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October 3, 2022

VIA FEDERAL ERULEMAKING PORTAL

U.S. Department of Health and Human Services, Office for Civil Rights
Attention: 1557 NPRM (RIN 0945-AA17)
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: Sarkes Tarzian, Inc. Comment Opposing Proposed Rule, "Nondiscrimination in Health Programs and Activities," RIN 0945-AA17

To Whom it May Concern:

I write to you on behalf of my client, Sarkes Tarzian, Inc., in opposition to the Department of Health and Human Services' (HHS) proposed rule under Section 1557 of the Affordable Care Act (ACA), entitled "Nondiscrimination in Health Programs and Activities." Sarkes Tarzian does not object to all aspects of the proposed rule, but takes issue with HHS' attempt to turn the Affordable Care Act's rather unremarkable prohibition of sex discrimination into a mandate that forces medical professionals to perform and insurance providers to cover so-called "gender transition" services, despite their religious, moral, and evidence-based objections against participating in the provision of such services.

Sarkes Tarzian is a media company based in Bloomington, Indiana. It currently operates television stations, radio stations, and websites in Indiana, Tennessee, and Nevada. Sarkes Tarzian's guiding philosophy is encapsulated by the company's motto, "For God and Our Neighbors." Consistent with this motto, Sarkes Tarzian strives to foster, in a number of ways, the common good of the communities it serves and the well-being of its neighbors in those communities, including by providing them accurate, honest, and balanced news coverage.

It is because Sarkes Tarzian is dedicated to its neighbors' well-being that it objects to HHS' proposed gender transition mandate. First, Sarkes Tarzian believes that the proposed mandates threaten the common good by attempting to cut short important public and medical debates over how best to care for adults and children experiencing gender dysphoria or are otherwise experiencing mental distress related to their gender identity. Second, Sarkes Tarzian suggests factors that the Department ought to consider when fulfilling its obligation to estimate the proposed rule's costs. Third, the proposed rule falls well short of the Department's obligation under the Religious Freedom Restoration Act—and by extension the Administrative Procedure Act—to protect religious freedom.

The Proposed Gender Transition Mandate Threatens the Common Good

As an initial matter, the proposed rule threatens the common good by propagating the unsupported and dangerous notion that there are no good reasons to categorically oppose treating gender dysphoria with novel and irreversible medical interventions. The proposed rule asserts that a provider cannot, consistent with the Department's interpretation of federal law, categorically refuse to participate in "gender transition" procedures for any reason, including the conclusion that such transitions "can never be beneficial for such individuals."[1] The Department's proposed rule categorically demeans such medical and moral judgments, stating that they do not constitute a "legitimate" or "nondiscriminatory" reason for declining to participate in gender transitions.[2]

As an initial matter, the Department lacks the statutory authority to override the professional judgment of individual health care professionals. Nothing in the Affordable Care Act supports the Department's claimed power to rule that a health care professional could not "legitimate[ly]" disagree with the Department's opinion that it is appropriate to perform irreversible procedures—including puberty blockers, cross-sex hormone therapy and even the surgical removal of healthy reproductive organs—to treat a mental health condition.[3]

More broadly, the Department's proposed rule would inappropriately attempt to cut short important conversations within the medical community and our society about the best ways help individuals who suffer from gender dysphoria or other types of mental distress related to their gender identity. The Department acts as though the medical and cultural debate is settled as to how best to care for people with gender dysphoria, but that is not the case.

The federal government's own statements and actions make this clear. In 2016, HHS' Centers for Medicare & Medicaid Services (CMS) declined to issue a National Coverage Determination on sex-reassignment surgery for Medicare beneficiaries with gender dysphoria ''because the clinical evidence is inconclusive.''[4] CMS determined, ''[b]ased on an extensive assessment of the clinical evidence,'' that ''there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries [which include non-seniors] with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.''

Similarly, in 2018 the Department of Defense (DOD) found that there is "considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment

[1] 87 Fed Reg. 47824, *Nondiscrimination in Health Programs and Activities* at 47918 (Aug. 4, 2022).

[2] *Id*. at 47918.

[3] *See, e.g., id*. at 47834 n.139.

