

April 11, 2025

### Via Federal eRulemaking Portal

Robert F. Kennedy, Jr.
Secretary
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9884-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: HHS CMS Proposed Rule: "Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability" RIN 0938-AV61, CMS-9884-P

Dear Secretary Kennedy:

We are scholars at the Ethics and Public Policy Center (EPPC). Eric Kniffin is an EPPC Fellow, member of EPPC's Administrative State Accountability Project (ASAP), and a former attorney in the U.S. Department of Justice's (DOJ) Civil Rights Division. Rachel Morrison is an EPPC Fellow, the director of EPPC's ASAP, and a former attorney with the Equal Employment Opportunity Commission. Mary Rice Hasson is the Kate O'Beirne Senior Fellow at EPPC, an attorney, and co-founder of EPPC's Person and Identity Project, an initiative that equips parents and faith-based institutions to counter gender ideology and promote the truth of the human person. Jamie Bryan Hall is the Director of Data Analysis and a Fellow in EPPC's Life and Family Initiative. He has more than two decades of experience performing quantitative analysis in the federal government, at think tanks, and for private businesses.

We write to offer public comment regarding the Department of Health & Human Services' (HHS) Centers for Medicare & Medicaid Services' (CMS) proposed rule, "Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability" (Proposed Rule). This rule contains seventeen proposals for Health Insurance Marketplaces and health insurance issuers, brokers, and agents who connect millions of consumers to Affordable Care Act (ACA) coverage. HHS explains that the proposals would establish "additional safeguards to protect consumers" and "standards to ensure the integrity of the Marketplaces," "with a goal of improving health care affordability and access while maintaining fiscal responsibility." We support these aims.

Our comment focuses on HHS's proposal to amend 45 C.F.R. § 156.115(d) "to provide that issuers of non-grandfathered individual and small group market health insurance coverage—that is,

<sup>&</sup>lt;sup>1</sup> 90 Fed. Reg. 12942 (Mar. 19, 2025), https://www.federalregister.gov/d/2025-04083.

<sup>&</sup>lt;sup>2</sup> See Fact Sheet, CMS, 2025 Marketplace Integrity and Affordability Proposed Rule (Mar. 10 2025), <a href="https://www.cms.gov/newsroom/fact-sheets/2025-marketplace-integrity-and-affordability-proposed-rule">https://www.cms.gov/newsroom/fact-sheets/2025-marketplace-integrity-and-affordability-proposed-rule</a> (summarizing seventeen proposals).

 $<sup>^{3}</sup>$  Id.

issuers of coverage subject to EHB requirements—may not provide coverage for sex-trait modification as an EHB beginning with PY 2026."

We support this proposal. However, we do not believe that the phrase employed in the Proposed Rule, "sex-trait modification," does not accurately designate the procedures that HHS describes in the preamble. We suggest that HHS adopt the term "sex-rejecting procedures" to avoid several significant problems inherent with the term "sex-trait modifications," which we outline below. For clarity, we use this proposed substitute term, "sex-rejecting procedures," throughout our comment.

Regardless of the term HHS chooses to use in its final rule, it is important that the term is defined, so we propose a definition for HHS's consideration.

The most important reason why Secretary Kennedy should exclude sex-rejecting procedures from the definition of EHB is because it is clear that a "typical employer plan" does not cover these dangerous and scientifically unproven procedures. Congress has entrusted the Secretary of HHS with the job of "ensur[ing] that the scope of essential health benefits . . . is equal to the scope of benefits provided under a typical employer plan." 42 U.S.C. § 18022(b)(2)(A). Thus, the Affordable Care Act requires Secretary Kennedy to ensure that neither the federal government nor states in their benchmark plans designate as an EHB procedures that are not covered by the typical employer plan.

HHS is also right to be concerned about the scientific integrity of claims made in favor of sexrejecting procedures. Here in America and across the globe, gender specialists, clinicians, and whistleblowers have raised alarm over the scant evidence supporting gender-affirming protocols, amid growing evidence that gender affirmation seriously harms vulnerable children.

We also provide additional reasons why HHS should finalize this proposal. This proposal would advance HHS's stated goal in the Proposed Rule to give Americans "relief from rising health care costs." HHS should also act to honor the 66% of Americans who believe that federal tax dollars should not go toward sex-rejecting procedures.

There is also no legal impediment to HHS finalizing this proposal. Excluding sex-rejecting procedures as an EHB would not violate the Fourteenth Amendment or federal nondiscrimination laws. Moreover, nothing in law prohibits HHS from rejecting gender ideology's radical anthropology, which claims that gender identity is immutable, but sex is not.

For all these reasons, we strongly encourage HHS to finalize the proposed amendment to § 156.115(d) and encourage Secretary Kennedy to recognize that sex-rejecting procedures are not "essential health benefits" as Congress has defined that term. The final rule should reaffirm that HHS's decision to exclude sex-rejecting procedures EHBs is not being made pursuant to executive orders, but pursuant to the independent reasons set out in this comment. And this is true notwithstanding the agency's acknowledgment that those orders exist, and that those orders discuss a similar topic, such as the kinds of procedures enclosed in HHS's proposed exclusion of sex-rejecting procedures. The fact that the topics overlap does not make this rule an implementation of those orders, because this rule is supported by independent statutory authority and reasoned decision-making. HHS should make that clear in the final rule to reduce its risk of litigation and improve its ability to defend this proposal in court.

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<sup>&</sup>lt;sup>4</sup> 90 Fed. Reg. at 12985.

# I. HHS should prohibit issuers from covering sex-rejecting procedures as "Essential Health Benefits."

The Proposed Rule details a proposal to "amend § 156.115(d) to provide that issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to EHB requirements—may not provide coverage for sex-trait modification as an EHB beginning with PY 2026." As the Proposed Rule notes, this proposal is rooted in Section 1302 of the ACA, 42 U.S.C. § 18022, where Congress gave the Secretary of HHS the authority to "define the essential benefits" subject to certain limits as set out in that section.

At present, 45 CFR § 156.115(d) prohibits four categories from being included as EHB: "routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia." The current regulation also states that "[f]or plan years beginning on or after January 1, 2027, an issuer of a plan offering EHB may not include routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB." In the Proposed Rule, HHS seeks "comment on whether it would be appropriate to exclude sex-trait modification as an EHB."

For the reasons set out below, it would be appropriate for Secretary Kennedy to exclude sexrejecting procedures as an EHB. In fact, we believe federal law requires Secretary Kennedy to do so.

# A. HHS is correct that a "typical employer plan" does not cover sex-rejecting procedures.

We agree with HHS that "the fact that sex-trait modification is not typically included in employer-sponsored plans is an independent, sufficient, and legally compelled reason for this rule." As noted above, Secretary Kennedy's authority to determine what counts as an "essential health benefit" is rooted in Section 1302 of the ACA, 42 U.S.C. § 18022, where Congress gave the Secretary of HHS the authority to "define the essential benefits" subject to certain limits as set out in that section.

One of the limitations that Congress set forth is that the "Secretary shall ensure that the scope of essential health benefits . . . is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary." 42 U.S.C. § 18022(b)(2)(A) (emphasis added). Congress only identified

For plan years beginning on any day in calendar year 2026, an issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, non-medically necessary orthodontia, or sex-trait modification as EHB. For plan years beginning on or after January 1, 2027, an issuer of a plan offering EHB may not include routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, non-medically necessary orthodontia, or sex-trait modification as EHB.

PY 2026 and PY 2027 are both mentioned in § 156.115(d) because the prohibition on providing coverage of sextrait modification services would apply starting in PY 2026 while CMS's 2025 Payment Notice removed the prohibition on providing routine non-pediatric dental services starting in PY 2027. *See* 89 Fed. Reg. 26218 (Apr. 15, 2024), https://www.federalregister.gov/d/2024-07274.

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> *Id.* at 12946.

<sup>&</sup>lt;sup>7</sup> *Id.* at 12986. The proposed text reads:

<sup>&</sup>lt;sup>8</sup> *Id.* at 12987.

<sup>&</sup>lt;sup>9</sup> *Id.* at 12986.

one source of information to "inform" the Secretary's "determination": a "survey of employer-sponsored coverage" performed by "the Secretary of Labor." *Id*.

To our knowledge, the most recent report from the Secretary of Labor on this matter is the April 11, 2011, document, "Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services." That report does not provide any information relevant to whether a "typical employer plan" covers sex-rejecting procedures. As recently as last year, legal scholars noted that "[t]here exist few data at present about the coverage or denial of gender-affirming care among employer plans."

In the absence of any data on this matter from a Department of Labor report, the only source of data specifically identified by Congress, and given that legal scholars believe there is "few data at present" on this matter, Secretary Kennedy has wide discretion to determine whether, in his judgment, a "typical employer plan" covers sex-rejecting procedures. In exercising this discretion, we encourage Secretary Kennedy to take the following considerations into account.

# 1. Large employer surveys are not relevant to the Secretary's determination as to what a "typical employer plan" covers.

We presume HHS will receive comments against this proposal citing studies showing that many *large* employers' health plans cover sex-rejecting procedures. For example, the Human Rights Campaign Foundation claims that 56% of Fortune 100 employers and 41% of Amlaw 200 law firms offer "transgender-inclusive health insurance benefits." However, these two groups do not represent the "typical employer plan." As this HRC report acknowledges, coverage of sex-rejecting procedures drops markedly as employers get smaller: according to the HRC, only 28% of Fortune 500 companies and 17% of Fortune 1000 companies offer "transgender-inclusive health insurance benefits." <sup>13</sup>

Most employers, however, look nothing like a Fortune 100 company, or even a Fortune 1000 company. According to the Small Business & Entrepreneurship Council, drawing on U.S. Census data, 98.1% of employers have less than 100 employees and 89% of employers have less than 20 employees. <sup>14</sup> Our review of the 2022 Statistics of U.S. Businesses (SUSB) dataset from the U.S. Census Bureau found that the median U.S. employer has between 4 and 5 employees. <sup>15</sup>

While very small employers dominate the U.S. economy, not all small employers offer health benefits. Thus, the "typical employer plan" reflects a business with more employees than the median U.S. employer. According to the Kaiser Family Foundation's (KFF) 2024 Employer Health Benefits Survey, 94% of firms with 50 or more employees offer health coverage, compared to only about 39% of firms

https://web.archive.org/web/20170528072852/https://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf.

<sup>14</sup> Small Business and Entrepreneurship Council, Facts & Data on Small Business and Entrepreneurship, <a href="https://sbecouncil.org/about-us/facts-and-data/">https://sbecouncil.org/about-us/facts-and-data/</a> (last visited April 10, 2025).

<sup>&</sup>lt;sup>10</sup> U.S. Dep't of Labor, Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services (April 15, 2011),

<sup>&</sup>lt;sup>11</sup> Valarie K. Blake & Elizabeth Y. McCuskey, Employer-Sponsored Reproduction, 124 Columbia L. Rev. 273, 296 n.141 (Mar. 2024).

<sup>&</sup>lt;sup>12</sup> Human Rights Campaign Foundation, *Transgender-Inclusive Benefits for Employees and Dependents* (last visited April 11, 2025), <a href="https://www.thehrcfoundation.org/professional-resources/transgender-inclusive-benefits-for-employees-and-dependents">https://www.thehrcfoundation.org/professional-resources/transgender-inclusive-benefits-for-employees-and-dependents</a>.

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>15</sup> U.S. Census Bureau, Statistics of U.S. Businesses 2022 Annual Data Tables, "U.S., all industries: Employment size of enterprise," https://www.census.gov/programs-surveys/susb/data.html.

with 3–9 employees. <sup>16</sup> Based on these statistics, the "typical employer plan" is likely held by an employer with between 10 and 20 employees. These statistics make clear that whatever statistics commenters cite to HHS about what the biggest companies cover in their health plans, such data do not tell HHS anything about whether sex-rejecting procedures are covered in a "typical employer plan."

# 2. Regardless, a clear minority of large employer cover sex-rejecting procedures.

But even if large employer plans were the measure, the Kaiser Family Foundation's Employer Health Benefits Survey—"widely cited and considered perhaps the most reliable source of information on employer and employee healthcare costs and premiums"<sup>17</sup>—would still support the Proposed Rule's position that the typical plan doesn't cover sex-rejecting procedures. KFF's 2024 Employer Health Benefits Survey found that, among "firms with 200 or more workers that offer health benefits, 24% cover gender affirming hormone therapy in their health plan with the largest enrollment." KFF found that employers "with 1,000 or more workers are more likely than smaller [large] firms to cover gender affirming hormone therapy (35% v. 21%)." Only among the very largest firms with 5,000 or more workers do more report that they cover than that they do not cover these procedures.

Though the KFF Survey does not separately track the number of large employers that cover sex-rejecting surgeries, it reasons that that number would be substantially less than those reported for cross-sex hormones, as sex-rejecting hormones are more common and not nearly as expensive as sex-rejecting surgeries.

# 3. The "typical employer plan" is subject to the state's EHB benchmark, and most states exclude sex-rejecting procedures from their benchmark plans.

As shown above, the "typical employer," and even the typical employer that offers health benefits, has less than 20 employees. Because such small employers generally lack the financial reserves, administrative capacity, and numbers to self-insure, it is safe to say that the "typical employer plan" is a fully-insured small group plan that must provide the ACA's "essential health benefits package." Thus, whether states include sex-rejecting procedures in their benchmark health plans is relevant to whether the "typical employer plan" provides such coverage.

<sup>&</sup>lt;sup>16</sup> Kaiser Family Foundation, 2024 Employer Health Benefits Survey (Oct. 8, 2024), <a href="https://www.kff.org/health-costs/report/2024-employer-health-benefits-survey/">https://www.kff.org/health-costs/report/2024-employer-health-benefits-survey/</a>.

