “the business of health care” and is not a subset thereof.³⁴ Consequently, the 2020 Rule limited the scope of applicability with respect to insurers to only that portion of their business for which they receive federal assistance.

Going forward, any attempt by the Department to reverse its position in the 2020 Rule on this issue of scope of applicability and reinstate the position it took in the 2016 Rule, would not only raise a significant issue of statutory interpretation but would also entail significant implications for assessments of regulatory impact.

Under the interpretations adopted by HHS in the 2020 Rule, an insurer is:

- Subject to these regulations only with respect to; coverage that consists of Medicaid managed care plans, Medicare Advantage plans, or Qualified Health Plans (QHPs) offered through the ACA exchanges (including instances of enrollees purchasing such plans off the exchanges).³⁵
- Not subject to these regulations with respect to any; 1) non-health insurance coverage, 2) health insurance coverage consisting of either grandfathered or ACA-compliant non-group or employer-group plans, or consisting of supplemental or limited benefit policies, *and* which is not otherwise a QHP offered on the ACA exchanges, or 3) non-insurance business operations such as contracts to provide administrative or consulting services to sponsors of self-insured plans.

Reinstating the 2016 Rule interpretation would have the effect of expanding the scope of the regulations to encompass the second set of insurer products and contracts. To the extent that an insurer determines that such a regulatory expansion would be costly or otherwise detrimental, it

34. See 85 FR 3171-3174.

35. HHS correctly noted that an insurer would also be subject to Section 1557 with respect to other lines of business that receive federal assistance from an “Executive Agency” other than HHS, but that in such cases application and enforcement would fall under the jurisdiction of the relevant agency. For instance, the Office of Personnel Management contracts with insurers to offer coverage through the Federal Employee Health Benefit Program and the Department of Defense contracts with insurers to offer coverage through the TRICARE program.

could be expected to alter its business to avoid exposure to the additional regulations. The possibility of such effects will need to be accounted for in any regulatory impact analysis.

To be clear, from the perspective of insurers, the implications of expanding the scope of Section 1557 regulations would go far beyond the discrete effects attributable to the Department reinterpreting the word “sex” to encompass “sexual orientation and gender identity.” The much larger effect would be the subjection of their business practices to an additional new regulatory regime that consisted of the Department applying supposed “non-discrimination” reviews of insurer decisions with respect to; 1) the types of benefits offered, 2) the setting of limits or conditions on the scope or duration of covered services, 3) the structure of enrollee cost sharing for covered benefits, and 4) the application of medical management tools such as “prior authorization” and “medical necessity” requirements.

In that regard, the Department’s recent Rule “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023” offers a portent of what insurers could expect.³⁶ One provision of that Rule revised regulations for Qualified Health Plans (QHPs) regarding “non-discrimination” in “benefit design.” In the proposed version of that provision, the Department intended to include a reinterpretation of the term “sex” but in the final version removed that portion and stated it would instead be addressed in future rulemaking on Section 1557.

However, it is notable that comments from several insurers on the provision in the proposed rule focused, not on the narrow issue of the Department’s intended reinterpretation of meaning of the word “sex,” but rather on the broader implications of the provision’s sweeping and vague regulatory construct. The concerns of the commenting insurers centered on the Department’s intention to essentially implement a “we can’t define it, but we’ll know it when we see it” regulatory posture that would effectively presume insurer benefit designs to be suspect unless and until the Department determined otherwise.

Obviously, such a regulatory approach increases costs and uncertainty for insurers. Expanding its scope to include *all* of an insurer’s business if *any* enrollees received federal assistance, would significantly raise the stakes. In such an environment, it would be prudent for insurers to avoid those increased operating costs and risks by taking steps such as, discontinuing affected product offerings, exiting affected markets, or divesting affected lines of business.

As noted, under the 2020 Rule, the scope of applicability extends only to insurer offerings of Medicaid managed care plans, Medicare Advantage plans, or Qualified Health Plans (QHPs). Were the Department to extend that scope to *all* of an insurer’s business (as in the 2016 Rule),

36. 87 FR 27208-27393.

those carriers for whom affected plans comprise a smaller share of their total business could be expected to at least consider discontinuing or divesting their affected plans.

Such actions would have significant implications for insurer competition in the ACA exchange, Medicaid managed care, and Medicare Advantage markets.

Our review of insurer enrollment data, as of the end of 2021, identified carriers for whom affected plans constitute a relatively small share of their current business. It would be rational for some, or all, of those carriers to respond to an expansion of scope by discontinuing or divesting their affected plans. The common characteristic of those carriers is that their current business is predominantly focused on the employer-group coverage market, for which they provide fully insured group policies and administrative services for self-insured plans. That is not surprising as more than 160 million Americans currently have health insurance coverage through employment-based plans.

