

Comment on Proposed Rule “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023”

Date: January 27, 2022

To: Secretary Xavier Becerra
Centers for Medicare and Medicaid
Department of Health and Human Services

In response to: Proposed Rule: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023; published at 87 FR 584

Reference: RIN 0938-AU65
CMS-9911-P

Dear Secretary Becerra,

This correspondence is submitted in response to the Department of Health and Human Services and Centers for Medicare and Medicaid Services’ request for comment regarding the proposed rule “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023,” at 87 Fed. Reg. 584 (January 5, 2021).

The proposed rule would reverse a 2020 rule promulgated by the previous administration regarding nondiscrimination provisions.¹ In particular, it would explicitly add “sexual orientation” and “gender identity” to nondiscrimination provisions in Title 45 of the Code of Federal Regulations sections 147.104(e), 155.120(c), 155.220(j)(2)(i), 156.125(b), 156.200(e), 156.1230(b)(2), reverting these sections to pre-2020 language, so that LGBTQI+ individuals may, as a result, receive “medically necessary” care. The 2020 rule was promulgated, however, to enforce the plain text enacted in the Affordable Care Act, prohibiting the discrimination on the basis of sex.

By adding sexual orientation and gender identity to the nondiscrimination provisions at the above sections, the new proposed rule would, in reliance on an illegitimate interpretation and application of *Bostock v. Clayton*, institute scientifically disputed “gender-affirming” procedures as essential health benefits in qualified health plans. This in turn would harm the recipients of such care, especially children, and force medical professionals to violate their medical expertise and/or consciences, thus potentially eliminating evidence-based alternatives to “gender-affirming” care.

The Heritage Foundation’s support for the 2020 regulation and opposition to the harms of surgical and chemical interventions aimed at altering secondary sex characteristics, above all for children, is a matter of public record. The Department’s proposed rule seeks to reverse the 2020

¹ Centers for Medicare and Medicaid Services, “Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority,” June 19, 2020, 85 FR 119 (RIN 0945-AA11).

rule in a manner that would contradict the plain meaning of well-established laws on sex discrimination, require insurance companies to pay for procedures of doubtful efficacy that in many cases could result in harm, and violate the religious and professional consciences of health care professionals.

Discrimination, *Bostock*, & Freedom of Conscience

According to the text, the proposed rule would “empower consumers” and “ensure program integrity” by ensuring that “Exchanges Issuers, and agents, and brokers are prohibited from discrimination based on sexual orientation and gender identity” consistent with President Biden’s Executive Order 13988 as well as HHS’ May 10, 2021 Notice.² Specifically, the Notice interprets section 1557 of the Affordable Care Act (ACA) and Title IX’s prohibition of discrimination on the basis of sex to include “sexual orientation” and “gender identity,” citing *Bostock v. Clayton County* as the justification for this interpretation.³

However, HHS’ claim that differential treatment based on actions related to gender identity or sexual orientation constitutes “sex” discrimination is not permissible—not under a plain reading of the designated nondiscrimination provisions nor on the basis of *Bostock* which it cites.

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 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.⁴ 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 proposal 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.

² Department of Health and Human Services (HHS), “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023,” January 1, 2022, 87 FR 584 (RIN 0938-AU65), 585. Hereafter, “Proposed Rule.” See, Executive Order 13988 on “Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,” January 20, 2021; 86 FR 7023; HHS, “Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972,” 86 FR 27984 (May 25, 2021).

³ *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020).

⁴ 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-threaten-freedom>; Ryan T. Anderson, “Sexual Orientation and Gender Identity Are Not Like Race: Why ENDA Is Bad Policy,” *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), 335–336.

Bostock has been cited mistakenly as a requirement that all civil rights law be altered to reflect sexual orientation and transgender status as stand-ins for sex.⁵ However, Justice Neil Gorsuch began his opinion for the court in that case as follows: “We proceed on the assumption that ‘sex’ signified what the employers suggest, referring only to biological distinctions between male and female.”

Justice Gorsuch anticipated attempts to use *Bostock* to reinterpret other Civil Rights laws and regulations. Therefore, he underscored the narrowness of the ruling in his opinion:

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 prejudge any such question today.⁶

In addition, the Court stressed that the Religious Freedom Restoration Act (RFRA) serves as a “super statute” that supersedes nondiscrimination provisions in many contexts. Responding to potential fears that compliance with Title VII would require employers to violate their consciences, Gorsuch cited the Religious Freedom Restoration Act of 1993 as a statute that

prohibits the federal government from substantially burdening a person’s exercise of religion unless it demonstrates that doing so both furthers a compelling governmental interest and represents the least restrictive means of furthering that interest. [42 U.S.C.] §2000bb–1 Because RFRA operates as a kind of super statute, displacing the normal operation of other federal laws, it might supersede Title VII’s commands in appropriate cases. See §2000bb–3.⁷

The HHS May 10, 2021 Notice thus misinterprets and misapplies *Bostock* to Section 1557 of the ACA in its expansion of nondiscrimination on the basis of sex to include sexual orientation and gender identity. Insofar as the proposed rule relies on this Notice, it too cannot rely on a simple citation of *Bostock* as justification to amend the identified nondiscrimination clauses.