<sup>&</sup>lt;sup>17</sup> Peter Wehrwein, *Premiums for Employer-based Health Insurance Increased by 7% in 2024, Says KFF Report*, Managed Healthcare Exec. (Oct. 9, 2024), <a href="https://www.managedhealthcareexecutive.com/view/premiums-for-employer-based-health-insurance-increased-by-7-in-2024-says-kff-report">https://www.managedhealthcareexecutive.com/view/premiums-for-employer-based-health-insurance-increased-by-7-in-2024-says-kff-report</a>.

<sup>&</sup>lt;sup>18</sup> Kaiser Family Foundation, 2024 Employer Health Benefits Survey at 210.

<sup>&</sup>lt;sup>19</sup> *Id*.

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>21</sup> See 42 U.S.C. § 300gg-6(a) (insurers must ensure that coverage in the "small group market" includes the "essential health benefits package" described in 42 U.S.C. § 18022(a)); 42 U.S.C. § 300gg-91(e)(5) ("small group market" means the health insurance market for plans "maintained by a small employer"); 42 U.S.C. § 18024 (b) (defining "small employer" to include those with less than 50 employees, but giving states discretion to define "small employer" for this purpose to be any employer with between 1 and 100 employees).

As HHS notes in the Proposed Rule, "[t]he EHB-benchmark plans of 40 States include language that excludes coverage of sex-trait modification." <sup>22, 23</sup> This survey provides further evidence that sex-rejecting procedures are not covered in the "typical employer plan."

# 4. Secretary Kennedy should also consider that most states have passed laws restricting the provision of sex-rejecting procedures.

Secretary Kennedy's assessment of whether a "typical employer plan" covers sex-rejecting procedures should also take note of state laws regarding these procedures. According to our survey of state laws, detailed in **Appendix B** to this public comment, only 16 states and the District of Columbia have passed laws mandating some insurance coverage of sex-rejecting procedures. In contrast, 27 states restrict provision of surgical or chemical procedures for minors, with 24 of these states prohibiting both:

### Status of State Laws on Sex-Rejecting Procedures (SRPs)

States (and D.C.) mandating some insurance coverage of SRPs	17
States restricting provision of surgical and chemical SRPs	24
States restricting provision of surgical SRPs only	3
States with no law	7

The fact that so many states have passed laws restricting the provision of sex-rejecting procedures provides further evidence that the American people do not support sex-rejecting procedures and that the typical employer plan does not cover these procedures.

# B. HHS is right to be concerned about the scientific integrity of claims made in favor of sex-rejecting procedures.

HHS is right to be "concerned about the scientific integrity of claims made to support" the use of "sex-trait modification" "in health care settings." Here in America and across the globe, gender specialists, clinicians, and whistleblowers have raised alarm over the scant evidence supporting genderaffirming protocols, amid growing evidence that gender affirmation seriously harms vulnerable children. <sup>25</sup>

Nearly thirty years after the Dutch initiated puberty suppression and hormonal interventions for gender dysphoric adolescents (the "Dutch Protocol"), the promised success—happy, healthy futures for

<sup>&</sup>lt;sup>22</sup> 90 Fed. Reg. at 12987 n.155.

<sup>&</sup>lt;sup>23</sup> Though not directly relevant to Secretary Kennedy's analysis relevant to § 156.115(d), we note that HHS's tally on 90 Fed. Reg. at 12987 n.155 incorrectly counts the District of Columbia as a "state." This is incorrect. As President Trump noted in a March 28, 2025, executive order, Washington, D.C. is "the Federal capital city," "the only city that belongs to all Americans and that all Americans can claim as theirs." Exec. Order No. 14252 "Making the District of Columbia Safe and Beautiful," 90 Fed. Reg. 14559 (March 27, 2025). Congresswoman Norton from DC responded to Trump's statement by saying that it "only helps to highlight the need for D.C. statehood so that D.C. can finally govern itself to the same extent afforded to the states." Press Release, Congresswoman Norton, Norton Releases Statement After President Trump Calls for Immediate House Vote on Bill to Correct D.C. Budget Issue Caused by the CR (March 28, 2025), <a href="https://norton.house.gov/media/press-releases/norton-releases-statement-after-president-trump-calls-immediate-house-vote">https://norton.house.gov/media/press-releases/norton-releases-statement-after-president-trump-calls-immediate-house-vote.</a>

<sup>&</sup>lt;sup>24</sup> *Id*.

<sup>&</sup>lt;sup>25</sup> The research provided here is a condensed version of some recent amicus briefs filed by EPPC scholars in lawsuits over laws that restrict sex-rejecting procedures. For more detailed information, see *Amicus Briefs*, "'*Gender Transition' Interventions*," Ethics & Public Policy Center, <a href="https://eppc.org/amicus-briefs/#19-%E2%80%9Cgender-transition%E2%80%9D-interventions-">https://eppc.org/amicus-briefs/#19-%E2%80%9Cgender-transition%E2%80%9D-interventions-</a>.

transgender-identified young people—is unrealized.<sup>26</sup> Clinical concerns over the outcomes of youth gender affirmation have escalated amid an epidemic of trans-identified youth with high rates of psychological illness, suicidality, and demonstrable medical harm, and a stunning lack of evidence of medical benefit.<sup>27</sup>

In April 2024, a four-year substantive evidence review (the "Cass Review"), commissioned by the UK National Health Service, delivered a definitive analysis of youth gender-affirming interventions. Overall, the Cass Review concluded that the evidence supporting gender-affirming interventions for minors, including social transition, is "remarkably weak," with "no good evidence on the long-term outcomes of interventions." For example, one of the systematic evidence reviews commissioned by the Cass Review "found no evidence that puberty blockers improve body image or dysphoria." The Cass Review noted that although "[t]ragically deaths by suicide in trans people of all ages continue to be above the national average," "there is no evidence that gender-affirmative treatments reduce this." The UK government responded to the Cass Review by imposing an emergency ban on puberty suppression for identity-distressed minors, which was upheld by a British court in July 2024.

Scandinavian countries that were early adopters of gender-affirming protocols have in recent years conducted their own substantive evidence reviews, reversed course, and curtailed medical transitions for minors. The leading gender clinic in Sweden has stopped using puberty blockers for minors. Finland has issued new guidelines that prioritize psychotherapy as the first-line treatment for gender dysphoric minors. Denmark recently followed Sweden and Finland, drastically limiting its use of puberty blockers and hormones in minors, citing high rates of adolescent psychiatric comorbidities and the lack of evidence justifying these life-altering interventions. <sup>34</sup>

<sup>&</sup>lt;sup>26</sup> Zhenya Abbruzzese, et al, *The Myth of Reliable Research in Pediatric Gender Medicine: A Critical Evaluation of the Dutch Studies – and research that has followed*, 49 J. Sex and Marital Therapy 673 (2023), <a href="https://pubmed.ncbi.nlm.nih.gov/36593754/">https://pubmed.ncbi.nlm.nih.gov/36593754/</a>.

<sup>&</sup>lt;sup>27</sup> See, e.g., Alison Clayton, Gender-Affirming Treatment of Gender Dysphoria in Youth: A Perfect Storm Environment for the Placebo Effect – The Implications for Research and Clinical Practice, 52 Archiv. Sex. Behav. 483 (2023), <a href="https://doi.org/10.1007/s10508-022-02472-8">https://doi.org/10.1007/s10508-022-02472-8</a>; Kirsty Entwistle, Debate: Reality check—Detransitioner's testimonies require us to rethink gender dysphoria, 26 Child & Adolescent Mental Health 15 (2020), <a href="https://pubmed.ncbi.nlm.nih.gov/32406585/">https://pubmed.ncbi.nlm.nih.gov/32406585/</a>.

<sup>&</sup>lt;sup>28</sup> Dr. Hilary Cass, OBE, Independent review of gender identity services for children and young people: Final Report at 13 (2024) [hereinafter "Cass Review"], <a href="https://cass.independent-review.uk/home/publications/final-report/">https://cass.independent-review.uk/home/publications/final-report/</a>. Ruth Hall, et al., <a href="https://cass.independent-review.uk/home/publications/final-report/">https://cass.independent-review.uk/home/publications/final-report/</a>. Ruth Hall, et al., <a href="https://pubmed.ncbi.nlm.nih.gov/38594055/">https://pubmed.ncbi.nlm.nih.gov/38594055/</a>.

<sup>&</sup>lt;sup>29</sup> Cass Review at 179.

<sup>&</sup>lt;sup>30</sup> *Id.* at 195.

<sup>&</sup>lt;sup>31</sup> Puberty blockers ban is lawful, says High Court, BBC (July 29. 2024), https://www.bbc.com/news/articles/c4ng3gz99nwo.

<sup>&</sup>lt;sup>32</sup> Lisa Nainggolan, *Hormonal Tx of Youth With Gender Dysphoria Stops in Sweden*, Medscape (May 12, 2021), <a href="https://www.medscape.com/viewarticle/950964">https://www.medscape.com/viewarticle/950964</a>.

<sup>&</sup>lt;sup>33</sup> June 16, 2020 Recommendations, Council for Choices in Healthcare (COHERE), Finland (summarized), <a href="https://palveluvalikoima.fi">https://palveluvalikoima.fi</a>. COHERE works in conjunction with the Finnish Ministry of Social Affairs and Health.

<sup>&</sup>lt;sup>34</sup> Society for Evidence-Based Gender Medicine, *Denmark Joins the List of Countries That Have Sharply Restricted Youth Gender Transitions*, SEGM (August 17, 2023), <a href="https://segm.org/Denmark-sharply-restricts-youth-gender-transitions">https://segm.org/Denmark-sharply-restricts-youth-gender-transitions</a>.

Other European countries increasingly take a cautious stance towards gender affirmation,<sup>35</sup> particularly as disturbing aspects of the gender affirming approach continue to emerge: insufficient evidence, uncertainty about long-term harms and benefits, harmful outcomes (including reduced bone density, sterility, serious complications), unexplained changes in patient demographics (predominately female with high rates of psychiatric comorbidities), persistently elevated suicide rates (post-transition), activist-suppressed research, political manipulation of supposedly evidence-based standards, and the rising numbers of detransitioners.<sup>36</sup>

Remarkably, there is *no* systematic review—the gold standard of evidence-based medicine—that finds high-quality (or even moderate quality) evidence supporting medical gender transition for children. Gordon Guyatt, a founder of evidence-based medicine principles, conducted two systematic reviews and meta-analyses after the Cass Review and concluded the "overarching theme" of these and other substantive evidence reviews is "the lack of high-quality evidence" to support gender affirmation.<sup>37</sup> Behind the puffery of activist clinicians, the affirmation model is propped up by flawed, cherry-picked studies.

The Cass Review's devastatingly thorough evidence review prompted baseless responses from proponents of gender affirmation, especially Yale Law School's so-called Integrity Project ("the Project"). The Project's response was described by one commentator as "an exceptionally misleading, confused, and fundamentally unprofessional document." It glossed over the many systematic reviews critical of gender affirmation, while drawing erroneous comparisons between medical gender transition and other areas of pediatrics characterized by low-quality evidence. The very low-quality evidence supporting medical gender transition, however, "stems not from a lack of randomised controlled trials, but from poor study design, inappropriate comparison groups, high attrition and inadequate follow-up." 40

The gender industry is responding to this stark reality not by producing better evidence but by moving the goalposts. Recent articles by gender clinicians attack "the normative assumption" that hormonal and surgical medical interventions are justified only if they "inevitably lead to 'positive' outcomes." These clinicians propose a new standard, analogized to the rationale for abortion, justifying gender interventions "on the basis of personal desire and autonomy." Objective evidence of medical

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<sup>&</sup>lt;sup>35</sup> Kasia Kozlowska, et al, *Evolving national guidelines for the treatment of children and adolescents with gender dysphoria: International perspectives*, Human Systems (2024), <a href="https://doi.org/10.1177/26344041241269298">https://doi.org/10.1177/26344041241269298</a>.

<sup>&</sup>lt;sup>36</sup> Leor Sapir, *Gender Medicine on the Ropes*, Manhattan Instit. Mag. (Winter 2025), <a href="https://www.city-journal.org/article/gender-medicine-trans-movement-donald-trump-election">https://www.city-journal.org/article/gender-medicine-trans-movement-donald-trump-election</a>.

<sup>&</sup>lt;sup>37</sup> Anna Miroshnychenko, et al., *Gender affirming hormone therapy for individuals with gender dysphoria aged* < 26 years: a systematic review and meta-analysis, Archiv. Diseases Child. (OnlineFirst issue) 7 (2025), <a href="https://adc.bmj.com/content/early/2025/02/11/archdischild-2024-327921.long">https://adc.bmj.com/content/early/2025/02/11/archdischild-2024-327921.long</a>; Anna Miroshnychenko, et al., <a href="https://adc.bmj.com/content/early/2025/01/29/archdischild-2024-327909.long">Puberty blockers for gender dysphoria in youth: A systematic review and meta-analysis, Archiv. Diseases Child. (OnlineFirst issue) (2025), <a href="https://adc.bmj.com/content/early/2025/01/29/archdischild-2024-327909.long">https://adc.bmj.com/content/early/2025/01/29/archdischild-2024-327909.long</a>.

<sup>&</sup>lt;sup>38</sup> Meredithe McNamara, et al., An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria (2024), <a href="https://tinyurl.com/mppm5cjz">https://tinyurl.com/mppm5cjz</a>.

<sup>&</sup>lt;sup>39</sup> Singal, *Yale's "Integrity Project" Is Spreading Misinformation*, Singal-Minded [Substack] (2024), Part 1 (<a href="https://perma.cc/FQQ4-434M">https://perma.cc/FQQ4-434M</a>) & Part 2 (<a href="https://perma.cc/8QSP-D6U6">https://perma.cc/8QSP-D6U6</a>).

<sup>&</sup>lt;sup>40</sup> C. Ronny Cheung, et al., *Gender medicine and the Cass Review: why medicine and the law make poor bedfellows*, 110 Archiv. Diseases Child. 251, 254 (2025), <a href="https://pubmed.ncbi.nlm.nih.gov/39401844/">https://pubmed.ncbi.nlm.nih.gov/39401844/</a>.