[4] CMS, *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (CAG–00446N) (Aug. 30, 2016), https://www.cms.gov/medicare-coverage-database/view/ncacal-decisionmemo.aspx?proposed=Y&NCAId=282.

surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria."[5]

In 2020, HHS' Office for Civil Rights addressed whether Section 1557 of the Affordable Care Act required health insurers to cover transgender procedures and treatments and doctors to perform and administer them. HHS again concluded that there is no federally-recognized or required standard of medical necessity for transgender procedures undertaken to ameliorate symptoms of gender dysphoria.[6]

These determinations—all by the federal government in the last decade—are one indication of the considerable and growing body of studies exploring the difficult and unsettled matter of how best to care for people suffering from mental distress regarding their gender identity. Given the ongoing debate over the short term and long-term outcomes for various approaches to gender identity issues, and given the profound consequences of therapies that harm or surgeries that remove sex-specific organs, it is contrary to the common good for the Department to use its bully pulpit to claim that categorical refusal to participate in "gender transition" procedures amounts to illegal discrimination on the basis of sex.

The proposed gender transition presents an even greater threat to the common good given that it makes no distinction between adults and children. Transgender advocates had once tried to reassure the public that puberty blockers were "fully reversible," but recent studies have shown that these interventions negatively impact bone density, social and emotional maturation, and other aspects of development.[7] Some gender clinicians admit that puberty blockers may impair the child's later sexual functioning as an adult.[8] Though there is solid evidence for these side-effects, there is little reason to believe that puberty blockers help reduce a child's gender dysphoria or improve mental health.[9]

One of the reasons why there is so little long-term data in this area is that, while parents are reassured that puberty blockers are just a simple "pause," nearly all children set down this path go on to receive cross-sex hormones, which undoubtedly have irreversible, life-altering consequences. Blocking a child's natural maturation and then introducing cross-sex hormones renders the child permanently sterile.[10] Cross-sex hormones may also cause genital or vaginal

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[5] Dep't of Defense, *Report and Recommendations on Military Service by Transgender Persons* at 5 (Feb. 22, 2018), https://news.usni.org/2018/03/23/pentagon-report-recommendations-transgender-troops-serving-military.

[6] 85 Fed. Reg. 37187, *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority* (June 19, 2020). HHS found "there is no medical consensus to support one or another form of treatment for gender dysphoria," *id.* at 37198, and that a prior HHS rule regulating coverage and performance of sex-reassignment surgeries "relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding—such as the factfinding that CMS undertook in deciding to not issue a National Coverage Determination with respect to sex reassignment surgeries (as discussed above) due to insufficient proof of medical necessity," *id*.

[7] Annelou L. C. de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. Sex Med. 2276 (2011), https://www.jsm.jsexmed.org/article/S1743-6095(15)33617-1/pdf.

[8] Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy Care,"* Common Sense (Oct. 4, 2021), https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle.

[9] Annelou L. C. de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. Sex Med. 2276 (2011), https://www.jsm.jsexmed.org/article/S1743-6095(15)33617-1/pdf.

[10] Stephen B. Levine, *Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria*, 44 J. Sex Marital Ther. 29 (2018), https://pubmed.ncbi.nlm.nih.gov/28332936/.

atrophy, hair loss or gain, and permanent voice changes. Other changes are less visible, but more serious—including cardiovascular, liver, and metabolic changes.[11]

Even these radical interventions for gender confused children pale in comparison with proposed surgical interventions. The World Professional Association for Transgender Health (WPATH), which Department relies on throughout the proposed rule,[12] recently lowered the recommended ages for adolescents to receive cross-sex hormones to age 14, double mastectomy ("chest masculinization") to age 15, male breast augmentation and facial surgery to age 16, and removal of testes, vagina, or uterus to age 17, with flexibility to provide these "gender affirming" interventions at even younger ages.[13]

The Department's proposed rule would pressure health care professionals and institutions to affirm that these irreversible and life-altering interventions are "medically necessary," even though research shows that the vast majority of these children will later come to accept their biological sex. According to the DSM-5, up to 98% of biological males and 88% of biological females formally diagnosed with gender dysphoria will accept their biological sex by the time they reach adulthood.[14]

Yet the proposed rule would cause even more harm by forcing medical professionals to approve "gender transition" procedures *even for children that are not formally diagnosed* with gender dysphoria. The Department states that "not all individuals for whom such ["gender transition"] care is clinically appropriate will specifically identify as transgender," and such individuals "may"—not must—"have a gender dysphoria diagnosis."[15] If studies show that the great majority of children *formally diagnosed* with gender dysphoria later accept their biological sex, it seems reasonable that the figures for children that do not meet the clinical criteria for such a diagnosis would be even higher.