ACA Section 1557 Litigation

⁵ Sarah Parshall Perry, “Education Secretary Prioritizes Transgender Students Over Biological Girls, Does What Supreme Court Hasn’t,” *Daily Signal*, June 16, 2021, <https://www.dailysignal.com/2021/06/16/education-secretary-prioritizes-transgender-students-over-biological-girls-does-what-supreme-court-hasnt/>

⁶ *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), 31.

⁷ *Ibid*, 32.

HHS is currently a party to litigation in which federal courts have concluded that Department regulations issued under the Affordable Care Act (ACA) violated RFRA by requiring religious stakeholders to provide and cover such procedures.⁸

Previously, the Obama administration tried to impose “gender-affirming” health care through its 2016 “transgender mandate.” Issued in 2016 by the Office for Civil Rights in the U.S. Department of Health and Human Services’ (HHS), the transgender mandate expanded the definition of sex to include “sexual orientation” and “gender identity” under Section 1557 of the Affordable Care Act. This rule provided no exemptions for religious conscience or dissenting professional medical opinions. As a result, it violated the conscience rights of those who recognize the reality of biological sex.

In August 2021, the Federal District Court for the Northern District of Texas permanently enjoined HHS and Secretary Becerra (*Franciscan Alliance v. Becerra*) from interpreting or enforcing Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116(a), or any implementing regulations against plaintiffs 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.

Absent clear congressional authorization, HHS is not 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.”

Under the proposed 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 and liability. 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.

Although it states it will comply with RFRA, the proposed rule’s presumption of discriminatory treatment in the refusal to cover gender transition procedures will inevitably create new conflicts with the federal Religious Freedom Restoration Act (RFRA). While *Franciscan Alliance v. Becerra* and *Religious Sisters of Mercy v. Azar* involved section 1557 of the ACA, the proposed regulations, if adopted, would fuel similar litigation in a guise only slightly different from the cases HHS has already lost in court. As a result, the proposal, if adopted in its present form, will draw the government and private parties into yet more litigation, and we expect that the government will lose those cases just as it lost earlier ones.

⁸ *Franciscan Alliance v. Becerra*, No. 7:16-cv-00108-O (N.D. Tex. Aug. 16, 2021), <https://becketnewsite.s3.amazonaws.com/Franciscan-order-8-9-2021.pdf>; see also, *Religious Sisters of Mercy v. Azar*, 513 F.Supp.3d 1113 (D. N.D. Jan. 19, 2021).

Clinical Evidence & “Gender Affirming Care”

The proposed rule seeks to amend section 156.125 “to ensure that benefit designs, and particularly benefit limitations and plan coverage requirements are based on clinical evidence.” (pp. 664). It then claims, “Clinical evidence supports medically necessary gender affirming care and demonstrates that such coverage can significantly improve the health and well-being of individuals accessing medically necessary care”.⁹ Consequently, any health plan design is “presumed to be discriminatory §§ 156.125 and 156.200(e) if it limits coverage of an EHB [essential health benefit] based on gender identity in treating gender dysphoria when clinical evidence demonstrates that such coverage is medically necessary to provide gender-affirming care.”¹⁰ In support of its claims, it cites guidelines for “gender-affirming care” that endorse hormone use and surgical intervention published by various professional societies.¹¹

Contrary to the proposed rule’s claims, the clinical evidence does not support the medical necessity of “gender-affirming” care. And some of the professional societies cited are reevaluating the medical necessity of gender-affirming therapies in light of the evidence.¹²

Most basically, “gender-affirming care” seeks to address gender dysphoria, the condition in which a person experiences significant psychological distress and discomfort in his or her bodily sex. Proponents claim that “gender-affirming” care is “medically necessary” because the presumed alternative to hormones or surgeries is suicide. Thus, the express goal of “gender affirming” care (e.g., puberty suppression, cross-sex hormones, surgical intervention, etc.) is to improve mental health, and so prevent suicide. But the best long-term studies have failed to establish this outcome. Quite the opposite. Published in 2019, a study of the largest dataset of patients who have undergone “gender-affirming” surgeries was found to have “demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care.”¹³ It also found no benefits to hormonal “transition.”

⁹ HHS, “Proposed Rule,” January 5, 2021, 667.

¹⁰ Ibid.

¹¹ American Medical Association (AMA), *Report of the Council on Science and Public Health*, “Hormone Therapies: Off-Label Uses and unapproved Formulations (Resolution 512-A-15),” August 1, 2016, <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/2016-interim-csaph-report-4.pdf>; World Professional Association for Transgender Health (WPATH), *Standards of Care Version 7* (2018), <https://www.wpath.org/publications/>; *Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (November 2017): 3869-3903.