<sup>&</sup>lt;sup>41</sup> Ezra D. Oosthoek, et al., *Gender-affirming medical treatment for adolescents: a critical reflection on "effective" treatment* outcomes, 25 BMC Med. Ethics. 154 (2024), <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC11667851/">https://pmc.ncbi.nlm.nih.gov/articles/PMC11667851/</a>.

<sup>42</sup> Id.

benefit is deemed irrelevant if "affirming" interventions fulfill an adolescent's "embodiment goals" or produce "experiential" benefits (e.g., being recognized as one's asserted identity). <sup>44</sup> In short, the gender industry wants to replace evidence-based medicine with consumer satisfaction metrics.

Even still, however, the best evidence seems to show that "gender-affirming" treatments fail this subjective standard. In February, The Journal of Sexual Medicine published a retrospective study of over 107 thousand U.S. adults with gender dysphoria. The study found that those who underwent "gender-affirming" surgery "were at significantly higher risk for depression, anxiety, suicidal ideation, and substance use disorders than those without surgery." <sup>45</sup>

## C. We agree that sex-rejecting procedures don't fit into the statutory EHB categories.

We also agree with those stakeholders, mentioned in the Proposed Rule, who "do not believe that sex-trait modification services fit into any of the 10 categories of EHB and, therefore, do not fit within the EHB framework." As noted in the Proposed Rule the ten categories of EHB outlined in the ACA are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. 47

Sex-rejecting procedures do not fit into any of the ten categories over EHBs. Some sex-trait modification procedures involve prescription drugs, but 42 U.S.C. § 18022(b)(4)(A) explicitly tasks Secretary Kennedy with ensuring that, "[i]n defining the essential health benefits," "such essential health benefits reflect an appropriate balance among the categories described in" (b)(1). This statutory command would be impossible for Secretary Kennedy to fulfill were he required to designate all prescription drugs as essential health benefits. There is no evidence that the typical employer plan covers sex-rejecting procedures and it would reasonable for Secretary Kennedy to conclude that allowing cross-sex hormones to be considered EHB would be contrary to his statutory obligation under 42 U.S.C. § 18022(b)(4)(A).

# D. HHS should adopt this proposal to stop federal tax dollars from funding these unproven, harmful procedures.

We also support this proposal because it would advance HHS's goal of giving Americans "relief from rising health care costs." President Trump and Secretary Kennedy are rightly concerned about making sure that taxpayer dollars are well spent. This proposal would advance the administration's goal for at least three reasons.

First, the federal government provides tax credits (premium subsidies) to help lower- and middle-income individuals and families afford insurance premiums on the ACA marketplaces. These subsidies

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<sup>&</sup>lt;sup>43</sup> Elizabeth R. Boskey, et al., *A Retrospective Cohort Study of Transgender Adolescents' Gender-Affirming Hormone Discontinuation*, 76 J. Adolesc. Health. 584 (2025), <a href="https://pubmed.ncbi.nlm.nih.gov/39818655/">https://pubmed.ncbi.nlm.nih.gov/39818655/</a>.

<sup>&</sup>lt;sup>44</sup> *Id*.

<sup>&</sup>lt;sup>45</sup> Joshua E. Lewis, et al., *Examining gender-specific mental health risks after gender-affirming surgery; a national database study*, J. Sex. Med. (2025), <a href="https://academic.oup.com/jsm/advance-article-abstract/doi/10.1093/jsxmed/gdaf026/8042063">https://academic.oup.com/jsm/advance-article-abstract/doi/10.1093/jsxmed/gdaf026/8042063</a>.

<sup>&</sup>lt;sup>46</sup> 90 Fed. Reg. at 12987.

<sup>&</sup>lt;sup>47</sup> See id. at 12987 n.154, citing Section 1302(b)(1) of the ACA.

<sup>&</sup>lt;sup>48</sup> *Id.* at 12942.

are funded by federal tax dollars. Since the plans people buy with these subsidies must cover EHBs, the cost of those procedures is indirectly supported by the subsidies.

Second, beyond premium subsidies, the government also funds cost-sharing reductions (like lower copays or deductibles) for eligible enrollees. When an EHB procedure is used, these reductions can lower out-of-pocket costs, further tying federal funds to the coverage of that service.

Third, designating something as an EHB often increases the overall cost of insurance plans because insurers must account for covering it. Since federal subsidies are tied to keeping premiums affordable, more expensive plans can mean higher subsidy amounts—again, paid for with tax dollars.

Moreover, the American people do not want their federal dollars used to pay for harmful and unproven sex-rejecting procedures. According to a recent Pew Research Center study, 56% of U.S. adults favor or strongly favor laws and policies that ban health care professionals from providing care related to gender transitions for minors. <sup>49</sup> The same survey found that 53% oppose or strongly oppose laws that require health insurance companies to cover medical care for "gender transitions." A recent Cygnal poll found that 66% of Americans say federal tax dollars should not go toward "gender transition" procedures. <sup>50</sup>

Finally, as shown above, so-called "gender-affirming medicine" has been built on shoddy science. Given that these procedures are expensive and turn vulnerable people into life-long medical patients, amending § 156.115(d) to clarify that "sex trait modifications" do not count as EHB would advance HHS's stated goal of "reduc[ing] the burden of the ACA premium subsidy expenditures to the Federal taxpayer" and ensure that limited federal funds are spent on medical procedures that are proven to help medical problems. <sup>51</sup>

E. HHS should adopt this proposal to reflect the ACA's commitment to ensuring that federal dollars are not used to subsidize procedures that Americans believe are immoral.

Secretary Kennedy should also adopt this proposal to reflect the Affordable Care Act's policy decision that Americans should not be forced to subsidize the cost of medical procedures that large numbers of Americans believe are immoral and harmful. Section 1303 of the ACA, codified at 42 U.S.C. § 18023, creates "special rules" that ensure that "no federal funds will be used to pay for abortions except those permitted under the Hyde Amendment (i.e. rape, incest, or life endangerment of the mother)." However, this itself does not prohibit states (like Colorado and Vermont have done) from designating abortion as an EHB in their own benchmark plans. The special rules in Section 1303 require insurers to collect a separate premium payment from enrollees in plans that cover abortion and ensure that only these private funds—not the federal subsidies identified above—are used to pay for abortions other than those that fall within Hyde exceptions. This compromise within the ACA created a path that allowed states to

<sup>&</sup>lt;sup>49</sup> Pew Research Center, *Americans have grown more supportive of restrictions for trans people in recent years* (Feb. 26, 2025), <a href="https://www.pewresearch.org/short-reads/2025/02/26/americans-have-grown-more-supportive-of-restrictions-for-trans-people-in-recent-years/">https://www.pewresearch.org/short-reads/2025/02/26/americans-have-grown-more-supportive-of-restrictions-for-trans-people-in-recent-years/</a>.

<sup>&</sup>lt;sup>50</sup> Mairead Elordi, EXCLUSIVE: Americans Don't Want Tax Dollars To Pay For Transgender Procedures, Poll Shows; Even 43% of Kamala Harris voters said so, Daily Wire (April 9, 2025), <a href="https://www.dailywire.com/news/exclusive-americans-dont-want-tax-dollars-to-pay-for-transgender-procedures-poll-shows">https://www.dailywire.com/news/exclusive-americans-dont-want-tax-dollars-to-pay-for-transgender-procedures-poll-shows</a>.

<sup>&</sup>lt;sup>51</sup> *Id*.

designate abortion as an EHB while respecting Americans' convictions about abortion, reflected in the Hyde Amendment.

However, the ACA includes no such work-around for sex-rejecting, as there was no suggestion that the ACA would cover sex-rejecting procedures when the law was under debate in 2010. As such, the ability of states to mandate coverage for "sex trait modifications" as an EHB raises conscience concerns. These conscience concerns provide yet another reason why Secretary Kennedy should prohibit "sex trait modification" from being designated as an EHB.

It is important to note here that, as the Proposed Rule recognizes, "nothing in this proposal would prohibit health plans from voluntarily covering sex-trait modification as a non-EHB consistent with applicable State law, nor would it prohibit States from requiring the coverage of sex-trait modification, subject to the rules related to State-mandated benefits at § 155.170." Under the proposed § 156.115(d) states remain free to "require a [Qualified Health Plan] to offer benefits in addition to the essential health benefits." However, under § 155.170(b) and (c) the payments required "to defray the cost of additional required benefits" could be paid by the State and not with federal tax dollars.

# F. There is no legal impediment to Secretary Kennedy clarifying that sex-rejecting procedures are not "essential health benefits."

We anticipate that HHS will receive comments claiming that either the Fourteenth Amendment's Equal Protection Clause or nondiscrimination law, including Section 1557 of the Affordable Care Act, preclude HHS from excluding STM as an EHB. These claims are incorrect.

# 1. Excluding sex-rejecting procedures as an EHB does not violate the Fourteenth Amendment.

To have a successful Fourteenth Amendment claim, advocates would have to prove that excluding sex-rejecting procedures as an EHB is sex-based, transgender-status-based, or gender identity-based and that such an exclusion violates equal protection.

Some will likely claim that the category of sex-rejecting procedures is sex-based, transgender status-based, or gender-identity-based. It is far from established that transgender status or gender identity qualifies as a protected class under the Equal Protection Clause. But even if sex-rejecting procedures are specific to a protected class, any equal protection arguments are otherwise foreclosed by Supreme Court precedent.

In *Geduldig v. Aiello* (reaffirmed in *Dobbs v. Jackson Women's Health Organization*), the Supreme Court held that "[t]he regulation of a medical procedure" specific to a protected class "does not trigger heightened constitutional scrutiny" absent "invidious discrimination." Here, there is no invidious discrimination because, as HHS point out, the proposed exclusion is required by law because most employer health plans do not cover sex-rejecting procedures.

The Court's forthcoming decision in *United States v. Skrmetti* is unlikely to change this. The *Skrmetti* plaintiffs have challenged the constitutionality of a Tennessee law that prohibits all medical treatments intended to allow "a minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or to treat "purported discomfort or distress from a discordance between a minor's sex and asserted identity." After the Supreme Court heard oral argument on the case in December, most

<sup>&</sup>lt;sup>52</sup> 90 Fed. Reg. at 12987.

<sup>&</sup>lt;sup>53</sup> Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 236-37 (2022).

observers came away from the argument believing that the Court will agree with the Sixth Circuit that Tennessee's law is only subject to deferential rational basis review.<sup>54</sup>

At the oral argument, many Justices seemed unpersuaded<sup>55</sup> by the Biden administration Solicitor General's claim that Tennessee's law presents a "facial sex classification" because "Someone assigned female at birth can't receive medication to live as a male, but someone assigned male [at birth] can."<sup>56</sup> The Solicitor General claimed that estrogen and testosterone "produce the same physical characteristics ... no matter whether your birth sex is male or female."<sup>57</sup> The ACLU's attorney, Chase Strangio, similarly told the Court that "Someone who has a sex of female at birth" seeks these interventions so she "can undergo puberty like other boys."<sup>58</sup>

These arguments are likely to lose because their factual predicates are plainly false. Testosterone does not have the same effect on pubescent males as it does on pubescent females. Contrary to Strangio's claim, Tennessee's challenged law does not prevent her female client from "undergo[ing] a typical male puberty." That is precluded by the fundamental, inalterable fact that a female cannot "undergo a typical male puberty," because puberty is the "condition of being or the period of becoming first capable of reproducing sexually" and a female cannot ever "reproduce sexually" as a male. No court decision could remedy a limitation that is rooted in nature itself.

This is consistent with the Trump administration's position. After oral argument and after the administration transition, DOJ notified the Supreme Court that in its view the Tennessee law "does not deny equal protection on account of sex or any other characteristic" and urged the Court to decide the case. 61

HHS's equal protection defense here would be even stronger than Tennessee's in the *Skrmetti* case. Unlike the Tennessee law which prohibits the procedures, the Proposed Rule does not prohibit sex-rejecting procedures, nor prohibit states from requiring coverage in health plans. HHS is merely proposing to clarify that sex-rejecting procedures do not qualify as an "essential health benefit" under the standards set out by Congress in the ACA. As such, there is no need for HHS to delay issuing its final rule until after the Supreme Court decides the *Skrmetti* case.

<sup>&</sup>lt;sup>54</sup> See Amy Howe, Argument Analysis: Supreme Court Appears Ready to Uphold Tennessee Ban on Youth Transgender Care, SCOTUSblog (Dec. 4, 2024), <a href="https://www.scotusblog.com/2024/12/supreme-court-appears-ready-to-uphold-tennessee-ban-on-youth-transgender-care/">https://www.scotusblog.com/2024/12/supreme-court-appears-ready-to-uphold-tennessee-ban-on-youth-transgender-care/</a>.

<sup>55</sup> See id.

<sup>&</sup>lt;sup>56</sup> Transcript of Oral Arg. at 4-5, *United States v. Skrmetti*, No. 23-477 (U.S. Dec. 4, 2024).

<sup>&</sup>lt;sup>57</sup> *Id.* at 26.

<sup>&</sup>lt;sup>58</sup> *Id.* at 95-96.

<sup>&</sup>lt;sup>59</sup> *Id.* at 76.

<sup>&</sup>lt;sup>60</sup> Merriam-Webster Dictionary, "puberty," https://www.merriam-webster.com/dictionary/puberty.

<sup>&</sup>lt;sup>61</sup> Letter from Curtis E. Gannon, Deputy Solicitor General, to Scott S. Harris, Clerk of the Supreme Court of the United States re: *United States v. Skrmetti*, No. 23-477 (Feb. 7, 2025), <a href="https://www.supremecourt.gov/DocketPDF/23/23-477/342223/20250207133625781\_Letter%2023-477.pdf">https://www.supremecourt.gov/DocketPDF/23/23-477/342223/20250207133625781\_Letter%2023-477.pdf</a>; see also Amy Howe, *Trump Changes Government's Position in Pending Trans Healthcare Case at Supreme Court*, SCOTUSblog (Feb. 7, 2025), <a href="https://www.scotusblog.com/2025/02/trump-changes-governments-position-in-pending-trans-healthcare-case-at-supreme-court/">https://www.scotusblog.com/2025/02/trump-changes-governments-position-in-pending-trans-healthcare-case-at-supreme-court/">https://www.scotusblog.com/2025/02/trump-changes-governments-position-in-pending-trans-healthcare-case-at-supreme-court/</a>.