The Department itself defines as "medically necessary" a "health care service[] . . . needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms."[16] Yet studies show that the great majority of children who "seek[] . . . gender-affirming or transition-related

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[11] Gender-Affirming Hormone in Children and Adolescents, BMJ EBM Spotlight Blog (Feb. 25, 2019), https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescentsevidence-review/.

[12] *See* 87 Fed. Reg. at 47834 n.139, 47867 n.416, 47868 n.423, 47870 n.448.

[13] WPATH Standards of Care, Version 8, Draft for Public Comment, December 2021, "Adolescent" Chapter, p. 3.

[14] American Psychiatric Association. (2013). Gender Dysphoria. In Diagnostic and statistical manual of mental disorders (5th ed.). https://doi.org/10.1176/appi.books.9780890425596.dsm05. *See also* Singh, D., Bradley, S. J., & Zucker, K. J. (2021). A Follow-Up Study of Boys With Gender Identity Disorder. *Frontiers in psychiatry*, 12, 632784. doi.org/10.3389/fpsyt.2021.632784; https://www.frontiersin.org/articles/10.3389/fpsyt.2021.632784/full; Steensma TD, Biemond R, de Boer F, Cohen Kettenis PT. Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study. Clinical Child Psychol Psychiatry. 2011 Oct; 16(4):499-516. doi: 10.1177/1359104510378303. Epub 2011 Jan 7. PMID: 21216800; Steensma TD, McGuire JK, Kreukels BP, Beekman AJ, Cohen-Kettenis PT. Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. J. Am. Acad. Child Adolesc. Psychiatry. 2013 Jun; 52(6):582-90. doi: 10.1016/j.jaac.2013.03.016. Epub 2013 May 3. PMID: 23702447.

[15] 87 Fed. Reg. at 47867.

[16] 87 Fed. Reg. at 47870 n.448.

care"[17] will accept their biological sex by the time they reach adulthood. Under these circumstances, it is arbitrary and capricious for the Department to judge that a health care professional may not reasonably or lawfully decline to take part in such procedures.

Consider a strain of breast cancer that multiple studies showed is highly likely to go into permanent remission on its own within a few years. It is impossible to imagine the Department would claim it was illegitimate or discriminatory for a health care professional to categorically refuse to perform a mastectomy for such cases and instead pursue noninvasive therapies. For the same reason, it is unlawful and unreasonable for the Department to declare it unlawful for a health care professional to reach the reasoned judgment that "gender transition" is not appropriate for adolescents.

Recent developments in Great Britain highlight the reckless and unwise nature of the proposed mandate. After a court decision found that there was not much evidence to support gender transition for adolescents, the British government ordered a detailed investigation of practices at The Tavistock Clinic, the center for "gender-affirming treatment" in England.[18] In February 2022, the investigative team released an Interim Report, which found that the "evidence base for the treatment Tavistock was providing" was "shaky" and "had already been repudiated by several other Western European countries, including Finland, Sweden, and France."[19] The British National Health Service responded by shutting down the Tavistock Clinic on July 28.[20] Exactly one week later, the Department published its Section 1557 NPRM, which declares that *no* health care institution can legitimately decline to perform gender transition surgeries on adolescents.

For all these reasons, it is arbitrary and capricious for the Department to declare it "illegitimate" for health care professionals to decline to participate in gender transition procedures. To attempt to shut down public and professional debate in the face of contrary evidence in the United States and abroad would be profoundly unwise and would likely result in vulnerable adults and adolescents undergoing irreversible procedures and surgeries without the information they would need to provide informed consent.