¹² E.g., WPATH, “Standards of Care 8, Chapter Draft for Public Comment – Adolescent,” <https://www.wpath.org/media/cms/Documents/SOC%20v8/SOC8%20Chapters%20for%20Public%20Comment/SOC8%20Chapter%20Draft%20for%20Public%20Comment%20-%20Adolescent.pdf?t=1638731433>.

¹³ Ned H. Kalin, “Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process,” *American Journal of Psychiatry* 177 (2020): 8, <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.20060803>; for original study, see: Richard Bränström and John E. Pachankis, “Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study,” *American Journal of Psychiatry* 177 (2020), 727–734, <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2019.19010080>.

And the most thorough follow-up study is far more troubling. It reports that individuals who have undergone “gender-affirming” surgeries are, after 10 to 15 years, 19.1 times *more likely* to commit suicide than are comparable peers.¹⁴

Previously, the Obama administration itself admitted that related studies were not well constructed enough to determine “whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria.”¹⁵ The four best studies the Obama CMS found did not show significant differences in psychometric test results after surgery. In fact, “mortality from this patient population did not become apparent until after 10 years.” Though that was six years ago, more recent research is not conclusive.

Some have cited a “growing body of research” showing that the “gender-affirming” approach has positive mental health outcomes.¹⁶ However, a closer look at the studies or databases frequently cited shows that they are quite debatable.

What We Know Project

Indeed, Nathaniel Blake, Ph.D., has shown that much of the research often cited is methodologically weak.¹⁷ Analyzing the studies linked in Cornell University’s “What We Know Project,” Blake found that only 10 percent of the fifty relevant papers had more than 300 subjects. This means that the other 90 percent are likely not representative of larger populations.

Moreover, several studies, large and small, reported results from surveys that recruited participants through transgender-supporting online groups and forums and offered some form of compensation or lottery prize for participating. Such self-selected, self-reported, often one-time surveys are “more anecdotal than authoritative.”

Other clinical studies in the “What We Know” database were likewise fraught with problems. Not only were they small, non-representative, and self-reported; they lacked controls. Ultimately, studies that found immediate improvements in perceived well-being were consistent with

¹⁴ Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén, “Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden,” PLOS ONE 6, no. 2 (2011), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885>.

¹⁵ Centers for Medicare and Medicaid Services, “Final Decision Memorandum on Gender Reassignment Surgery for Medicare Beneficiaries with Gender Dysphoria,” August 2016, CAG-00446N, <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282&bc=ACAAAAAQAAA&>

¹⁶ E.g., Nathaniel Frank, “The Pentagon Is Wrong. Gender Transition Is Effective.” The New York Times, April 9, 2018, <https://www.nytimes.com/2018/04/09/opinion/pentagon-transgender.html>; “Outlawing Trans Youth: State Legislatures and the Battle over Gender-Affirming Healthcare for Minors,” Harvard Law Review 134, no. 6 (April 2021), <https://harvardlawreview.org/2021/04/outlawing-trans-youth-state-legislatures-and-the-battle-over-gender-affirming-healthcare-for-minors/>.

¹⁷ Nathaniel Blake, “What We Don’t Know: Does Gender Transition Improve the Lives of People with Gender Dysphoria?” Public Discourse, April 30, 2019, <https://www.thepublicdiscourse.com/2019/04/51524/>.

accounts of regrets in the long-term. What is lacking is long-term follow up to determine the longitudinal health outcomes for those who pursue “gender-affirming” care.

2015 United States Transgender Survey

Various studies make use of the data collected by the 2015 US Transgender Survey (See Appendix). This was an online survey of transgender and genderqueer adults recruited by trans-advocacy websites. Despite the large number of participants, the survey is ultimately self-selected and self-reported. This means that those who report being refused medical care, being denied chemical or surgical intervention, or discrimination did not have to document or verify their claims with, say, receipts of medical visits, doctor’s statements, police reports, and the like. Ultimately, the survey is a convenience sample, which results in highly skewed results.¹⁸ Recent studies that depend on this data should not be considered reliable or definitive.¹⁹

Despite this lack of evidence of “gender affirming care,” this rule deems such care “medically necessary.” It is not in the best interest of U.S. citizens for the Department to impose such controversial interventions as new standards of care since they have failed to achieve their express goal: improved mental health. Indeed, long-term studies suggest that such procedures may harm mental health. Therefore, the Department should allow the medical providers and researchers to study these questions without government interference and bias.

Risks of “Gender-Affirming Care”

In addition to the lack of conclusive evidence, there are many risks and harms of “gender-affirming” care, i.e., puberty suppression, hormone “therapy,” and surgical intervention. Recipients of these chemical and surgical interventions are at risk of loss of bone density and associated complications, sterilization, increased chances of suicide, surgical complications, and more. Again, recall the express goal of these interventions is to reduce the patient’s psychological discomfort with his or her body.