# 2. Excluding sex-rejecting procedures as an EHB does not violate federal nondiscrimination laws.

Clarifying that sex-rejecting procedures are not "essential health benefits" under the Affordable Care Act would neither violate HHS's nondiscrimination obligations under the Affordable Care Act nor, by extension, other applicable federal nondiscrimination laws.

As Rachel Morrison explained in her forthcoming law review article titled, "Avoiding Pandora's Box: Why Federal Nondiscrimination Statutes Don't Prohibit Health-Insurance Coverage Exclusions of 'Gender-Transition' Procedures," federal nondiscrimination laws like Section 1557 of the Affordable Care Act, do not "support claims that gender-transition coverage exclusions are discriminatory." 62

As HHS notes in the Proposed Rule, one district court recently held that President Trump's E.O. 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" (Jan. 20, 2025), likely violates the sex discrimination prohibitions of Section 1557 of the Affordable Care Act and Section 1908 of the Public Health Services Act. <sup>63</sup> This decision, *PFLAG v. Trump*, which has been appealed, is not a reason for HHS to reject or wait to adopt the Proposed Rule.

First, as HHS has clarified, it "does not rely on the enjoined sections" of this executive order "in making this proposal." Second, the current preliminary injunction on the E.O. does not bind Secretary Kennedy's decision making and HHS rulemaking under the Affordable Care Act.

Third, the court's analysis is wrong and should not be perpetuated by HHS. The district court, working under the premise that the Supreme Court's interpretation of Title VII in *Bostock* "applies to Title IX's sex-discrimination prohibition, as incorporated into Section 1557," found that President Trump's executive order constituted "textbook sex discrimination" because one can determine its application "solely from knowing [the patient's] sex" and because its prohibition on sex-rejecting procedures "stems from gender stereotypes about how men or women should present." The court also claimed that the executive order "appears ... to deny the existence of transgender persons altogether" and "rest[s] on the premise that the group to which the policy is directed does not exist." Curiously, the district court did not ask whether the sexes are "similarly situated" related to the sex-based discrimination at issue, though the Fourth Circuit did in *Kadel*, which is cited throughout the court's decision. The court's premises and reasoning are suspect, will likely be undermined by the Supreme Court's decision in *Skrmetti*, and should not affect HHS's decisions here.

Finally, even if the district court's analysis were correct, its claims about President Trump's executive order could not reasonably be applied to HHS's proposed amendment to § 156.115(d). Whereas the district court claimed the executive order was premised on the belief that transgender people do not exist, HHS's final rule would merely be based on the constraints Congress placed on EHBs and Secretary

<sup>&</sup>lt;sup>62</sup> Rachel N. Morrison, Avoiding Pandora's Box: Why Federal Nondiscrimination Statutes Don't Prohibit Health-Insurance Coverage Exclusions of "Gender-Transition" Procedures, 75 Catholic U. L. Rev. \_\_\_ (forthcoming 2026), available at <a href="https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=5141509">https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=5141509</a>.

<sup>&</sup>lt;sup>63</sup> PFLAG, Inc. v. Trump, No. 25-337-BAH, 2025 WL 685124 (D. Md. Mar. 4, 2025), available at https://caselaw.findlaw.com/court/us-dis-crt-d-mar/117019317.html.

<sup>64 90</sup> Fed. Reg. at 12986.

<sup>&</sup>lt;sup>65</sup> PFLAG, 2025 WL 685124 at \*23.

<sup>&</sup>lt;sup>66</sup> Id.

<sup>&</sup>lt;sup>67</sup> *Id*.

Kennedy's judgment that sex-rejecting procedures are "not typically included in employer-sponsored plans." 68

For all these reasons, HHS should not abandon its proposal to finalize § 156.115(d) in response to claims that federal nondiscrimination laws require Secretary Kennedy to conclude that sex-rejecting procedures are typically included in employer-sponsored health plans.

# 3. Nothing in law prohibits HHS from rejecting gender ideology's faulty anthropology, which claims that gender identity is immutable, but sex is not.

Finally, Judge Lagoa of the Eleventh Circuit got it right: the push for sex-rejecting procedures is based on "ideology, not science." *Eknes-Tucker* v. *Governor of Ala.*, 114 F.3th 1241, 1261 (11th Cir. 2024) (Lagoa, J., concurring in the denial of rehearing en banc). While those who advocate for and against sex-rejecting procedures may have different assessments of the scientific evidence, their policy differences are rooted in fundamentally different visions of what a human person is. Last summer, Justice Blacklock of the Texas Supreme Court described these two contrasting visions of what it means to be human:

The first vision—call it the Traditional Vision—holds that a boy is a boy, a girl is a girl, and neither feelings and desires nor drugs and surgery can change this immutable genetic truth, which binds us all. Within the Traditional Vision, human males and females do not "identify" as men and women. We are men and women, irreducibly and inescapably, no matter how we feel. . . .

The second vision—call it the Transgender Vision—holds that we all have a "sex assigned at birth," which usually corresponds to our physical traits but which may or may not correspond to our inwardly felt or outwardly expressed "gender identity." It holds that a person's gender identity is a constitutive part of his or her humanity and that when a person's biological sex and gender identity diverge, often gender identity should be given priority."

State v. Loe, 692 S.W.3d 215, 239-40 (Tex. 2024) (Blacklock, J., concurring). These two visions, as Justice Blacklock set out, lead to two "irreconcilably conflicting visions of what it means for doctors to do 'harm or injustice' to children experiencing confusion and distress about the normal biological development of their bodies." *Id.* at 239.

Justice Blacklock's discussion of these competing anthropologies is relevant here because HHS's critical mission requires it to have a working theory over what a human being is and what human flourishing entails. "The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services." Likewise, HHS's Strategic Direction aims at a "health system that achieves optimal outcomes through high quality, affordable, person-centered care."

<sup>&</sup>lt;sup>68</sup> *Id.* at \*22-27.

<sup>&</sup>lt;sup>69</sup> HHS, *About HHS*, <a href="https://www.hhs.gov/about/index.html">https://www.hhs.gov/about/index.html</a> (last visited April 11, 2025).

<sup>&</sup>lt;sup>70</sup> CMS, *Strategic Direction*, <a href="https://www.cms.gov/priorities/innovation/about/strategic-direction">https://www.cms.gov/priorities/innovation/about/strategic-direction</a> (last visited April 11, 2025).

HHS, with these important mission statements in mind, has recently clarified its understanding of what a human person is and how sex relates to sound health policy.<sup>71</sup> As relevant here, HHS stated:

- "A person's sex is unchangeable and determined by objective biology;"
- "The use of hormones or surgical interventions do not change a person's sex because such actions do not change the type of gamete that the person's reproductive system has the biological function to produce;"
- "The Department has long recognized that the biological differences between females and males require sex-specific practices in medicine and research to ensure optimal health outcomes and rigorous research, including by considering sex as a biological variable;"
- "Recognizing the immutable and biological nature of sex ... is critical to scientific inquiry, public safety, morale, and trust in government itself."

To the extent that HHS's final rule relies on the policy commitments reflected in this guidance document, Justice Blacklock is right that it is not discriminatory for HHS to find what he labels the Traditional Vision of the human person compelling and to develop policies based on this conviction. It is not discriminatory for HHS to recognize that the basic premise of gender ideology, and thus the push for sex-rejecting procedures, is irreconcilable with HHS's definition of sex and HHS's understanding of what a human being is and what human flourishing entails.

The anthropology behind the push for sex-rejecting procedures denies the immutable reality of sex while insisting that gender identity is innate and unchanging. These false beliefs contradict sound medical ethics, which requires clinicians to treat patients with "honesty, beneficence [doing good], nonmaleficence [doing no harm], justice, and respect for patient autonomy." Good medicine facilitates human flourishing, where mind and body function well and achieve their ends. A person's thoughts and feelings achieve their ends by being in contact with reality—in this case, the reality of sex, specifically the binary, immutable nature of sex.

According to the National Academy of Science's Committee on Understanding the Biology of Sex and Gender Differences, sex is "the classification of living things . . . as male or female according to their reproductive organs and functions assigned by the chromosomal complement." A person's sex (male or female) is imprinted in every cell of the body and cannot change. <sup>74</sup>

Gender ideology disregards the permanence of sex but treats "gender identity" as self-determined but unchanging, regardless of the person's sex. As such, gender ideology makes an erroneous metaphysical claim about the nature of the human person.

<sup>&</sup>lt;sup>71</sup> HHS, Defining Sex: Guidance for Federal Agencies, External Partners, and the Public Implementing Executive Order 14168, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (Feb. 19, 2025),

 $<sup>\</sup>underline{https://womenshealth.gov/sites/default/files/\_images/2025/2.19.25\%20Defining\%20Sex\%20Guidance\%20for\%20Federal\%20Agencies\%2C\%20External\%20Partners\%2C\%20and\%20the\%20Public\%20FINAL.pdf.}$ 

<sup>&</sup>lt;sup>72</sup> Stephen B. Levine, *Informed Consent for Transgendered Patients*, 45 J. Sex & Marital Therapy 218 (2019), https://doi.org/10.1080/0092623X.2018.1518885.

<sup>&</sup>lt;sup>73</sup> Inst. of Medicine, *Exploring the Biological Contributions to Human Health: Does Sex Matter*? 1 n.1 (2001), https://www.ncbi.nlm.nih.gov/books/NBK222288/.

<sup>&</sup>lt;sup>74</sup> *Id.* at 28-44 (Chapter 2: "Every Cell has a Sex").

The American people deserve a federal government and a Department of Health and Human Services that rejects this erroneous view of the human person. It would be profoundly unethical for HHS to promulgate policies that would, for example, use federal tax dollars to reinforce a male child's belief that he is *not* a boy, or that he "is" or can "become" a female. It is similarly unethical to claim that "essential health benefits" include procedures meant to affirm a female patient's belief or self-perception that she "is" a boy, and that these beliefs override the reality of her female-sexed body.

Gender ideology treats a minor's transgender identification or expressed "gender identity" as "a fixed or stable entity, rather than a state of mind with multiple causative factors," and thus "closes down opportunities for doctors and patients to explore the meaning of any discomfort." Despite the "affirmative" rhetoric that gender ideology employs, the claim that "transgender" self-identification is "permanent, or 'stable," is contradicted by a growing body of research. Psychological assessments that measure gender identity already incorporate the concept of "change," regardless of direction. A narrative review of "pediatric gender measures" reveals that "change," including the client's predictions of and desires for change, and change over time are common areas of clinical assessment.

For example, the Perth Gender Picture, a "pictorial and narrative tool used . . . with young people aged 11-18 to reflect on and communicate gender identity," asks the child to "use colored markers to show . . . their current gender identity, how it was in the past, and how they hope or wish it will be in five or ten years in the future." The Genderqueer Identity Scale, "a tool to measure non-binary and genderqueer identities and expression across time, including before, during and after medical transition," asks whether "[i]n the future, I think my gender will be fluid or change over time." The Gender Preoccupation and Stability Questionnaire probes the client's experience of gender dysphoria and response to treatment, asking: "Over the past two weeks how often has your sense of what gender you identify with changed at all?" \*\*

A 2024 study of sexual and gender minority youth (SGM) found that "18.2% reported a different gender identity over time," indicating that "gender identity can evolve." "Non-binary" and "gender-fluid" identity labels defy claims that gender identity is fixed and demonstrate that an individual's "relationship to the body can vary at different time points in relation to a dynamic gender identity."

Finally, the compelling testimonies of detransitioners are impossible to ignore: their experience centers on change over time—in opposing directions. For detransitioners, the change promoted under the

<sup>79</sup> *Id.* at 13.

<sup>&</sup>lt;sup>75</sup> Lucy Griffin, et al., *Sex, gender and gender identity: a re-evaluation of the evidence*, 45 B. J. Psych. Bull. 291 (2021), https://doi.org/10.1192/bjb.2020.73.

<sup>&</sup>lt;sup>76</sup> Society for Evidence-Based Gender Medicine, *Denmark Joins the List of Countries That Have Sharply Restricted Youth Gender Transitions*, SEGM (August 17, 2023), <a href="https://segm.org/Denmark-sharply-restricts-youth-gender-transitions">https://segm.org/Denmark-sharply-restricts-youth-gender-transitions</a>.

<sup>&</sup>lt;sup>77</sup> Penelope Strauss, et al., *A critical discussion of pediatric gender measures to clarify the utility and purpose of "measuring" gender*, Int'l J. Transgender Health (Aug. 2024), https://www.tandfonline.com/doi/full/10.1080/26895269.2024.2375409.

<sup>&</sup>lt;sup>78</sup> *Id*.

<sup>&</sup>lt;sup>80</sup> *Id*. at 12.

<sup>&</sup>lt;sup>81</sup> *Id.* at 13.

<sup>&</sup>lt;sup>82</sup> Andre Gonzales Real, et al., *Trajectories of Gender Identity and Depressive Symptoms in Youths*, 7 JAMA Open Network e2411322 (2024), <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11112442/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11112442/</a>.

<sup>&</sup>lt;sup>83</sup> Nastasja M. de Graaf, et al., *Psychological Functioning in Non-binary Identifying Adolescents and Adults*, 47 J. Sex Marital Therapy 773 (2021), https://pubmed.ncbi.nlm.nih.gov/34344272/.

banner of gender affirmation brought amputated body parts, mental illness, and lifelong disability.<sup>84</sup> Their suffering and loss bear witness to the tragic consequences of mandating gender-affirming protocols.<sup>85</sup>

HHS's mission and delegated authority from Congress not only permit but require it to take these facts into account as it develops health policy that will Make America Healthy Again.