The Department has not Adequately Considered the Potential Burdens and Costs of the Proposed Gender Transition Mandate

Sarkes Tarzian, as a self-insured employer, also offers comment in response to the Department's request for feedback on "the potential burdens and costs" of its proposed gender transition mandate.[21] The Department is required to assess the costs of its anticipated

[17] 87 Fed. Reg. at 47867.

[18] Valerie Hudson, *Perspective: The tide has turned in the UK on gender-affirming treatment for children*, DESERET NEWS, Aug. 11, 2022, https://www.deseret.com/2022/8/11/23301586/perspective-the-tide-has-turned-in-the-uk-on-gender-affirming-treatment-for-children-puberty-blocker.

[19] *Id*.

[20] Jasmine Andersson & Andre Rhoden-Paul, *NHS to close Tavistock child gender identity clinic*, BBC NEWS, July 28, 2022, https://www.bbc.com/news/uk-62335665.

[21] 87 Fed. Reg. at 47853.

regulatory actions, including the costs to "others in complying with the regulation, and any adverse effects on the efficient functioning of the economy [and] private markets."[22]

As an initial matter, any realistic assessment of the mandate's costs must detail the range of procedures that will be mandated. The proposed rule makes little effort to do so, merely stating in a footnote that "gender-affirming care" "may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designated to treat gender dysphoria or support gender affirmation or transition."[23]

The Department's list should also include those procedures that it approved to be part of Colorado's 2023 Health Benefit (EHB)-benchmark plan, which stated that required "services for transgender individuals" include "at least the following":

> Blepharoplasty (eye and lid modification)
> Face/forehead and/or neck tightening
> Facial bone remodeling for facial feminization
> Genioplasty (chin width reduction)
> Rhytidectomy (cheek, chin, and neck)
> Cheek, chin, and nose implants
> Lip lift/augmentation
> Mandibular angle augmentation/creation/reduction (jaw)
> Orbital recontouring
> Rhinoplasty (nose reshaping)
> Laser or electrolysis hair removal
> Breast/chest surgeries[24]

Once the Department has developed a list of procedures covered by the mandate, it can then proceed to determine the estimated frequency each procedure will be sought under the mandate (including whether some procedures are likely to be repeated) and the cost of each. Only with these estimates will the Department be able to meet its legal obligation to assess the cost of the proposed mandate.

Second, an assessment of potential burdens and costs must also try to estimate the number of people that will seek coverage under the mandate. This estimate should account for the dramatic increase in people seeking gender transitions in recent years. In 2011, the Williams Institute at the UCLA School of Law estimated that about 700,000 American adults identified as

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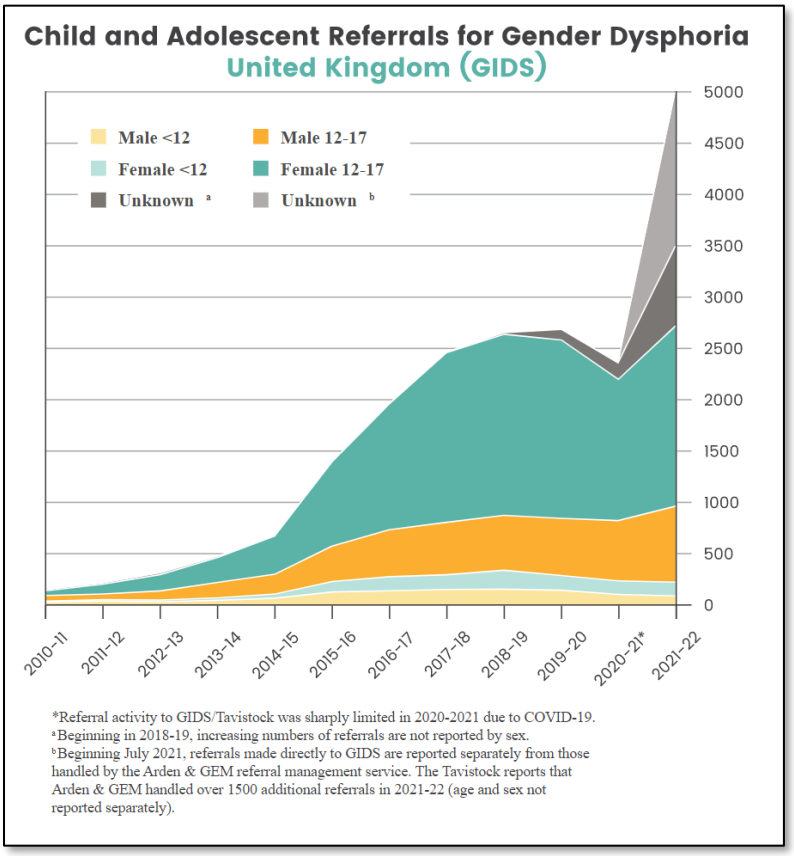
[22] Exec. Order No. 12866, "Regulatory Planning and Review," 58 Fed. Reg. 51735 (Sept. 30, 1993).