Children

¹⁸ Roberto D’Angelo, Ema Syrulnik, Sasha Ayad, et al., “One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria,” *Archives of Sexual Behavior* 50 (2020): 8, <https://doi.org/10.1007/s10508-020-01844-2>; cf. Marc H Bornstein, Justin Jager, Diane L Putnick, “Sampling in developmental science: Situations, shortcomings, solutions, and standards,” *Developmental Review* 33, no. 4 (2013): 357–370. <https://doi.org/10.1016/j.dr.2013.08.003>.

¹⁹ Jack L. Turban, Dana King, Julia Kobe, Sari L. Reisner, Alex S. Keuroghlian, “Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults,” *PLOS ONE* 17, no. 1 (January 2022), accessed January 24, 2022, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039>; Jack L. Turban, Dana King, Jeremi M. Carswell, Alex S. Keuroghlian, “Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation,” *Pediatrics* 145, no. 2 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269/>.

There are concerns that this rule’s discussion of age requirements as “presumptively discriminatory” may grant gender dysphoric minors access to surgical and chemical interventions that would cause irreversible harms and regret later in life.²⁰

According to the DSM-5 as many as 98% of gender-confused boys and 88% of gender-confused girls eventually accept their biological sex after naturally passing through puberty.²¹ For this reason, the “Dutch Approach” of “watchful waiting” has been most widely respected and widely used when it comes to treating children struggling with gender dysphoria.²² The Dutch Approach is comprised of the following components: (a) no social transition before age 12; (b) no puberty blockers before age 12; (c) cross-sex hormones considered only after age 16; and (d) resolution of mental health issues before any transition.²³

Puberty Blockers

Puberty blockers are designed to stop the development of secondary sex characteristics—but their use is controversial. Some have claimed that their effects are fully reversible. However, puberty blockers are not reversible socially or statistically speaking. Worse, they have been found to be harmful to health.

First, puberty suppression is not socially and statistically reversible.²⁴ Pubertal suppression stops the further endogenous masculinization or feminization of the patient. Suppressing the normal puberty of an adolescent is not *socially* reversible. Halting a child’s physiological development as his or her peers undergo puberty can be psychosocially isolating. Pre-pubertal boys or girls will be less able to identify with members of their respective sex.

Second, add social impersonation of the opposite sex to pubertal suppression, and the child’s adoption of a transgender identity becomes virtually inevitable. Statistically speaking, the vast majority of those who begin puberty suppression go on to take cross sex hormones. In one study, of those adolescents who started puberty blockers, only 1.9 percent of these chose not to undergo hormone therapy.²⁵

²⁰ Pp. 666-667.

²¹ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition (Arlington, VA, American Psychiatric Association, 2013), pp. 451-459. See page 455 re: rates of persistence of gender dysphoria.

²² Annelou L. C. de Vries and Peggy T. Cohen-Kettenis, “Clinical management of gender dysphoria in children and adolescents: The Dutch Approach,” *Journal of Homosexuality* 59 (2012): 301–320.

²³ Clinical management of gender dysphoria in children and adolescents: The Dutch Approach (de Vries & Cohen-Kettenis, 2012).

²⁴ American College of Pediatricians, “Gender Dysphoria in Children.”

²⁵ Annelou L. C. de Vries, Thomas D. Steensma, Theo A. H. Doreleijers, and Peggy T. Cohen-Kettenis, “Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study,” *Journal of Sexual Medicine* 8 (2011): 2276-2283.

In addition to preventing the development of secondary sex traits, puberty suppressing drugs “arrest bone growth, decrease bone accretion, prevent the sex-steroid dependent organization and maturation of the adolescent brain, and inhibit fertility by preventing the development of gonadal tissue and mature gametes for the duration of treatment.”²⁶

Loss of bone density is especially concerning. Currently, the World Professional Association for Transgender Health’s (WPATH) is drafting updated guidelines for gender dysphoric adolescents that acknowledge “concerns that delaying exposure to sex hormones (endogenous or exogenous) at a time of peak bone mineralization may lead to decreased bone mineral density.”²⁷ An investigative report of Lupron, a drug prescribed to stop precocious puberty, found that many of those who had took the drug suffered from a range of problems related to decreased bone density.²⁸

Hormone Therapy

Adverse effects of hormone therapy are real and apparent. According to a report from the American College of Pediatricians (ACPed), most experts agree that males who take oral ethinyl estradiol have an increased risk for coronary artery disease.²⁹ For adult males who received female sex steroid therapy, they were at higher risk for: thrombosis/thromboembolism; cardiovascular disease; weight gain; hypertriglyceridemia; elevated blood pressure; decreased glucose tolerance; gallbladder disease; prolactinoma; depression; and breast cancer.