# II. HHS's Final Rule should not designate the targeted interventions as "sex-trait modifications" but "sex-rejecting procedures."

As noted in the introduction, we agree with HHS that the terms "gender-affirming care" and "gender-affirming treatment" are inaccurate and should be displaced. These terms incorrectly imply that the fundamental reality in policy discussions regarding trans-identifying persons is the dissonance between the person's body and asserted identity and that the goal should therefore be to help the person resolve this tension in favor of the patient's asserted identity.

We appreciate HHS's interest in finding a replacement term, but we believe that the term used in the Proposed Rule, "sex-trait modification," is problematic because it fails to convey that there are critical distinctions between a drug or surgery used as part of "gender-affirming care" and when that same drug or surgery is used to treat a physical medical problem. Furthermore, because "sex-trait modification" fails to make these distinctions, we are concerned that using this term makes it easy for gender ideology advocates to claim that the failure to cover "transition"-related procedures constitutes unlawful or unconstitutional sex discrimination.

After detailing our concerns regarding the deficiency of the term "sex-trait modification," we propose a substitute term, "sex-rejecting procedures," and explain why we believe this term better communicates and advances the policy priorities that HHS has articulated in the Proposed Rule and elsewhere.

# A. "Sex-trait modification" is overinclusive because it designates a category that includes legitimate medical procedures.

HHS recognizes in the Proposed Rule that "there are some medical conditions, such as precocious puberty, or therapy subsequent to a traumatic injury, where items and services that are also used for sextrait modification may be appropriate." 12987. We agree. As HHS notes, "sex-trait modification" procedures generally fall into one of three categories: "puberty blockers, sex hormones, and surgical procedures." None of these categories is exclusive to "sex-trait modification."

Puberty blockers are prescribed and FDA-approved for treating precocious puberty. 86 Testosterone therapy is common prescribed for men when their bodies do not produce sufficient levels of this hormone naturally, including hypogonadism, delayed puberty, and osteoporosis. Likewise, estrogen therapy is widely used in women to manage symptoms of hormonal imbalance or deficiency, including menopause, hypoestrogenism, or in the wake of a hysterectomy or oophorectomy. In these cases, dosages are tailored to mimic natural levels that support the patient's sexual identity and healthy biological

<sup>85</sup> Sarah C. J. Jorgensen, et al., *Puberty Suppression for Pediatric Gender Dysphoria and the Child's Right to an Open Future*, 53 Archiv. Sex. Behav. 1941, 1945-46 (2024), <a href="https://pubmed.ncbi.nlm.nih.gov/38565790/">https://pubmed.ncbi.nlm.nih.gov/38565790/</a>.

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<sup>&</sup>lt;sup>84</sup> Kristine Parks, *Young mother facing permanent health problems after gender transition warns she was sold a 'lie,'* Fox News (Dec. 22, 2024), <a href="https://www.foxnews.com/media/young-mother-facing-permanent-health-problems-after-gender-transition-warns-she-sold-lie">https://www.foxnews.com/media/young-mother-facing-permanent-health-problems-after-gender-transition-warns-she-sold-lie</a>.

<sup>&</sup>lt;sup>86</sup> Carla M. Lopez, et al., *Trends in the "Off-Label" Use of GnRH Agonists Among Pediatric Patients in the United States*, 57 Clinical Pediatrics 1432 (2018), <a href="https://pubmed.ncbi.nlm.nih.gov/30003804/">https://pubmed.ncbi.nlm.nih.gov/30003804/</a> ("Gonadotropin-releasing hormone (GnRH) agonists are FDA approved for the treatment of precocious puberty.").

function. This is entirely different from what happens with transgender hormone interventions, which seek to produce secondary sexual characteristics that are at odds with the patient's biology and to suppress healthy reproductive functions. In transgender-identified females, for example, taking testosterone in dosages typically for males (but not females), "can induce epithelial thinning reminiscent of the estrogen-deprived post-menopausal...vagina," and cause "elevated levels of inflammation, edema, collagen fibrosis, and granulation tissues." <sup>87</sup> Consequently, transgender-identified females who use testosterone "frequently experience symptoms of vaginal atrophy... including dryness, irritation, bleeding with vaginal penetration (sex or medical examination), and dyspareunia....These symptoms can have a substantial impact on quality of life." <sup>88</sup> In transgender-identified males who seek to suppress their masculine features and to appear more feminine, the use of estrogen in doses designed to achieve female levels of the hormone results in "an increased risk of myocardial infarction and stroke." <sup>89</sup>

In much the same way, many surgeries that could be performed for purposes of "sex-trait modification" are often performed on men and women to treat medical conditions wholly unrelated to gender dysphoria. Examples include:

- Breast Reduction (Reduction Mammoplasty) may be performed for women or men (e.g., in cases of gynecomastia) to alleviate physical discomfort such as back, neck, or shoulder pain, or to address medical issues like chronic rashes.
- **Breast Reconstruction** is often covered after a mastectomy due to breast cancer or other medical conditions. This procedure restores the appearance of breast tissue for women and in this context is typically considered reconstructive rather than cosmetic.
- Hysterectomy (removal of uterus) or Oophorectomy (removal of ovaries) may be performed to treat endometriosis, fibroids, chronic pelvic pain, or to treat or prevent cancer.
- Orchiectomy (removal of one or both testicles) may be performed in cases of testicular cancer, severe trauma, or chronic infection.
- Hair Removal (Electrolysis or Laser) covered in some cases for individuals with conditions like hirsutism (excessive hair growth due to hormonal imbalances, e.g., polycystic ovary syndrome in women) or chronic ingrown hairs causing infections. This alters a sex-linked trait (hair distribution) for medical reasons.
- **Penile or Testicular Implants** may be covered for men after prostate cancer surgery, trauma, or erectile dysfunction when deemed medically necessary to restore or modify male sex traits for functional or health purposes.
- Likewise, circumcision and contraception could arguably be viewed as modifying sex traits.

We also note that "sex-trait modifications" could also be understood to include medical procedures to support detransitioners. "Medical detransition involves ceasing or switching" hormones

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<sup>&</sup>lt;sup>87</sup> Yanoh Krakowsky, et al., *The Effect of Gender-affirming Medical Care on the Vaginal and Neovaginal Microbiomes of Transgender and Gender-Diverse People*, Front. Cell. Infect. Microbiol. 11:769950 (2022), <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC8814107/">https://pmc.ncbi.nlm.nih.gov/articles/PMC8814107/</a>

<sup>&</sup>lt;sup>88</sup> *Id*.

<sup>&</sup>lt;sup>89</sup> Laurens D'hoore, *Gender-affirming hormone therapy: An updated literature review with an eye on the future*, 291 J. Intern. Med. 574 (2022), https://onlinelibrary.wiley.com/doi/10.1111/joim.13441.

"and/or surgical reconstruction or reversal." A survey of 237 detransitioners reported a variety of medical needs in the wake of detransitioning, from procedures to remove hormonal implants to endocrine treatments necessary to restore healthy, sex-based levels and hormonal functions. Those procedures would modify sex-traits to be more in line with healthy functioning, based on the person's sex.

In short, the term "sex-trait modification" is overinclusive because it applies equally to "gender-transition" procedures and to medical procedures meant to address medical conditions and help males and females develop and live healthy lives.

# B. "Sex-trait modification" fails to distinguish between primary and secondary sex characteristics.

We also suggest that "sex-trait modification" is inadequate because it fails to distinguish between primary and secondary sex characteristics, which is a critical distinction related to the definition of sex. As HHS recognizes, sex is fundamentally a classification based on an organism's design to produce large or small gametes, which in mammals is a function of either ovaries or testes.<sup>92</sup>

Under the Biden administration, the National Academies of Sciences published a new definition of "sex," which it said was "a multidimensional construct based on a cluster of anatomical and physiological traits that include external genitalia, secondary sex characteristics, gonads, chromosomes, and hormones." This ideologically-driven definition aims to advance gender ideology by suggesting that sex is equally defined by primary or secondary sex characteristics and that changing secondary sex characteristics can change a person's sex. "Sex-trait modification" lends implicit support to this claim.

# C. "Sex-trait modification" is inaccurate as many "gender transition" procedures do not "modify" but rather *remove* or destroy primary and secondary sex organs.

Because "sex-trait modification" does not distinguish between primary and secondary sex characteristics, it and thus understates the severity and permanency of "gender transition" procedures. On its face, "sex-trait modification" suggests that these interventions merely tweak existing organs. However, even if "bottom surgeries" could be seen as merely "modifying" the vagina and penis, these surgeries do not "modify" ovaries and testes, which can only be removed.

# D. "Sex-trait modification" would make it easier for gender ideology proponents to advance legal arguments against common-sense state laws and President Trump's gender ideology executive orders.

The term "sex-trait modification" plays into gender ideology proponents' legal and moral arguments that excluding transition-related treatments is sex discrimination.

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<sup>&</sup>lt;sup>90</sup> Kinnon R. MacKinnon, et al., *Health Care Experiences of Patients Discontinuing or Reversing Prior Gender-Affirming Treatments*. 5 JAMA Network Open. e2224717 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9315415/.

<sup>&</sup>lt;sup>91</sup> Elie Vandenbussche, *Detransition-Related Needs and Support: A Cross-Sectional Online Survey*, 69 J. Homosex. 1602 (2022), <a href="https://pubmed.ncbi.nlm.nih.gov/33929297/">https://pubmed.ncbi.nlm.nih.gov/33929297/</a>.

<sup>&</sup>lt;sup>92</sup> HHS, Defining Sex: Guidance for Federal Agencies, External Partners, and the Public Implementing Executive Order 14168, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (Feb. 19, 2025),

https://womenshealth.gov/sites/default/files/\_images/2025/2.19.25%20Defining%20Sex%20Guidance%20for%20Federal%20Agencies%2C%20External%20Partners%2C%20and%20the%20Public%20FINAL.pdf.

In many lawsuits, <sup>93</sup> including *United States v. Skrmetti* pending before the Supreme Court, advocates for gender ideology have claimed that laws restricting "gender-transition" procedures violate civil rights laws. These arguments generally claim that such procedures discriminate on the basis of sex under the Equal Protection Clause of the Fourteenth Amendment or nondiscrimination statutes because the availability of the procedures depends on the sex of the patient.

For example, it is claimed that if a *male* wants to take testosterone so he can have a deeper voice, he can get it, but a *female* with the same goal in mind cannot. Those challenging restrictions on "gender-transition procedures" claim this constitutes sex discrimination because the only difference between a male and female who want a deeper voice is their sex.

To defeat these arguments, government must demonstrate that males and females are not similarly situated with regard to these procedures. For example, in the hypothetical above, the male and the female want testosterone **for different purposes** (the male to support healthy puberty; the female to mimic changes her body is not designed to support), **to treat different medical conditions** (the male to treat hypogonadism, the female to treat gender dysphoria), and **with different medical effects** (the male has a typical puberty, the female suffers vaginal atrophy, impaired fertility, pain, tumors, and mental and emotional effects).

The term "sex-trait modifications" makes no distinction between the sexes or the purpose for which interventions are sought, thus playing into the Left's nondiscrimination arguments. The use of such an abstract term makes the Left's sex discrimination arguments more plausible as a legal matter and likely at a popular level as well. We are seeing increasing claims that "cis" people get "gender-affirming care," too.

It is important to avoid using terminology—in legislation, regulations, and public debate—that makes gender ideology's legal arguments even stronger.

# E. The term "sex-rejecting procedures" addresses these problems and offers many advantages.

To avoid the problems identified above, we urge HHS to adopt a less confusing term than "sextrait modification" in its Final Rule. **We propose the term "sex-rejecting procedures."** This term offers many advantages over "sex-trait modification" and more accurately communicates the intent and the focus of the Department's proposed amendment to § 156.115(d).

Significantly, the term "sex-rejecting procedures":

- Uses plain language that clearly excludes procedures that modify sex-traits to address "medical conditions, such as precocious puberty, or therapy subsequent to a traumatic injury, where items and services that are also used for sex-trait modification may be appropriate";<sup>94</sup>
- Does not use language that supports gender ideology's unscientific, misleading claim that someone can have an authentic identity that is antithetical to his or her sex;
- Does not use words—such as "affirming," "care," or "treatment"—that incorrectly communicate that there is something positive or good about procedures intended to enable a person to reject his or her sex;
- Does not use charged language that could unnecessarily alienate people of goodwill;

<sup>&</sup>lt;sup>93</sup> See Appendix A for excerpts from court decisions, legal briefs, and oral arguments making these arguments.

<sup>&</sup>lt;sup>94</sup> 90 Fed. Reg. at 12987.

- Includes a reference to sex, which accurately communicates that there are material differences between a sex-trait related medical procedure that is performed on a male and the same procedure performed on a female;
- Includes a reference to purpose, which accurately communicates that procedures are different whether performed to address a medical condition or to address gender dysphoria or reject
- More effectively communicates the unnatural and disruptive nature of the targeted procedures.

We also note that ten of the states identified in Appendix B have adopted laws that, like this proposed term, use the word "procedures" to designate both surgical and chemical sex-rejecting interventions. 95

#### III. Regardless of the term used, HHS should provide a definition.

HHS notes out that its Proposed Rule does not propose a definition of "sex-trait modification" and asks for comment on whether it should adopt a formal definition. <sup>96</sup> We strongly urge HHS to do so.

We appreciate HHS's observation that the "other listed benefits that issuers must not cover as an EHB at § 156.115(d)" do not have a separate definition. But unlike the proposed addition, "sex-trait modification," each of the existing exclusions is qualified within the text of § 156.115(d). Section 156.115(d) does not exclude all "non-pediatric" "dental services" and "eye exam services" but only those that are *routine*. Likewise, the exclusion does not apply to all "orthodontia" but only services that are non-medically necessary. As noted in our introduction, and as detailed below, we believe that the term proposed in the Proposed Rule, "sex-trait modification," is too general and that the policy objective HHS has identified in the Proposed Rule would be better served by using a different term. We suggest that HHS use instead a term that, like the exclusions in the current § 156.115(d), qualifies the scope of the exclusion. As noted above, we propose HHS abandon the phrase "sex-trait modifications" in favor of the term "sex-rejecting procedures."