[23] 87 Fed. Reg. at 47834 n.139.

[24] Colorado Div. of Ins., *Benefits for Health Care Coverage, Colorado 2023 Benchmark Plan* at 38, https://drive.google.com/drive/folders/16HGzRJYpPJ3KQNepXmNdMg7pq1hmTofa. Allison Bell, *Colorado adds gender-affirming care to essential health benefits*, ALM Benefits Pro, Oct. 15, 2021, https://www.benefitspro.com/2021/10/15/colorado-adds-gender-affirming-care-to-essential-health-benefits-package-412-122583/; HHS, *Biden-Harris Administration Greenlights Coverage of LGBTQ+ Care as an Essential Health Benefit in Colorado* (Oct. 12, 2021), https://www.hhs.gov/about/news/2021/10/12/biden-harris-administration-greenlights-coverage-of-lgbtqplus-care-as-an-essential-health-benefit-in-colorado.html. Colorado's EHB-benchmark plan only requires coverage for these cosmetic procedures when prescribed as "treatment for gender dysphoria." However, the Department's proposed mandate removes this requirement.

transgender.[25] In 2016, the Williams Institute doubled its estimate to 1.4 million.[26] In 2022, the Williams Institute raised its estimate to 1.6 million, including an astonishing 1.6% of youth ages 13-17, twice as many youth as the Institute had previously estimated.[27]

To cite one concrete example, the Gender Identity Development Service for Children and Adolescents (GIDS) in London received 250 referrals in 2011-12 and over 5,000 in 2021-22, *a twenty-fold increase over a decade*[28]:



[25] UCLA School of Law, Williams Institute, *How Many People are Lesbian, Gay, Bisexual, and Transgender?* (April 2011), https://williamsinstitute.law.ucla.edu/publications/how-many-people-lgbt/.

[26] Jan Hoffman, *Estimate of U.S. Transgender Population Doubles to 1.4 Million Adults*, NY TIMES (June 30, 2016) https://www.nytimes.com/2016/07/01/health/transgender-population.html.

[27] UCLA School of Law, Williams Institute, *How Many Adults and Youth Identify as Transgender in the United States?* (June 2022) https://williamsinstitute.law.ucla.edu/publications/trans-adults-united-states/.

[28] Lucy Middleton, *Britain's only children's gender identity clinic to shut down*, REUTERS (July 28, 2022), https://www.reuters.com/article/news/britains-only-childrens-gender-identity-clinic-to-shut-down-idUKL8N2Z97IB. Graphic produced by Society for Evidence Based Gender Medicine, available at https://segm.org/images/280.UK_full.svg. *See also* Libby Brooks, *Tavistock gender identity clinic is closing: what happens next?*, GUARDIAN (July 28, 2022), https://www.theguardian.com/society/2022/jul/28/tavistock-gender-identity-clinic-is-closing-what-happens-next.

Without taking into account the dramatic increase in children and adolescents referred for gender dysphoria, and providing some reasoned estimate about what these numbers will be in the near future, the Department cannot meet its obligation to estimate the costs of the proposed mandate.