For adult females who received male sex steroid therapy, they were at higher risk for: low HDL and elevated triglycerides; increased homocysteine levels; hepatotoxicity; polycythemia; increased risk of sleep apnea; insulin resistance; and unknown effects on breast, endometrial and

²⁶ American College of Pediatricians, “Gender Dysphoria in Children,” November 2018, <https://acped.org/position-statements/gender-dysphoria-in-children>; Lauren Schmidt and Rachel Levine, “Psychological outcomes and reproductive issues among gender dysphoric individuals,” *Endocrinology and Metabolism Clinics of North America* 44, no. 4 (2015): 773-785; Wylie C Hembree, Peggy T. Cohen-Kettenis, Henriette A Delemarre-van de Waal, et al., “Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline,” *The Journal of Clinical Endocrinology & Metabolism* 94, no. 9 (2009): 3132-3154.

²⁷ WPATH, “Standards of Care 8, Chapter Draft for Public Comment – Adolescent,” accessed January 25, 2022, https://www.wpath.org/media/cms/Documents/SOC%20v8/SOC8%20Chapters%20for%20Public%20Comment/SOC8%20Chapter%20Draft%20for%20Public%20Comment%20-%20Adolescent.pdf?_t=1638731433.

²⁸ Christina Jewett, “Women Fear Drug They Used To Halt Puberty Led To Health Problems,” *Kaiser Health News*, February 2, 2017, <https://khn.org/news/women-fear-drug-they-used-to-halt-puberty-led-to-health-problems/>.

²⁹ American College of Pediatricians, “Gender Dysphoria in Children,” November 2018, accessed January 24, 2022, <https://acped.org/position-statements/gender-dysphoria-in-children>.

ovarian tissues.³⁰ Youth who receive cross-sex hormone therapy may be rendered infertile.³¹ Additionally, as one report notes: “There are potentially long-term safety risks associated with hormone therapy but none have been proven or conclusively ruled out.”³²

Surgical Intervention

Many who receive cross-sex hormones go on to receive “sex reassignment” surgery (SRS). Again, the goal of these surgeries is to reduce the psychological distress experienced by one’s body. There are at least four major categories of “gender-affirming” surgeries: transfeminine top, transfeminine bottom, transmasculine top, transmasculine bottom. There are many other cosmetic surgeries to change facial structure and appearance to match one’s perceived gender identity. Each kind of surgical intervention carries significant risks and may lead to long-term complications.³³

Long-term follow up of those who have received hormone therapy and “gender-affirming” surgeries do not themselves yield significant improvement in mental health. Many recipients report “considerably lower general health and general life satisfaction”.³⁴ Other studies find significant increased rate of suicide attempts and suicides.³⁵ These risks are an important reminder that gender reassignment, though it may relieve gender dysphoria for a time, “should not be considered a cure.”³⁶

³⁰ Jamie Feldman, George R Brown, Madeline B Deutsch, et al., “Priorities for transgender medical and healthcare research,” *Current Opinion in Endocrinology, Diabetes and Obesity* 23, no. 2 (2016):180-187; Vin Tangpricha and Joshua D. Safer, “Treatment of transsexualism,” UpToDate.com, www.uptodate.com/contents/treatment-of-transsexualism?source=search_result&search=treatment+of+transsexualism&selectedTitle=1percent7E8; Eva Moore, Amy Wisniewski, Adrian Dobs, “Endocrine Treatment of Transsexual People: A Review of Treatment Regimens, Outcomes, and Adverse Effects,” *The Journal of Clinical Endocrinology & Metabolism* 88, no. 8 (August 2003): 3467–3473, <https://doi.org/10.1210/jc.2002-021967>.

³¹ American College of Pediatricians, “Gender Dysphoria in Children,” November 2018, <https://acped.org/position-statements/gender-dysphoria-in-children>

³² Hayes, Inc., “Hormone therapy for the treatment of gender dysphoria,” Hayes Medical Technology Directory (Lansdale, Pa: Winifred Hayes), May 19, 2014.

³³ For detailed descriptions of these procedures and associated risks, see American Society of Plastic Surgeons, “Gender Confirmation Surgeries,” <https://www.plasticsurgery.org/reconstructive-procedures/gender-confirmation-surgeries>.

³⁴ Kristen Clements-Nolle, Rani Marx, Robert Guzman et al., “HIV prevalence, risk behaviors, health care use and mental health status of transgender persons: implications for public health intervention,” *American Journal of Public Health* 91, no. 6 (2001): 915-21.

³⁵ Dhejne et al., “Long-Term Follow-Up of Transsexual Persons”; Annette Kuhn , Christine Bodmer, Werner Stadlmayr, et al., “Quality of Life 15 years after sex reassignment surgery for transsexualism,” *Fertility and Sterility* 92, no. 5 (2009): 1685-89

³⁶ Eva Moore, Amy Wisniewski, Adrian Dobs, “Endocrine Treatment of Transsexual People: A Review of Treatment Regimens, Outcomes, and Adverse Effects,” *The Journal of Clinical Endocrinology & Metabolism* 88, no. 8 (August 2003): 3467–3473, <https://doi.org/10.1210/jc.2002-021967>.

By requiring the above interventions as “medically necessary” care for LGBTQI+ people, the proposed rule would impose disputed standards of care that do not address the root causes of gender dysphoria and instead create long-term health risks for the very population it proposes to help.