However, regardless of whether HHS keeps with "sex-trait modifications" or adopts "sexrejecting procedures" or some other term, we strongly urge HHS to define its term so the public, plan sponsors, insurance companies, third party administrators, and medical providers understand the scope of HHS's exclusion. A clear and focused definition will also help bolster against any legal challenges that claim the exclusion is vague or overbroad. Any definition should be defined in terms of purpose not procedure. As such, we advise against including a list of procedures. But if such a list is included in a definition it should be inclusive, not exhaustive, as it will be hard to capture all conceivable procedures now and in the future that would be used for a "gender transition."

HHS also sought comment "regarding whether we should define explicit exceptions to permit the coverage of such items and services as EHB for other medical conditions, and what those conditions are, for potential inclusion in finalizing as part of this rule."97 We think it is best to include explicit exceptions in the definition, even if such exceptions should be clear from the text of the definition. A belt-andsuspenders approach will help avoid claims that the exclusion is vague or overbroad and covers

<sup>95</sup> See Appendix B (excerpted laws from Arkansas, Florida, Georgia, Indiana, Mississippi, Missouri, Nebraska, Oklahoma, South Carolina and Tennessee all use "procedure" to refer to both surgical and nonsurgical medical procedures).

<sup>&</sup>lt;sup>96</sup> 90 Fed. Reg. at 12987.

<sup>97</sup> Id.

procedures that HHS does not intend. Our proposed definition below addresses these concerns and includes an exception defined in terms of purpose.

**Definition.** The phrase "sex-rejecting procedures" includes the following, when done for the purpose of treating gender dysphoria or otherwise attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex: the use of pharmaceutical or surgical interventions intended to (a) disrupt or suppress natural development of natural biological functions, or (b) alter an individual's physical appearance or body, including the amputation, destruction or alteration of an individual's sexual and reproductive organs to minimize or destroy their natural biological functions. Sex-rejecting procedures are sometimes referred to as "gender-affirming care" or "gender-transition procedures."

**Exception.** "Sex-rejecting procedures" does not apply to procedures undertaken (a) to treat a person born with a medically verifiable disorder of sexual development, or (b) for purposes other than treating gender dysphoria or otherwise attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex.

#### IV. **Effective Date**

In the Proposed Rule, HHS seeks comment on the proposed effective date of PY 2026 for when issuers subject to EHB requirements would be prohibited from covering sex-rejecting procedures as an EHB, and whether and earlier or later effective date is justified.<sup>98</sup>

We agree that excluding sex-rejecting procedures beginning in PY 2026 is the best timing. While there is precedent of changes mid-plan year<sup>99</sup> and coverage of sex-rejecting procedures as an EHB is prohibited by statute, we still think it is best to wait to impose the exclusion until the next plan year. This will avoid any disruption mid-plan year and ensure that plan terms of coverage and estimated out-ofpocket costs relied on by individuals choosing a plan will not change mid-plan year. But since changes are made each plan year as to what is covered as an EHB, and there is an annual open enrollment period for all individuals, there are no reliance interests for changes made at the beginning of a plan year.

We also agree there is no need to wait to make this change until PY 2027 or later. As explained above, coverage of sex-rejecting procedures is prohibited by statute because it is not commonly covered by employer plans and sex-rejecting procedures are not supported by the science. To wait longer would allow unlawful coverage of sex-trait modification in EHBs and perpetuate the misuse of federal taxpayer dollars. Moreover, as HHS acknowledges, this change will only affect a few states and states are still free to provide coverage as a non-EHB.

#### V. Costs/Benefits

HHS seeks comment on its regulatory impact estimates and assumptions. We agree with the Department's statement that, with respect to the coverage of sex-rejecting procedures, "Utilization of sex-

<sup>&</sup>lt;sup>98</sup> *Id*.

<sup>99</sup> See HHS, Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond, 86 Fed. Reg. 53412 (Sept. 27, 2021) (rule made mid-year changes to how plans were billed; it did not change the out-of-pocket costs owned on a plan).

trait modification is low; therefore, the impact of this proposal would be limited."<sup>100</sup> We agree with HHS's explanation of the main costs and benefits. We further note that the reduction in coverage of these procedures will reduce the use of these procedures, reducing complications that would be covered as EHB, leading to a small reduction in both premiums and premium tax credits and well as improvements in the health of these enrollees. These omitted benefits of the proposed rule are admittedly difficult to quantify but should also be noted as such.

### VI. HHS should mention its Section 156.115(d) proposal in the final rule's Statement of Need.

In the Proposed Rule's Regulatory Impact Analysis (RIA) section, the Statement of Need does not mention the need for excluding sex-rejecting procedures. <sup>101</sup> We encourage HHS to correct this oversight in its final rule. The need for this change is well-supported by the fact that covering sex-rejecting procedures as an EHB, as some states have done, violates Congress' definition of an EHB. While that plain fact is sufficient to establish need for the change, HHS should also cite other reasons identified in this public comment, including the lack of scientific support for such procedures.

We urge HHS to acknowledge, in the final rule's Statement of Need section, that there is no need, as defined by law, for sex-rejecting procedures to be included as an EHB.

# VII. HHS need not consider regulatory alternatives because it would be unlawful to include sexrejecting procedures as an EHB.

Similarly, the Proposed Rule's RIA section on regulatory alternatives, the Proposed Rule does not mention any alternatives considered for the sex-rejecting procedures exclusion. <sup>102</sup> As acknowledged elsewhere in the rule and as explained above, providing sex-rejecting procedures as an EHB violates the statutory text. HHS does not have statutory authority to include sex-rejecting procedures as an EHB because these procedures are not covered in the "typical employer plan." HHS therefore does not have leeway to require coverage as an EHB. Further, because some states have improperly designated sex-rejecting procedures as an EHB, and thus require the federal government to make payments related to these procedures, it is necessary for HHS to explicitly exclude coverage to ensure compliance with the statutory text. Not regulating on this matter would allow these states to continue violating the ACA and illegally directing federal taxpayer dollars to sex-rejecting procedures.

We urge HHS to explicitly acknowledge in the final rule why regulatory alternatives fall short for this proposal.

### VIII. Federalism Implications

The Proposed Rule acknowledges that while the rule "will not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to potential direct effects on the distribution of power and responsibilities among the State and Federal Governments relating to determining standards relating to health insurance that is offered in the individual and small group markets." <sup>103</sup>

We agree that the Proposed Rule will have federalism implications but support the changes which will help balance powers appropriately between the federal government and the states. The federal

<sup>102</sup> *Id.* at 13026.

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<sup>&</sup>lt;sup>100</sup> 90 Fed. Reg. at 13017.

<sup>&</sup>lt;sup>101</sup> *Id.* at 13004.

<sup>&</sup>lt;sup>103</sup> *Id.* at 13029.

government will prohibit sex-rejecting procedures from being an EHB as required by federal law, but states remain free to cover the costs of such procedures if they choose to.

# IX. Severability

The Proposed Rule also sought public comment on whether the various proposals are severable. <sup>104</sup> We agree. The 17 proposals in the Proposed Rule are distinct and could easily be severed if required by court. Further, HHS's Proposed Rule is well organized and it is easy for the reader to understand what portions of the preamble apply to each proposal. This structure makes the Proposed Rule easier to sever if necessary.

### Conclusion

We support HHS's proposal to amend 45 CFR § 156.115(d) to "exclude sex-trait modification"—which we recommend that HHS call "sex-rejecting procedures"—as an essential health benefit.

Sincerely,

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<sup>&</sup>lt;sup>104</sup> 90 Fed. Reg. at 12997.

# **APPENDIX A: Excerpts from Relevant Legal Cases**

Courts that have enjoined laws restricting "gender-affirming" procedures have accepted the argument that these procedures may be generally described as helping a patient (whether a "cis" or "trans" child) develop desired sex traits and that it is therefore discriminatory to permit their use to support a healthy puberty but not as part of a "gender transition." The following excerpts illustrate this pattern and thus make it easier to see the dangers, identified above, with choosing to employ the sex-neutral and purposeneutral term "sex-trait modification."

• *Washington v. Trump*, No. 2:25-244-LK, 2025 WL 659057 (W.D. Wash. Feb. 28, 2025)<sup>105</sup> (holding that President Trump's E.O. 14187, "Protecting Children from Chemical and Surgical Mutilation" (Jan. 28, 2025), likely violates the Fourteenth Amendment's Equal Protection Clause)

"Put simply, a biological male can have hormone therapy and surgery to look more stereotypically male, but a biological female cannot.... [T]hese prohibitions on federally funded treatments cannot function without relying on direct discrimination.... For all these reasons, heightened scrutiny applies."

• *PFLAG, Inc. v. Trump*, No. 25-337-BAH, 2025 WL 685124 (D. Md. Mar. 4, 2025)<sup>106</sup> (holding that President Trump's E.O. 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" (Jan. 20, 2025), likely violates Section 1557 of the Affordable Care Act).

"Defendants assert that the Healthcare Order 'targets only specified treatments for minors based on their medical purpose'.... In making this argument, Defendants ignore that to determine the 'medical purpose' of each treatment and to determine whether it is permitted or restricted under the Order necessarily requires the evaluation of a patient's sex assigned at birth and then a determination of whether the treatment is sought to align the patient's physical characteristics with that birth sex or with a different sex—one that aligns with the person's identity. This is ... 'textbook sex discrimination.'"

• *Moe v. Yost*, No. 24AP-483 (Ohio Ct. App. March 18, 2025)<sup>107</sup>

"If the state's concerns about the propriety of prescribing gender-affirming medications to minors were genuine, the state would prohibit use of puberty blockers and hormone therapy for all patients under 18 *irrespective* of the type of medical condition they are being used to treat. The state's choice to allow the same treatment for cisgender minors ... undermines its contention that the challenged provisions are aimed at protecting children from 'experimental' treatment and the longer-term, irreversible effects that may be associated with some aspects of that treatment."

• **Doe v. Ladapo**, 737 F. Supp. 3d 1240 (N.D. Fla. June 11, 2024)<sup>108</sup>

"[C]onsider a child that a physician wishes to treat with GnRH agonists to delay the onset of puberty. Is the treatment legal or illegal? To know the answer, one must know whether the child is cisgender or transgender. The treatment is legal if the child is cisgender but illegal if the child

<sup>&</sup>lt;sup>105</sup> Transcript of Oral Arg. available at https://caselaw.findlaw.com/court/us-dis-crt-w-d-was-at-sea/117014674.html.

<sup>&</sup>lt;sup>106</sup> Transcript of Oral Arg. available at https://caselaw.findlaw.com/court/us-dis-crt-d-mar/117019317.html.

 $<sup>^{107}</sup>$  Transcript of Oral Arg. available at  $\underline{\text{https://www.supremecourt.ohio.gov/rod/docs/pdf/10/2025/2025-Ohio-914.pdf}.$ 

<sup>108</sup> Transcript of Oral Arg. available at https://caselaw.findlaw.com/court/us-dis-crt-n-d-flo/116263363.html.

is transgender, because the statute prohibits GnRH agonists only for transgender children, not for anyone else."

• *United States v. Skrmetti* (During the Dec. 4 oral argument, the Biden administration's Solicitor General, the ACLU's attorney, and several justices argued that a male and female are equally situated with regard to certain "gender-transition" procedures)<sup>109</sup>

# • Solicitor General Prelogar

- o (4-5): "The law restricts medical care only when provided to induce physical effects inconsistent with birth sex. Someone assigned female at birth can't receive medication to live as a male, but someone assigned male can."
- o (26): "Both males and females alike for decades have been prescribed puberty blockers, hormones, testosterone, estrogen. They produce the same physical characteristics ... no matter whether your birth sex is male or female."
- O (27): But, here, there's a facial sex classification. No one can take these medications if it would be inconsistent with their sex. And that's imposing on the face of the statute two parallel rules on classes of people according to their sex: all adolescent males who want to take these medications to feminize their bodies and all adolescent females who want to take these medications for masculinizing purposes. That's a facial sex classification through and through."
- ACLU Attorney Strangio (95-96): "[I]f you're someone who was born male and you are going through puberty too early, [y]ou may receive puberty blockers so that you can develop as a typical boy. Someone who has a sex of female at birth is also receiving puberty blockers so that they can undergo a puberty like other boys. And so it is the same purpose, and what makes the treatment prohibited for the birth sex female is their sex."
- **J. Kagan** (125-126): "The whole thing is imbued with sex. I mean, it's based on sex. You might have reasons for thinking that it's an appropriate regulation, and those reasons should be tested and respect given to them, but it's a dodge to say that this is not based on sex, it's based on medical purpose, when the medical purpose is utterly and entirely about sex."
- **J. Alito** (21): "[Y]ou have a *Bostock*-like argument, and you say that a girl who wants to live like a boy cannot be administered testosterone, but a boy who wants to live like a boy can be administered testosterone."
- **J. Jackson** (68-69): "[Consider] a minor who would like to take this medication to affirm their gender as a male because the medication deepens their voice, for example. They want a deeper voice, and they are biologically male.... They, I think, can get that.... But a person who is biologically female who wants to take the medication for that same purpose, to deepen their voice because they would like to live as a male, can't get it? Is that right?"
- **J. Sotomayor** (117-118): "The question is: Can you stop one sex ... from receiving that benefit? ... [T]he medical condition is the same."

<sup>&</sup>lt;sup>109</sup> Transcript of Oral Arg., *United States v. Skrmetti*, No. 23-477 (U.S. Dec. 4, 2024), available at https://www.supremecourt.gov/oral arguments/argument transcripts/2024/23-477 c07d.pdf.