The enrollment profiles of two major national carriers illustrate the point:

- Cigna is the sixth largest carrier nationally and currently offers QHPs in 13 states. However, only six percent of Cigna’s total enrollment is in plans for which the company or its subscribers meet the criteria of receiving federal assistance.
- CVS Health (the parent company of Aetna) is the third largest carrier nationally, has the third largest Medicare Advantage plan enrollment (offering MA plans in 28 states), and currently offers QHPs in eight states. Even so, only 21 percent of Aetna’s total enrollment meets the criteria of receiving federal assistance.

As shown in the following table, we also identified 19 Blue Cross and Blue Shield carriers that currently offer QHPs in 30 states where they are a BCBS licensee, but for whom less than one-quarter of their total enrollment is in plans that meet the criteria of receiving federal assistance.

BCBS Licensees That Offer QHPs and Have Less Than One-Quarter of Their Total Enrollment in Plans Receiving Federal Assistance

Parent Company	State(s) Where BCBS Licensee	Total Enrollment in Comprehensive Coverage Plans*	Subset Enrolled in Plans Receiving Federal Assistance**	Share Receiving Federal Assistance
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Premera Blue Cross	AK and WA	2,594,665	112,506	4%
Blue Cross Blue Shield of Massachusetts	MA	2,890,949	139,079	5%
Wellmark, Inc.	IA and SD	1,343,283	72,852	5%
Blue Cross and Blue Shield of Kansas City	KS (2 Counties) and MO (30 Counties)	675,962	41,593	6%
CareFirst BlueCross BlueShield	MD, DC and VA (4 Counties)	3,044,350	272,358	9%
Blue Cross Blue Shield of Vermont	VT	170,710	15,536	9%
Cambia Health Solutions, Inc.	ID, OR, WA, UT	1,995,591	183,545	9%
Noridian Mutual Insurance Company	ND	279,431	26,358	9%
Blue Cross and Blue Shield of Kansas, Inc.	KS (All but 2 Counties)	561,814	56,016	10%
Louisiana Health Service & Indemnity Company	LA	1,436,188	153,560	11%
Blue Cross and Blue Shield of Alabama	AL	2,589,149	309,831	12%

Health Care Service Corporation	IL, MT, NM, OK and TX	16,722,380	2,104,880	13%
USAbles Mutual Insurance Company	AR	1,766,896	244,549	14%
Capital BlueCross	PA (21 Counties)	752,318	113,478	15%
Blue Cross Blue Shield of Michigan Mutual Insurance Company	MI	5,069,389	869,490	17%
Blue Cross of Idaho Health Service, Inc.	ID	566,148	98,502	17%
Blue Cross & Blue Shield of Rhode Island	RI	405,728	79,648	20%
Blue Cross Blue Shield of Arizona, Inc.	AZ	1,644,444	337,413	21%
Highmark, Inc.	DE, NY (21 Counties), OH (1 County), PA (63 Counties) and WV	4,616,541	1,018,995	22%

Source: Mark Farrah Associates (www.markfarrah.com), compiled using data from NAIC, CA-DMHC, CMS and other state government and private sources.

Notes:

* Enrollment figures are for comprehensive coverage plans only and do not include enrollment in supplement plans (dental, vision, etc.).

** Combined enrollment in individual market, Medicare Advantage and Medicaid managed care plans.

Furthermore, six of those carriers (collectively offering coverage in 11 states) are organized as member-owned mutual insurance companies.³⁷ Unlike traditional non-profit Blues, they are not subject to “community benefit” requirements that could potentially complicate or impede their exiting a state or a line of business.

In fact, several of them previously avoided or exited the ACA exchange market due to unfavorable conditions. For instance, Wellmark has never offered exchange coverage in South Dakota and did not offer exchange coverage in Iowa until 2017, then exited in 2018, but returned in 2019. Similarly, Health Care Service Corporation withdrew its New Mexico Blue Cross subsidiary from that state’s exchange in 2016, though it returned the following year. Blue Cross and Blue Shield of Nebraska exited the exchange in 2017 and has not returned. Currently, only two percent of that company’s enrollees are receiving federal assistance (consisting of few than 7,000 individuals in Medicare Advantage plans). Blue Cross & Blue Shield of Mississippi is also a mutual insurer. It has never offered exchange coverage and has no Medicare Advantage or Medicaid manage care enrollees.

Any resulting insurer exits could also have significant localized effects. For instance, Blue Cross Blue Shield of Vermont is one of only two insurers offering coverage in that state’s exchange. The same holds true for both Noridian in North Dakota and Highmark in West Virginia. Also, Highmark is the only insurer offering exchange coverage in Delaware. Blue Cross and Blue Shield of Alabama is the only insurer offering exchange coverage in 63 of that state’s 67 counties.