Third, a proper estimate must also account for other populations that will seek coverage under the proposed mandate. For example, the mandate would also cover those who have found that gender transition did not solve or even worsened their mental distress and are now seeking to detransition. As more adolescents and young adults continue to seek irreversible "transgender" body modifications, the associated medical, psychological, and financial costs are rising as well, resulting in regret and growing ranks of detransitioners.[29]

The Department must also account for the near certainty that its mandate will be interpreted by insurers and by courts as requiring coverage for the same wide range of cosmetic procedures for similarly situated non-transgender patients. As noted above, the proposed mandate is not contingent upon someone receiving a confirmed diagnosis of gender dysphoria: "not all individuals for whom such care is clinically appropriate will specifically identify as transgender, nor will all gender-affirming care specifically be related to transition from one binary gender to another. . . . A person's use of particular identity terminology is not determinative of whether the care in question is appropriate."[30] The Department does not state what triggers an insurer's obligations to provide mandated coverage. But it would presumably be sufficient for a covered person's physician to state, in his or her medical judgment, that a given procedure is "medically necessary" to address mental distress related to the dissonance between an individual's gender identity and his or her outward appearance.

Given these parameters, it would be unreasonable for the Department to presume in its cost estimates that only transgender persons would be able to benefit from coverage mandates for the "gender affirmation" cosmetic surgeries approved by CMS. The Department has taken the position that "[c]ategorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination."[31] Under this measure, it would be unlawful for the Department to mandate "gender-affirming care" coverage for women who appear more feminine than their gender identity, but exclude coverage for women who appear more masculine than their gender identity.

The Proposed Rule Threatens Religious Liberty

The Department claims that it has undertaken this rulemaking "to reflect recent developments in civil rights case law."[32] However the proposed mandate does not provide any concrete exemption or accommodation for the known and easily predictable situations where the mandate would substantially burden religious exercise. Instead, the Department's approach is merely to inform religious organizations that they "may notify OCR of [their] view that [they are]

[29] Littman, L. Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav* 50, 3353–3369 (2021). https://doi.org/10.1007/s10508-021-02163-w; https://link.springer.com/article/10.1007/s10508-021-02163-w.

[30] 87 Fed. Reg. at 47867.

[31] 87 Fed. Reg. at 47828 (citation omitted).

[32] 87 Fed. Reg. at 47829.

exempt from certain provisions of this part due to the application of a Federal conscience or religious freedom law."[33]

The Department pledges that OCR "shall promptly consider those views,"[34] but makes no promises about ever deciding whether a given religious claim is valid. The Department merely says that "OCR *may determine* at any time whether a recipient is exempt" or entitled to a "modified application" of the mandate.[35]

What is clear, however, is that the Department intends to enforce its gender transition mandate against objecting religious organizations. First, the Department has refused to honor the religious exemption in Title IX, which states that the law "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization,"[36] though Section 1557 explicitly incorporates Title IX by reference.

Second, and even more significantly, the Department has announced it will try to impose its gender transition mandate on organizations with religious objections: respecting the religious convictions of these entities would, the Department claims, "seriously compromise" the government's interests.[37]

The Department's tepid offer to review complaints from religious organizations and its stated intent to impose the mandate on objecting religious organizations is grossly inadequate. The proposed rule correctly notes that in each lawsuit brought by religious organizations against the 2016 Section 1557 mandate, courts have found that the Department violated its obligations under the Religious Freedom Restoration Act and granted injunctive relief.[38]

Since the Department issued its proposed rule, the Fifth Circuit has issued a new opinion in one of these cases. The Fifth Circuit's August 26, 2022, order in *Franciscan Alliance v. Becerra*[39] upheld the district court's decision, which found that the Department's 2016 Section 1557 rule violated RFRA as applied to plaintiffs.[40] The Fifth Circuit upheld the district court's decision that Franciscan Alliance was entitled to a permanent injunction not just from the Department's 2016 Section 1557 rule, but also from future regulations promulgated under Section 1557—such as the proposed rule.

The Department's stated intent to enforce its mandate against entities with religious objections stands in stark contrast to the consistent judgment from federal courts that the Section 1557

[33] 87 Fed. Reg. at 47918.

[34] *Id*.

[35] 87 Fed. Reg. at 47919 (emphasis added).

[36] 20 U.S.C. § 1681(a)(3).

[37] 87 Fed. Reg at 47841.