# **APPENDIX B: State Laws Restricting Sex-Rejecting Procedures**

#### 1. Alabama

- o SB 184 (2022), <a href="https://legiscan.com/AL/text/SB184/id/2566425%22">https://legiscan.com/AL/text/SB184/id/2566425%22</a> blank%22
- $\circ$  Sec. 4(a).

Except as provided in subsection (b), no person shall engage in or cause any of the following practices to be performed upon a minor if the practice is performed for the purpose of attempting to alter the appearance of or affirm the minor's perception of his or her gender or sex, if that appearance or perception is inconsistent with the minor's sex as defined in this act:

- (1) Prescribing or administering puberty blocking medication to stop or delay normal puberty.
- (2) Prescribing or administering supraphysiologic doses of testosterone or other androgens to females.
- (3) Prescribing or administering supraphysiologic doses of estrogen to males.
- (4) Performing surgeries that sterilize, including castration, vasectomy, hysterectomy, oophorectomy, orchiectomy, and penectomy.
- (5) Performing surgeries that artificially construct tissue with the appearance of genitalia that differs from the individual's sex, including metoidioplasty, phalloplasty, and vaginoplasty.
- (6) Removing any healthy or non-diseased body part or tissue, except for a male circumcision.

#### 2. Arizona

- Arizona Revised Statutes § 23-3230, SB 1138 (2022), <a href="https://www.azleg.gov/legtext/55leg/2R/laws/0104.pdf">https://www.azleg.gov/legtext/55leg/2R/laws/0104.pdf</a>
- o Sec. 32-3230:
  - A. A physician may not provide irreversible gender reassignment surgery to any individual who is under eighteen years of age.
  - C(3). "Gender Transition" means the process in which a person goes from identifying with and living as a gender that corresponds to the person's biological sex to identifying with and living as a gender different from the person's biological sex and may involve social, legal or physical changes.
  - C(4). "Irreversible Gender Reassignment Surgery" means a medical procedure performed for the purpose of assisting an individual with a gender transition, including any of the following:
    - (a) Penectomy, orchiectomy, vaginoplasty, clitoroplasty or vulvoplasty for biologically male patients or hysterectomy or ovariectomy for biologically female patients.
    - (b) Metoidioplasty, phalloplasty, vaginectomy, scrotoplasty or implantation of erection or testicular prostheses for biologically female patients.
    - (c) Augmentation mammoplasty for biologically male patients and subcutaneous mastectomy for female patients.

#### 3. Arkansas

- o Arkansas Code § 20-9-1501, Act 626 (HB 1570) (2021), https://arkleg.state.ar.us/Home/FTPDocument?path=%2FACTS%2F2021R%2FPublic%2FACT626.pdf
- o Subchapt. 15:
  - 6(A). "Gender transition procedures" means any medical or surgical service, including without limitation physician's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition that seeks to:
    - (i) Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex; or
    - (ii) Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex, including without limitation medical services that provide puberty-blocking drugs, cross-sex hormones, or other mechanisms to promote the development of feminizing or masculinizing features in the opposite biological sex, or

genital or nongenital gender reassignment surgery performed for the purpose of assisting an individual with a gender transition.

#### 4. Florida

- Florida Statutes § 456.001, SB 254 (2023): https://www.flsenate.gov/Session/Bill/2023/254/BillText/Filed/PDF
- Subsec. 9(a).

"Sex-reassignment prescriptions or procedures" means:

- 1. The prescription or administration of puberty blockers for the purpose of attempting to stop or delay normal puberty in order to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex as defined in subsection[.]
- 2. The prescription or administration of hormones or hormone antagonists to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex[.]
- 3. Any medical procedures, including a surgical procedure, to affirm a person's perception of his or her sex if that perception is inconsistent with the person's sex[.]

### 5. Georgia

- Georgia Code § 31-7-3.5, SB 140 (2023), https://www.legis.ga.gov/api/legislation/document/20232024/218904
- Sec. 2(a)

Except as provided in subsection (b) of this Code section, none of the following irreversible procedures or therapies shall be performed on a minor for the treatment of gender dysphoria in an institution licensed pursuant to this article:

- (1) Sex reassignment surgeries, or any other surgical procedures, that are performed for the purpose of altering primary or secondary sexual characteristics; or
- (2) Hormone replacement therapies.

#### 6. Idaho

- o Idaho Code § 18-1506B, HB 71 (2023), <a href="https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2023/legislation/H0071.pdf">https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2023/legislation/H0071.pdf</a>
- O Subsec. 2.

[A]ny medical practitioner who knowingly engages in any of the following practices upon a child for the purpose of attempting to alter the appearance of or affirm the child's perception of the child's sex if that perception is inconsistent with the child's biological sex shall be guilty of a felony:

- (a) Performing surgeries that sterilize or mutilate, or artificially construct tissue with the appearance of genitalia that differs from the child's biological sex, including castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, clitoroplasty, vaginoplasty, vulvoplasty, ovariectomy, or reconstruction of the fixed part of the urethra with or without metoidioplasty, phalloplasty, scrotoplasty, or the implantation of erection or testicular prostheses;
- (b) Performing a mastectomy;
- (c) Administering or supplying the following medications that induce profound morphological changes in the genitalia of a child or induce transient or permanent infertility:
  - (i) Puberty-blocking medication to stop or delay normal puberty
  - (ii) Supraphysiological doses of testosterone to a female; or
  - (iii) Supraphysiological doses of estrogen to a male;
- (d) Removing any otherwise healthy or nondiseased body part or tissue.

#### 7. Indiana

- Indiana Code § 25-1-22, SB 480 (2023), <a href="https://iga.in.gov/pdf-documents/123/2023/senate/bills/SB0480/SB0480.05.ENRH.pdf">https://iga.in.gov/pdf-documents/123/2023/senate/bills/SB0480/SB0480.05.ENRH.pdf</a>
- Sec. 5(a)

As used in this chapter, "gender transition procedures" means any medical or surgical service, including physician's services, practitioner's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition, that seeks to:

- (1) alter or remove physical or anatomical characteristics or features that are typical for the individual's sex; or
- (2) instill or create physiological or anatomical characteristics that resemble a sex different from the individual's sex, including medical services that provide puberty blocking drugs, gender transition hormone therapy, or genital gender reassignment surgery or nongenital gender reassignment surgery knowingly performed for the purpose of assisting an individual with a gender transition.

### 8. Iowa

- o Iowa Code § 147.164, SF 538 (2023), <a href="https://legiscan.com/IA/text/SF538/2023">https://legiscan.com/IA/text/SF538/2023</a>
- o Sec. 1 (2)(a)

Except as otherwise provided in paragraph "c", a health care professional shall not knowingly engage in or cause any of the following practices to be performed on a minor if the practice is performed for the purpose of attempting to alter the appearance of, or affirm the minor's perception of, the minor's gender or sex, if that appearance of perception is inconsistent with the minor's sex.

- (1) Prescribing or administering gonadotropin-releasing hormone analogues or other synthetic drugs used to stop luteinizing hormone and follicle-stimulating hormone secretion, synthetic antiandrogen drugs used to block the androgen receptor, or any drug to suppress or delay normal puberty.
- (2) Prescribing or administering testosterone, estrogen, or progesterone to a minor in an amount greater than would normally be produced endogenously in a healthy individual of that individual's age and sex.
- (3) Performing surgeries that sterilizie, including castration, vasectomy, hysterectomy, ophorectomy, orchiectomy, and penectomy.
- (4) Performing surgeries that articificially construct tissue with the appearance of genitalia that differs from the individual's sex, including metoidioplasty, phalloplasty, and vaginoplasty.
- (5) Removing and healthy of nondiseased body part or tissue.

#### 9. Kansas

- o Kansas Statutes § 65-2837, SB 63, (2025), <a href="https://kslegislature.gov/li/b2025\_26/measures/documents/sb63">https://kslegislature.gov/li/b2025\_26/measures/documents/sb63</a> enrolled.pdf
- o Sec. 3
  - (a) Except as provided in subsection (c) or (d), a healthcare provider shall not knowingly perform the following surgical procedures or prescribe, dispense or administer the following medications to a female child for the purpose of treatment for distress arising from such female child's perception that such child's gender or sex is not female:
    - (1) Surgical procedures, including, but not limited to, a vaginectomy, hysterectomy, oophorectomy, ovariectomy, reconstruction of the urethra, metoidioplasty, phalloplasty, scrotoplasty, implantation of erection or testicular protheses, subcutaneous mastectomy, voice surgery, liposuction, lipofilling or pectoral implants;
    - (2) supraphysiologic doses of testosterone or other androgens; or
    - (3) puberty blockers such as GnRH agonists or other synthetic drugs that suppress the production of estrogen and progesterone to delay or suppress pubertal development in female children.
  - (b) Except as provided in subsection (c) or (d), a healthcare provider shall not knowingly perform the following surgical procedures or prescribe, dispense or administer the following medications to a male child for the purpose of treatment for distress arising from such male child's perception that such child's gender or sex is not male:
    - (1) Surgical procedures, including, but not limited to, a penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty, augmentation mammoplasty, facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction or gluteal augmentation;

- (2) supraphysiologic doses of estrogen; or
- (3) puberty blockers such as GnRH agonists or other synthetic drugs that suppress the production of testosterone or delay or suppress pubertal development in male children.

### 10. Kentucky

- Kentucky Revised Statutes ch. 311, SB 150 (2023), https://apps.legislature.ky.gov/recorddocuments/bill/23RS/sb150/bill.pdf
- o Sec. 4
  - (2) Except as provided in subsection (3) of this section, a health care provider not, for the purpose of attempting to alter the appearance of, or to validate a minor's perception of, the minor's sex, if that appearance or perception is inconsistent with the minor's sex, knowingly:
    - (a) Prescribe or administer any drug to delay or stop normal puberty;
    - (b) Prescribe or administer testosterone, estrogen, or progesterone, in amounts greater than would normally be produced endogenously in a healthy person of the same age and sex:
    - (c) Perform any sterilizing surgery, including castration, hysterectomy, oophorectomy, orchiectomy, penectomy, and vasectomy
    - (d) Perform any surgery that artificially constructs tissue having the appearance of genitalia differing from the minor's sex, including metoidioplasty, phalloplasty, and vaginoplasty; or
    - (e) Remove any healthy or non-diseased body part or tissue.

#### 11. Louisiana

- Louisiana Revised Statutes § 40:1098, HB 648, (2023), https://legiscan.com/LA/text/HB648/id/2825013
- o Sec. 1, § 1098.2
  - A. A healthcare professional shall not knowingly engage in any of the 6 following acts that attempt to alter a minor's appearance in an attempt to validate a minor's perception of the minor's sex, if the minor's perception is inconsistent with the minor's sex:
    - (1) The prescription or administration of gonadotropin-releasing hormone analogues or other synthetic drugs used to stop luteinizing hormone and follicle stimulating hormone secretion, synthetic antiandrogen drugs used to block the androgen receptor, or any drug to suppress or delay normal puberty.
    - (2) The prescription or administration of testosterone, estrogen, or progesterone, in amounts greater than would normally be produced endogenously in a healthy individual of the same age and sex.
    - (3) The performance of any sterilizing surgery, including but not limited to castration, hysterectomy, oophorectomy, orchiectomy, penectomy, and vasectomy.
    - (4) The performance of any surgery that artificially constructs tissue having the appearance of genitalia differing from the minor's sex, including metoidioplasty, phalloplasty, and vaginoplasty.
    - (5) The removal of any healthy or non-diseased body part or tissue
    - (6) The performance of augmentation mammoplasty, facial feminization surgery, liposuction, lipofilling, pectoral implants, voice surgery, thyroid cartilage reduction, gluteal augmentation, hair reconstruction, or any aesthetic surgical procedure.

### 12. Mississippi

- o HB 1125 (2023), https://billstatus.ls.state.ms.us/documents/2023/pdf/HB/1100-1199/HB1125SG.pdf
- o Sec. 2
  - (d) "Gender reassignment surgery" means any medical or surgical service that seeks to surgically alter or remove healthy physical or anatomical characteristics or features, except for a male circumcision that are typical for the individual's sex, in order to instill or create physiological or

anatomical characteristics that resemble a sex different from the individual's sex, including, without limitation:

- (i) Surgical procedures such as penectomy, castration, orchiectomy, vaginoplasty, clitoroplasty, or vulvoplasty for male patients;
- (ii) Surgical procedures such as hysterectomy, oophorectomy, reconstruction of the urethra, metoidioplasty, phalloplasty, vaginectomy, scrotoplasty, or implantation of erection or testicular prostheses for female patients;
- (iii) Surgical procedures such as augmentation mammoplasty, facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation, hair reconstruction, or various aesthetic procedures for male patients; or
- (iv) Surgical procedures such as subcutaneous mastectomy, voice surgery, liposuction, lipofilling, pectoral implants, or various aesthetic procedures for female patients;

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- (f) (i) "Gender transition procedures" means any of the following medical or surgical services performed for the purpose of assisting an individual with a gender transition:
  - 1. Prescribing or administering puberty-blocking drugs;
  - 2. Prescribing or administering cross-sex hormones; or
  - 3. Performing gender reassignment surgeries.

#### 13. Missouri

- Missouri Revised Statutes § 191.1720, SB 49 (2023), https://www.senate.mo.gov/23info/BTS Web/Bill.aspx?SessionType=R&BillID=44407
- o Sec. 2
  - (6) "Gender transition procedures":
  - (a) Any medical or surgical service, including, but not limited to, physician's services, inpatient and outpatient hospital services, or prescribed drugs, related to gender transition that seeks to:
    - a. Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex; or
    - b. Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex, including, but not limited to:
      - (i) Medical services that provide puberty-blocking drugs, cross-sex hormones, or other mechanisms to promote
      - (ii) Genital or nongenital gender reassignment surgery performed for the purpose of assisting an individual with a gender transition[.]