The above table is not exhaustive. There also are non-Blue carriers that are similarly situated, as well as more than two dozen other insurers for whom 25 percent to 50 percent of their total enrollment is in affected plans. Some of those insurers might also act to eliminate their exposure to increased regulation.

In sum, expanding the scope of Section 1557 regulations could reduce insurer competition in the ACA exchange, Medicaid managed care, and Medicare Advantage markets and would further dissuade currently unaffected insurers from entering any of those markets. That would, in turn, result in fewer coverage options for exchange enrollees and Medicare beneficiaries, and fewer

37. Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross of Idaho Health Service, Inc., Health Care Service Corporation, Noridian Mutual Insurance Company, USABLE Mutual Insurance Company, and Wellmark, Inc.

bidders for state Medicaid managed care contracts. Those effects would all need to be accounted for in any regulatory impact assessment of expanding the scope of Section 1557.

Unnecessary Regulatory Overreach

Section 1557 of the Affordable Care Act is meant to extend *existing* protections against discrimination in federal programs to health care or health insurance programs that receive federal funds or are run by the federal government. The health care law does not create special privileges, new protected classes, or new rights to particular procedures. The proposed regulation is therefore unnecessary and outside the proper scope of agency rulemaking. The Department nevertheless proposed in 2016 another regulatory scheme under Obamacare that injected Washington bureaucrats into intimate medical decisions without adequate justification. This problem was rectified in 2020. We are concerned that the new proposed regulation will simply resuscitate the problems of the 2016 rule.

Medical professionals should remain free to operate according to their best medical judgments. No American should be forced to violate his or her moral and religious beliefs, especially in morally fraught issues in health care. Individuals, employers, and all Americans should be able to choose health care and health insurance that best fits the needs of their families and respects their beliefs. Likewise, the federal government should not force taxpayers to subsidize medically and ethically controversial procedures. Yet a proposed gender identity mandate could violate all of these principles.

This would not be the first time, nor is it likely to be the last, that federal agencies would use the power given to them under Obamacare to promulgate rules that trample on the conscience rights of Americans. Just a few weeks after this earlier proposed rule was published, the Supreme Court agreed to hear numerous cases challenging a different Obamacare regulation that forced religious nonprofits to provide coverage of abortion-inducing drugs and devices, contraception, and sterilization in their employee health plans—under threat of heavy fines.³⁸ After years of litigation and controversy, the Supreme Court finally ruled in favor of religious conscience in 2020. in *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, by 7 to 2.

38. Elizabeth Slattery and Sarah Torre, “Supreme Court Will Hear Obamacare Abortion-Inducing Drugs Case. Why That’s Important for Religious Freedom,” *The Daily Signal*, November 6, 2015, <http://dailysignal.com/2015/11/06/supreme-court-will-hear-obamacare-abortion-inducingdrugs-case-why-thats-important-for-religious-freedom/>

We are concerned that the new proposed rule will lead to a replay of the same legal controversies. Indeed, the outcome of a related 2020 executive order by President Biden suggests precisely that.

The Department has proffered *Bostock v. Clayton County*,³⁹ and the Supreme Court’s determination that “sex discrimination” within the scope of employment discrimination under Title VII of the Civil Rights Act of 1964 also included discrimination on the basis of sexual orientation and transgender status, as its rationale to similarly expand sec. 1557’s prohibition against sex discrimination in healthcare.

However, in his opinion for the majority in *Bostock*, Supreme Court Justice Neil Gorsuch began: “We proceed on the assumption that ‘sex’ signified what the employers suggest, referring only to biological distinctions between male and female.”⁴⁰ From there, the Court noted:

An individual's homosexuality or transgender status is not relevant to employment decisions. That's because it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.⁴¹

Though *Bostock* has been cited endlessly for the proposition that the decision demands all civil rights law be altered to reflect sexual orientation and transgender status as stand-ins for sex, the decision offers no such basis. The court explicitly limited its holding to Title VII. Writing for the majority, Gorsuch explained:

The employers worry that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination. And, under Title VII itself, they say sex-segregated bathrooms, locker rooms, and dress codes will prove unsustainable after our decision today. But none of these other laws are before us; we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudice any such question today. Under Title VII, too, we do not purport to address bathrooms, locker rooms, or anything else of the kind. The only question before us is whether an employer who fires someone simply for being homosexual or transgender has discharged or otherwise discriminated against that individual ‘because of such individual’s sex.’⁴²

The Court’s Title VII precedent supports the proposition that relying at least in part on an individual’s biological sex (as with the case of sexual orientation or transgender status) is

39. 140 S. Ct. 1731 (2020).

40. *Ibid.*, at 1739.

41. *Ibid.*, at 1741.