[38] 87 Fed. Reg at 47826 (listing cases).

[39] *Franciscan All., Inc. v. Becerra*, 47 F.4th 368 (5th Cir. 2022)

[40] *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361, 378 (N.D. Tex. 2021), amended, No. 7:16-CV-00108-O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021).

mandate violates RFRA as applied to objecting religious organizations. The Fifth Circuit's recent decision in *Franciscan Alliance* provides yet further confirmation that the Department's proposed "tell us your religious objections and we'll think about it" approach fails to meet the Department's obligations under RFRA and thus under the Administrative Procedure Act.[41]

Finally, the assurances required under proposed Section 92.5 may interfere with a religious employer's right to religious exercise under federal law. The proposed rule requires a covered entity to affirm that its "health programs and activities will be operated in compliance with Section 1557 and this part."[42] This phrasing does not seem to take into account situations where a TPA could lawfully administer a plan that does not conform to HHS' current position on what Section 1557 requires.

First, as the Department itself acknowledges, TPAs are "not generally responsible for the benefit designs of the self-insured group health plans they administer."[43] Further, ERISA requires TPAs to administer self-insured plans "according to their terms."[44] As such, it would be unreasonable for the Department to take the position that a TPA was legally obliged to violate its legal obligation under ERISA to honor its contract with the plan sponsor and honor the plan's terms.

Second, the Department is currently subject to injunctions that prohibit it from enforcing its gender transition mandate against hundreds of religious employers. These injunctions prohibit the Department from enforcing its mandate against these employers *and their insurers and TPAs.*

For example, the permanent injunction recently upheld by the Fifth Circuit:

> [P]ermanently enjoins HHS . . . from interpreting or enforcing Section 1557 . . . or any implementing regulations thereto against Plaintiffs, their current and future members, and those acting in concert or participation with them*, including . . . any insurers or third-party administrators* in connection with such health plans, in a manner that would require them to perform or provide insurance coverage for gender-transition procedures or abortions, including by denying Federal financial assistance because of their failure to perform or provide insurance coverage for

[41] A new decision in one of the lawsuits cited in the proposed rule provides further evidence that the Department's effort to expand the reach of Section 1557 violates the Administrative Procedure Act. The proposed rule notes that the State of Texas had already filed a lawsuit against the Department's March 2, 2022, Notice and Guidance, which like the proposed rule claims that "[c]ategorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination" under Section 1557 of the ACA. 87 Fed. Reg. at 47828 (quoting U.S. Dep't of Health & Human Servs., HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (Mar. 2, 2022)).

On October 1, the district court in that case found that the March 2 Guidance was "arbitrary and capricious," and therefore unlawful under the APA, because the Defendants offered 'no explanation at all'" to support their claim that "denial of . . . care solely of [a patient's] sex assigned at birth or gender identity likely violates Section 1557." *State of Texas v. EEOC*, No. 74 at 18, Civ. 2:21-CV-194-Z (N.D. Tex. Oct. 1, 2022). The court found the Department's effort to interpret Section 1557 unlawful, vacating and setting aside the March 2 Guidance. *Id*. at 32.

[42] 87 Fed. Reg. at 47913.

[43] 87 Fed. Reg. at 48786.

[44] *Id*.

> such procedures *or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions.*[45]

It is not clear whether the Department would take the position that a covered entity had made a false assurance where it had served as a TPA that excluded gender transition services under either of the circumstances set out above. But it would be wrong and arguably unlawful for the Department to leave this matter unclear, thereby intimidating TPAs into refusing to honor a plan sponsor's religious convictions, or forcing them to choose between risks of liability for violating either ERISA or the Department's interpretation of the ACA. The Department should remedy this obvious deficiency by making clear that a TPA, by administering a plan under either of the circumstances set out above, does not act contrary to the required assurance that its "health programs and activities will be operated in compliance with Section 1557 and this part."

* * *

Sarkes Tarzian encourages the Department to take these concerns into account as it considers whether and how to proceed with the proposed rulemaking.

Sincerely,

Eric Kniffin
Lewis Roca Rothgerber Christie LLP

[45] *Franciscan All*., 553 F. Supp. 3d at 378 (emphases added).