Conclusion

Differential treatment based on actions related to gender identity or sexual orientation does not constitute “sex” discrimination. For the above reasons, we believe HHS’ proposal to incorporate disputed standards of care for LGBTQI+ people as essential health benefits in qualified health plans by redefining sex discrimination to include sexual orientation and gender identity is wrongheaded. The proposed amendments to nondiscrimination provisions lack any basis in *Bostock*, despite HHS’ argument in its prior May 10, 2021 Notice. Moreover, such care would harm the very patient population it seeks to help as well as violate the expertise and conscience rights of countless medical professionals. We therefore respectfully ask HHS to refrain from moving forward with this proposed rule.

Respectfully,

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Appendix: Studies on the effects of “gender-affirming care”

I. Recent Studies

Jack L. Turban, Dana King, Julia Kobe, Sari L. Reisner, Alex S. Keuroghlian, “Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults,” *PLOS ONE* 17, no. 1 (January 2022), accessed January 24, 2022, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261039>.

Summary: Based on the data from the 2015 U.S. Transgender Survey, the study found that accessing “gender-affirming” hormones (GAH) “was associated with lower odds of past-year suicidal ideation.” Those who accessed GAH during adolescence had “lower odds of past-year suicidal ideation when compared to accessing GAH during adulthood.”

Analysis: The 2015 US Transgender Survey is a convenience sample. It lacks any control group and the data was collected online through “trans-affirming” organizations. It is not representative of the transgender population. This study also finds that “respondents who started these hormones as adults had higher odds of binge drinking and of illegal drug use--though this finding does not appear in the abstract, introduction or conclusion” (Comment by Michael Biggs, Jan 19, 2022; see: <https://journals.plos.org/plosone/article/comment?id=10.1371/annotation/dcc6a58e-592a-49d4-9b65-ff65df2aa8f6>). See below for more analysis on the 2015 US Transgender Survey.

Amy E. Green, Jonah P. DeChants, Myeshia N. Price, and Carrie K. Davis, “Association of Gender-Affirming Hormone Therapy With Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth,” *Journal of Adolescent Health*, December 14, 2021, [https://www.jahonline.org/article/S1054-139X\(21\)00568-1/fulltext#secsectitle0010](https://www.jahonline.org/article/S1054-139X(21)00568-1/fulltext#secsectitle0010).

Summary: This is a “study,” reporting results of a survey of 34,759 youth aged 13-24, which found: (1) “half of transgender and nonbinary youth said they were not using GAHT [gender-affirming hormone therapy] but would like to”; and (2) “use of GAHT [gender-affirming hormone therapy] was associated with lower odds of recent depression and seriously considering suicide compared to those who wanted GAHT but did not receive it.”

Analysis: This is a convenience sample. There is no control group. Data collected online and participants were recruited by targeted ads on Facebook, Instagram, and Snapchat.

II. What We Know Project (Bank of Studies at Cornell)

In general:

- Some have cited this as a “growing body of research” that “make it indisputable that gender transition has a positive effect on transgender well-being.” (cf. Nathaniel Frank, “The Pentagon Is Wrong. Gender Transition Is Effective.” *The New York Times*, April 9,

2018, <https://www.nytimes.com/2018/04/09/opinion/pentagon-transgender.html>;
“Outlawing Trans Youth: State Legislatures and the Battle over Gender-Affirming Healthcare for Minors,” *Harvard Law Review* 134, no. 6 (April 12, 2021),
<https://harvardlawreview.org/2021/04/outlawing-trans-youth-state-legislatures-and-the-battle-over-gender-affirming-healthcare-for-minors/>.)

- However, a closer look at various studies finds that the research cited does not actually support these claims.
 - The bank includes 52 studies, two of which are irrelevant. One is double-counted and the other is a mathematical modeling of the cost and benefit of gender transition that is not original research.
 - Of the 50 relevant studies, only five had samples of over 300 and 26 had samples of less than 100. Seventeen studies had 50 or fewer, five of which had sample sizes less than 25.
- **The below analysis is taken from Nathaniel Blake’s piece on the What We Know Project: Nathaniel Blake, “What We Don’t Know: Does Gender Transition Improve the Lives of People with Gender Dysphoria?” *Public Discourse*, April 30, 2019, <https://www.thepublicdiscourse.com/2019/04/51524/>.**

Louis Bailey, Sonja J. Ellis, and Jay Mcneil, “Suicide risk in the UK Trans population and the role of gender transition in decreasing suicidal ideation and suicide attempt,” *Mental Health Review Journal* 19, no. 4 (December 2014): 209-220, https://www.researchgate.net/publication/281441727_Suicide_risk_in_the_UK_Trans_population_and_the_role_of_gender_transition_in_decreasing_suicidal_ideation_and_suicide_attempt.