42. *Bostock v. Clayton Cty.*, 140 S.Ct. at 1737.

prohibited within an employment setting. Yet, unlike Title VII, which is a sex-“prohibitive” anti-discrimination law, Title IX differs significantly in its text, purpose, operation, and in certain of its applications including athletics, for example, it is “sex-affirmative,” requiring consideration of a student’s biological sex. For example, longstanding Department regulations permit educational programs to “operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport” and instructs universities to consider male or female sex in their distribution of athletic scholarships.⁴³

Title IX’s application and interpretation post-Bostock is critical because sec. 1557 incorporates T.IX’s definition of sex discrimination by reference. Section 1557 guarantees that no individual can “be excluded from participation in, be denied the benefits of, or be subjected to discrimination under,” any federally run or federally funded health program “*on the ground prohibited under ... Title IX.*”⁴⁴ As you are aware, simultaneous rule-making is transpiring at the Department of Education on Title IX’s sex non-discrimination provisions in any educational program that receives federal funds.

As a result, the Department’s altered definition of “sex discrimination” within Title IX will directly affect Section 1557 and health care more generally. As such, in issuing its proposed Title IX rule, the Department must also evaluate the impact of the rule on Section 1557 and the healthcare context. The entanglement on “gender identity” vis a vis Title IX will have significant implications for medical professionals with conscience objections, healthcare facilities operated by faith-based organizations, and will immediately create a conflict within the medical community between those who want to promote the use of gender-affirming medical treatments, and those who prefer a “wait and see” approach.

The Department must consider the impact of any purported revision on other laws and in other contexts before moving forward with rulemaking of any kind, and there is scant evidence it has done so.

A Foretaste of Legal Problems for Proposed Rule

On August 9, 2021, District Judge Reed O’Connor issued a permanent injunction Aug. 9 against an executive order by President Biden, which redefine references to discrimination based on sex in Section 1557 of the Affordable Care Act to include “sexual orientation” and “gender

43. 34 C.F.R. §§ 106.41(b), and 106.37(c).

44. 42 U.S.C. § 18116 (a), citing Title IX, 20 U.S.C. § 1681 et seq.

identity.”⁴⁵ The measure would have forced medical professionals to participate in gender transition surgery and similar measures, even against their medical or moral judgment.

Judge O’Connor found that the order provided no exemption for religious conscience or professional opinion based on medical training and experience. As a result, it also trumped the conscience rights of doctors and hospitals who recognize that the biological differences between males and females can’t be erased with drugs or surgery. Specifically, he found that it violated the Religious Freedom Restoration Act, which he said was violated by the transgender mandate.

The case under consideration involved a Catholic hospital association, which would have had “to perform and provide insurance coverage for gender-transition procedures” or face fines and civil liability, O’Connor wrote in his decision.

The Religious Freedom Restoration Act, passed with the opposition of only three senators and signed into law in 1993 by President Bill Clinton, ensures protection of the rights of conscience against an overreaching federal law or policy that impinges on someone’s religious beliefs or practices, requiring the federal government to satisfy a “strict scrutiny” standard.⁴⁶

This means that the federal government may interfere with the exercise of someone’s religion only if it can establish that such interference is the least restrictive means available to achieve a compelling purpose.

The proposed rule we are considering in this comment would seem to be attempting to accomplish by regulatory fiat what could not be accomplished by executive order. But it seems quite likely that a new rule on Section 1557, with the same deficiencies, would encounter the same legal hurdles encountered by this quite similar executive order, *mutatis mutandis*.

An Unnecessary Rule

Executive Order 12866 of September 30, 1993 on Regulatory Planning and Review,⁴⁷ requires that “each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.”

45. *Franciscan Alliance, Inc. et al. v. Xavier Becerra*, 553 F.Supp.3d 361 (N.D. TX 2021).

46. Fred Lucas, “Marking Anniversary of Religious Freedom Law, Acting AG Whitaker Laments Loss of Support From Left,” January 16, 2019, *The Daily Signal*, <https://www.dailysignal.com/2019/01/16/marking-anniversary-of-religious-freedom-law-acting-ag-whitaker-laments-loss-of-support-from-left/>

47. Executive Order 12866, *Regulatory Planning and Review*, 58 FR 90 (October 4, 1993).

But the Department has failed to articulate a reason behind its activation of the regulatory review process, nor has it identified the problem it seeks to address. Instead, it has proposed a significant investment of taxpayer dollars, increased paperwork, and government manhours to solve an unidentified dilemma.

The proposed rule on non-discrimination in healthcare is a solution in search of a problem. We urge OIRA to carefully approach the regulatory process with a thorough understanding of the negative direct impact that such rulemaking will have on medical practitioners, health care facilities, and providers. These entities and individuals deserve protection against discrimination. We respectfully request that OIRA halt the regulatory process to provide sufficient opportunity to consider economic impacts, burdens of implementation, conflicts with freedom of conscience, and intersecting laws on non-discrimination.