Summary: This paper presents findings from the “Trans Mental Health Study,” the largest survey of “UK trans population to date.” “The study revealed high rates of suicidal ideation (84 per cent lifetime prevalence) and attempted suicide (48 per cent lifetime prevalence) within this sample. A supportive environment for social transition and timely access to gender reassignment, for those who required it, emerged as key protective factors. Subsequently, gender dysphoria, confusion/denial about gender, fears around transitioning, gender reassignment treatment delays and refusals, and social stigma increased suicide risk within this sample.”

Analysis: This is a 2012 online survey promoted by UK LGBT groups and support organizations. This survey may provide us with some data, but it is not reliable or representative scientific evidence for the efficacy of transition.

Colton M. St. Amand, Kara M. Fitzgerald, Seth T. Pardo, and Julia C. Babcock, “The Effects of Hormonal Gender Affirmation Treatment on Mental Health in Female-to-Male Transsexuals,” *Journal of Gay & Lesbian Mental Health* 15, no. 3 (July 2011): 281-299, https://www.researchgate.net/publication/233068152_The_Effects_of_Hormonal_Gender_Affirmation_Treatment_on_Mental_Health_in_Female-to-Male_Transsexuals.

Summary: “Results of the study indicate that female-to-male transsexuals who receive testosterone have lower levels of depression, anxiety, and stress, and higher levels of social

support and health related quality of life. Testosterone use was not related to problems with drugs, alcohol, or suicidality. Overall findings provide clear evidence that HRT is associated with improved mental health outcomes in female-to-male transsexuals.”

Analysis: ‘This study recruited subjects for its online survey by advertising “on online groups and discussion forums that were dedicated to FTM [female-to-male] members. . . . Upon survey completion, participants were entered into a lottery drawing for cash prizes.’ This survey may provide us with some data, but it is not reliable or representative scientific evidence for the efficacy of transition.

Emily Sarah Newfield, Tae L Hart, Suzanne Dibble, and Lori Kohler, “Female-to-male transgender quality of life,” *Quality of Life Research* 15, no. 9 (November 2006): 1447-1457, https://www.researchgate.net/publication/7025219_Female-to-male_transgender_quality_of_life.

Summary: Survey results found “FTM transgender participants who received testosterone (67%) reported statistically significant higher quality of life scores ($p < 0.01$) than those who had not received hormone therapy. FTM transgender participants reported significantly reduced mental health-related quality of life and require additional focus to determine the cause of this distress.”

Analysis: This study used an online survey ‘that recruited subjects online and via flyers and postcards in the San Francisco area, though in that case participants only “received a discount coupon redeemable at an Internet store.”’ This survey may provide us with some data, but it is not reliable or representative scientific evidence for the efficacy of transition.

Tiffany R. Glynn, Kristi E. Gamarel, Christopher W. Kahler, Mariko Iwamoto, Don Operario, and Tooru Nemoto, “The role of gender affirmation in psychological well-being among transgender women” *Psychology of sexual orientation and gender diversity* 3, no. 3 (September 2016): 336-344, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5061456/>.

Published by American Psychological Association.

Summary: “A community sample of 573 transgender women with a history of sex work completed a one-time self-report survey that assessed demographic characteristics, gender affirmation, and mental health outcomes. In multivariate models, we found that social, psychological, and medical gender affirmation were significant predictors of lower depression and higher self-esteem while no domains of affirmation were significantly associated with suicidal ideation.”

Analysis: This study consisted of “1-time self-report survey” completed by a “community sample of 573 transgender women with a history of sex work” who “received financial compensation for their time.” This survey may provide us with some data, but it is not reliable or representative scientific evidence for the efficacy of transition.

Cecilia Dhejne, Katarina Oberg, Stefan Arver, Mikael Landen, “An Analysis of All Applications for Sex Reassignment Surgery in Sweden, 1960-2010: Prevalence, Incidence, and Regrets,” *Archives of Sexual Behavior* 43, no. 8 (May 2014), https://www.researchgate.net/publication/262734734_An_Analysis_of_All_Applications_for_Sex_Reassignment_Surgery_in_Sweden_1960-2010_Prevalence_Incidence_and_Regrets.

Summary: “The regret rate defined as application for reversal of the legal gender status among those who were sex reassigned was 2.2 percent for the whole period 1960–2010.”

Analysis: Blake writes, “The first problem is that this methodology probably undercounts the regret rate, as its definition of regret overlooks those who were unhappy with their transition but did not apply to reverse it. It would not count those who succumbed to depression or addiction, or who lived unhappily after transition. Nor does the What We Know Projects note that a related study by some of the same researchers showed a horrifyingly high rate of suicide among its post-surgery subjects—nineteen times that of the general population. Finally, this data is drawn from a population with strict pre-transition screening, and the results likely do not apply where transition is less regulated. It is dangerous to assume that the regret rate of rigorously screened Swedish adults will apply to poorly screened American adolescents.”

III. 2015 US Transgender Survey

In general:

- “This survey used convenience sampling, a methodology which generates low-quality data (Bornstein, Jager, & Putnick, 2013). Specifically, the participants were recruited through transgender advocacy organizations and subjects were asked to “pledge” to promote the survey among friends and family. This recruiting method yielded a large but highly skewed sample.” From **Roberto D’Angelo, Ema Syrulnik, Sasha Ayad, et al., “One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria,”** *Archives of Sexual Behavior* 50 (2020): 8, <https://doi.org/10.1007/s10508-020-01844-2>.

Jack L. Turban, Noor Beckwith, Sari L. Reisner, Alex S. Keuroghlian, “Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults,” *JAMA Psychiatry* 77, no. 1 (2020): 68–76, <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2749479>.

Summary: This study finds that “recalled exposure to gender identity conversion efforts was significantly associated with increased odds of severe psychological distress during the previous month and lifetime suicide attempts compared with transgender adults who had discussed gender identity with a professional but who were not exposed to conversion efforts. For transgender adults who recalled gender identity conversion efforts before age 10 years, exposure was significantly associated with an increase in the lifetime odds of suicide attempts.”

Analysis: The 2015 US Transgender Survey is a convenience sample. It lacks any control group and the data was collected online through “trans-affirming” organizations.

Jack L. Turban, Dana King, Jeremi M. Carswell, Alex S. Keuroghlian, “Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation,” *Pediatrics* 145, no. 2 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7073269/>.

Summary: Turban finds, using the 2015 US Transgender Survey, “those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation.”

Analysis: This study is, retrospective and cross-sectional (“...cross-sectional design, which does not allow for determination of causation”). The data is drawn from self-reported history of adolescent puberty suppression. It did not control for other mental health factors. “...it is plausible that those without suicidal ideation had better mental health when seeking care and thus were more likely to be considered eligible for pubertal suppression.” Those with worse mental health would often be denied puberty blockage. Desisters and regretters would not likely be in this study group, which also only included adults, so “it does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender.” In summary, this is a very limited group of respondents, and tells us little.

contra Turban:

Michael Biggs, “Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of Sexual Behavior*,” *Archives of Sexual Behavior* 49 (2020): 2227-2229, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8169497/>.

This article identifies weaknesses of both the Turban study (just above) and general use of the 2015 US Transgender Survey.

IV. Other Studies

Wiepjes CM, Nota NM, de Blok CJ, et al, “The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets” *The Journal of Sexual Medicine* 15, no. 4 (2018): 582-90.

Summary: Concluded “The percentage of people who regretted gonadectomy remained small and did not show a tendency to increase.”

Analysis:

- “Not all data were available from the hospital registries, particularly older data or surgeries performed in other centers” (p. 590)

- “A large number of transgender people...were lost to follow-up. Although transgender people receive lifelong care, a large group (36%) did not return to our clinic after several years of treatment” (p. 589).
- Regret only tabulated for those who had gonadectomies and then requested hormone therapy consist with biological sex “and expressed regret” (p.584); excluded all who died (p. 584).
- No uniform stats on average follow-up time and variance.
- Admitted average regret time was 130 months. Page 589 admission: “...it might be too early to examine regret rates in people who started with HT in the past 10 years.” Many more patients came later in the study, counted as non-regret without allowing the expected time for such, which shifts results.

Joseph Tobin, Joanna Ting, Gary Butler, “The effect of GnRHa treatment on bone density in young adolescents with gender dysphoria: findings from a large national cohort,” *Endocrine Abstracts* 58 (2018).

Summary: Although there was a decline in age-related Z-scores, there was no significant change in Bone Mineral Apparent Density (BMAD) after one year on GnRHa (puberty suppression) and no significant changes between DEXA scans for tBMD or BMAD when analyzed cross-sectionally or longitudinally over 3 years.

Analysis: For the 39 adolescent girls, “Initially, they were in the 40th percentile for bone density. By the end of two years, however, they were in the lower 3rd percentile for bone density.”

Richard Bränström and John E. Pachankis, “Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study,” *American Journal of Psychiatry* 177 (2020), 727–734, <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2019.19010080>.

Summary: The study found that “gender-affirming surgeries” reduced mental health treatment use in transgender-identified individuals.

Analysis: The American Journal of Psychiatry issued a major correction retracting the study’s main finding after a handful of letters were sent in expressing concerns. See, Ned H. Kalin, “Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process,” *American Journal of Psychiatry* 177 (2020): 8, <https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.20060803>.

Johanna Olson-Kennedy, Jonathan Warus, Vivian Okonta, Marvin Belzer, and Leslie F. Clark, “Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts” *JAMA Pediatr* 172, no. 5 (2018): 431–436, <https://pubmed.ncbi.nlm.nih.gov/29507933/>.

Summary: This study finds that, “Chest dysphoria was high among presurgical transmasculine youth, and surgical intervention positively affected both minors and young adults.”

Analysis: “Chest dysphoria” is not a DSM-5 diagnosis and the “chest dysphoria scale” employed by the authors “is not yet validated.”