#### 14. Montana

- o Montana Code § 50-4-1003, SB 99 (2023), https://archive.legmt.gov/bills/2023/billpdf/SB0099.pdf
- o Sec. 4
  - (1) (a) Except as provided in subsection (1)(c), a person may not knowingly provide the following medical treatments to a female minor to address the minor's perception that her gender or sex is not female:
    - (i) surgical procedures, including a vaginectomy, hysterectomy, oophorectomy, ovariectomy, reconstruction of the urethra, metoidioplasty, phalloplasty, scrotoplasty, implantation of erection or testicular protheses, subcutaneous mastectomy, voice surgery, or pectoral implants;
    - (ii) supraphysiologic doses of testosterone or other androgens; or
    - (iii) puberty blockers such as GnRH agonists or other synthetic drugs that suppress the production of estrogen and progesterone to delay or suppress pubertal development in female minors.
  - (b) Except as provided in subsection (1)(c), a person may not knowingly provide the following medical treatments to a male minor to address the minor's perception that his gender or sex is not male:

- (i) surgical procedures, including a penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty, augmentation mammoplasty, facial feminization surgery, voice surgery, thyroid cartilage reduction, or gluteal augmentation; (ii) supraphysiologic doses of estrogen; or
- (iii) puberty blockers such as GnRH agonists or other synthetic drugs that suppress the production of testosterone or delay or suppress pubertal development in male minors.
- (c) The medical treatments listed in subsections (1)(a) and (1)(b) are prohibited only when knowingly provided to address a female minor's perception that her gender or sex is not female or a male minor's perception that his gender or sex is not male.

#### 15. Nebraska

- Nebraska Revised Statutes § 71-7304, LB 574 (2023)
   <a href="https://nebraskalegislature.gov/laws/statutes.php?statute=71-7304">https://nebraskalegislature.gov/laws/statutes.php?statute=71-7304</a>
- o Sec. 16
  - (6)(a) Gender-altering procedures includes any medical or surgical service, including without limitation physician's services, inpatient and outpatient hospital services, or prescribed drugs related to gender alteration, that seeks to:
    - (i) Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex; or
    - (ii) Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex, including without limitation medical services that provide puberty-blocking drugs, cross-sex hormones, or other mechanisms to promote the development of feminizing or masculinizing features in the opposite biological sex, or genital or nongenital gender-altering surgery performed for the purpose of assisting an individual with a gender alteration.

### 16. New Hampshire

- New Hampshire Laws 2024, Ch. 332-M, HB 619 (2024), https://www.billtrack50.com/billdetail/1518647
- Ch. 332-M:2
  - V. "Genital gender reassignment surgery" means surgical procedures in people born without disorders of sex development including but not limited to metoidioplasty, phalloplasty, or vaginoplasty which seek to change genitalia:
    - (a) From male genitalia to female genitalia;
    - (b) From female genitalia to male genitalia;
    - (c) To form a combination of male and female genitalia or absence of genitalia in those born with exclusively male or exclusively female genitalia;
    - (d) By removing non-malignant genitalia.
  - VI. "Male circumcision" means surgery which removes all or a portion of the foreskin covering the glans of the penis, performed for religious, cultural or health reasons.
  - VII. "Male genitalia" means:
    - (a) Internal male genitalia which are the testes, epididymis, and vas deferens; and
    - (b) External male genitalia which are the penis and scrotum.
    - VIII. "Malignant" means cancerous or otherwise dangerous to the physical health of the person including physiology compromised by infection, lack of blood flow, or physical injury.
  - IX. "Malformation" means a structural defect in the body due to abnormal embryonic or fetal development.
  - X. "Metoidioplasty" means a surgery to transform the clitoris into a penis.
  - XI. "Minor" means a person who has not reached the age of majority.
  - XII. "Phalloplasty" means the surgical construction of a penis from other parts of the body.
  - XIII. "Physician" means a person who is licensed to practice medicine in this state under RSA 329.
  - XIV. "Reconstructive surgery" means surgery to restore normal form and function of tissue after it has been compromised by malformation, infection, trauma, cancer or other physical pathologies.
  - XV. "Vaginoplasty" means the surgical creation of a vagina from other parts of the body and includes but is not limited to:

- (a) Penile inversion vaginoplasty, which is a first-line "gold standard" approach for those with sufficient penile tissue;
- (b) Peritoneal vaginoplasty, which is an emerging surgical approach using the membrane that lines the abdominopelvic cavity and surrounds the abdominal organs, for people with insufficient penile tissue including those with a history of puberty blocking medications.
- (c) Rectosigmoid vaginoplasty, which uses a section of the sigmoid colon to create the vaginal lining, providing an option for those without sufficient penile tissue or as a revision for failed vaginoplasty.

#### 17. North Carolina

North Carolina General Statutes § 90-21.150, HB 808 (2023), https://www.ncleg.gov/Sessions/2023/Bills/House/PDF/H808v8.pdf

#### Sec. 1

- (4) Gender reassignment surgery. Any surgical service that seeks to surgically alter or remove healthy physical or anatomical characteristics or features that are typical for the individual's biological sex, in order to instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex, including a genital or non-genital gender reassignment surgery as defined in this section.
- (5) Gender transition. The process in which a person goes from identifying with and living as a gender that corresponds to his or her biological sex to identifying with and living as a gender different from his or her biological sex and may involve social, legal, or physical changes.
- (6) Genital gender reassignment surgery. A gender reassignment surgery performed for the purpose of assisting an individual with a gender transition, including, without limitation, any of the following:
  - a. Surgical procedures such as penectomy, orchiectomy, vaginoplasty, clitoroplasty, or vulvoplasty for biologically male patients or hysterectomy or ovariectomy for biologically female patients.
  - b. Reconstruction of the fixed part of the urethra with or without a metoidioplasty.
  - c. Phalloplasty, vaginectomy, scrotoplasty, or implantation of erection or testicular prostheses for biologically female patients.
- (9) Non-genital gender reassignment surgery. A gender reassignment surgery performed for the purpose of assisting an individual with a gender transition, including, without limitation, any of the following:
  - a. Surgical procedures for biologically male patients, such as augmentation mammoplasty, facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation, or hair reconstruction.
  - b. Surgical procedures for biologically female patients, such as subcutaneous mastectomy, voice surgery, liposuction, lipofilling, or pectoral implants.
- (10) Puberty-blocking drugs. Gonadotropin releasing hormone analogues or other synthetic drugs used in biological males to stop luteinizing hormone secretion and therefore testosterone secretion, or synthetic drugs used in biological females which stop the production of estrogens and progesterone, when used to delay or suppress pubertal development in children for the purpose of assisting an individual with a gender transition.
- (11) Surgical gender transition procedure. Any surgical service, including, without limitation, genital gender reassignment surgery and non-genital reassignment surgery, physician's services, and inpatient and outpatient hospital services related to gender transition, that seeks to do any of the following for the purpose of effecting a gender transition:
  - a. Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex.
  - b. Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex.

## 18. North Dakota

North Dakota Century Code § 12.1-36-01, HB 1254 (2023), https://legiscan.com/ND/text/HB1254/id/2771423target=%22 blank%22

### o Sec. 1, 12.1-36.1-02

- 1. Except as provided under section 12.1-36.1-03, if a minor's perception of the minor's sex is inconsistent with the minor's sex, a health care provider may not engage in any of the following practices for the purpose of changing or affirming the minor's perception of the minor's sex:
  - a. Perform castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, or vaginoplasty;
  - b. Perform a mastectomy;
  - c. Prescribe, dispense, administer, or otherwise supply any drug that has the purpose of aligning the minor's sex with the minor's perception of the minor's sex when the perception is inconsistent with the minor's sex, including:
    - (1) Puberty-blocking medication to stop normal puberty;
    - (2) Supraphysiologic doses of testosterone to females; or
    - (3) Supraphysiologic doses of estrogen to males; or
  - d. Remove any otherwise healthy or nondiseased body part or tissue, except for a male circumcision.

#### 19. Ohio

Ohio Revised Code § 3129.01, HB 68 (2024), <a href="https://search-prod.lis.state.oh.us/solarapi/v1/general">https://search-prod.lis.state.oh.us/solarapi/v1/general</a> assembly 135/bills/hb68/EN/05/hb68 05 EN?format=pdf

#### o Sec. 1 § 3129.01

(F) "Gender transition services" means any medical or surgical service (including physician services, inpatient and outpatient hospital services, or prescription drugs or hormones) provided for the purpose of assisting an individual with gender transition that seeks to alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex, or to instill or create physiological or anatomical characteristics that resemble a sex different from the individual's birth sex, including medical services that provide puberty blocking drugs, cross-sex hormones, or other mechanisms to promote the development of feminizing or masculinizing features in the opposite sex, or genital or non-genital gender reassignment surgery.

### 20. Oklahoma

Oklahoma Statutes § 63-2607.1, SB 613 (2023), <a href="http://webserver1.lsb.state.ok.us/cf\_pdf/2023-24%20ENR/SB/SB613%20ENR.PDF">http://webserver1.lsb.state.ok.us/cf\_pdf/2023-24%20ENR/SB/SB613%20ENR.PDF</a>

#### Sec. 1

- 2.a. "Gender transition procedures" means the following medical or surgical services performed for the purpose of attempting to affirm the minor's perception of his or her gender or biological sex, if that perception is inconsistent with the minor's biological sex:
  - (1) surgical procedures that alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex, or
  - (2) puberty-blocking drugs, cross-sex hormones, or other drugs to suppress or delay normal puberty or to promote the development of feminizing or masculinizing features consistent with the opposite biological sex.

### 21. South Carolina

O South Carolina Code § 44-42-310, H. 4624 (2024), <a href="https://www.scstatehouse.gov/sess125\_2023-2024/prever/4624\_20240507.htm">https://www.scstatehouse.gov/sess125\_2023-2024/prever/4624\_20240507.htm</a>

### o Sec. 1, § 44-42-310

- (6) "Gender transition procedures" means puberty-blocking drugs, cross-sex hormones, or genital or nongenital gender reassignment surgery, provided or performed for the purpose of assisting an individual with a physical gender transition.
- (7) "Genital gender reassignment surgery" means a surgical procedure performed for the purpose of assisting an individual with a physical gender transition including, without limitation, penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty, hysterectomy, ophorectomy, reconstruction of the urethra, metoidioplasty or phalloplasty, vaginectomy, scrotoplasty, or implantation of erection and/or testicular prostheses.

- (8) "Nongenital gender reassignment surgery" means surgical procedures performed for the purpose of assisting an individual with a physical gender transition including, without limitation, augmentation mammoplasty, facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation, hair reconstruction, subcutaneous mastectomy, pectoral implants, or various aesthetic procedures.
- (9) "Puberty-blocking drugs" means gonadotropin releasing hormone analogues or other synthetic drugs used to stop luteinizing hormone and follicle stimulating hormone secretion, synthetic antiandrogen drugs used to block the androgen receptor, or any drug to suppress or delay normal pubertal development in children.

#### 22. South Dakota

 South Dakota Codified Laws § 34-24-37, HB 1080, (2023), https://sdlegislature.gov/Session/Bill/23635

#### o Sec. 2, ch. 34-24

Except as provided in section 3 of this Act, a healthcare professional may not, for the purpose of attempting to alter the appearance of, or to validate a minor's perception of, the minor's sex, if that appearance or perception is inconsistent with the minor's sex, knowingly:

- (1) Prescribe or administer any drug to delay or stop normal puberty;
- (2) Prescribe or administer testosterone, estrogen, or progesterone, in amounts greater than would normally be produced endogenously in a healthy individual of the same age and sex;
- (3) Perform any sterilizing surgery, including castration, hysterectomy, oophorectomy, orchiectomy, penectomy, and vasectomy;
- (4) Perform any surgery that artificially constructs tissue having the appearance of genitalia differing from the minor's sex, including metoidioplasty, phalloplasty, and vaginoplasty; or
- (5) Remove any healthy or non-diseased body part or tissue

#### 23. Tennessee

Tennessee Code § 68-33-103, SB 1 (2023), https://legiscan.com/TN/text/SB0001/id/2755783target=%22\_blank%22

#### o Sec. 1, 68-33-103

- (a)(1) A healthcare provider shall not knowingly perform or offer to perform on a minor, or administer or offer to administer to a minor, a medical procedure if the performance or administration of the procedure is for the purpose of:
  - (A) Enabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex; or
  - (B) Treating purported discomfort or distress from a discordance between the minor's sex and asserted identity.
  - (2) Subdivision (a)(1) applies to medical procedures that are:
    - (A) Performed or administered in this state; or
    - (B) Performed or administered on a minor located in this state, including via telehealth[.]

### 24. Texas

Texas Health & Safety Code § 161.702, SB 14 (2023), https://capitol.texas.gov/tlodocs/88R/billtext/html/SB00014F.htm

#### o Sec. 2, § 161.702

For the purpose of transitioning a child's biological sex as determined by the sex organs, chromosomes, and endogenous profiles of the child or affirming the child's perception of the child's sex if that perception is inconsistent with the child's biological sex, a physician or health care provider may not knowingly:

- (1) perform a surgery that sterilizes the child, including:
  - (A) castration
  - (B) vasectomy;
  - (C) hysterectomy;
  - (D) oophorectomy;

- (E) metoidioplasty;
- (F) orchiectomy;
- (G) penectomy;
- (H) phalloplasty; and
- (I) vaginoplasty;
- (2) perform a mastectomy;
- (3) provide, prescribe, administer, or dispense any of the following prescription drugs that induce transient or permanent infertility:
  - (A) puberty suppression or blocking prescription drugs to stop or delay normal puberty;
  - (B) supraphysiologic doses of testosterone to females; or
  - (C) supraphysiologic doses of estrogen to males; or
- (4) remove any otherwise healthy or non-diseased body part or tissue.

#### 25. Utah

O Utah Code § 58-1-603, SB 16 (2023), https://le.utah.gov/~2023/bills/sbillenr/SB0016.pdf

### o Sec. 2, § 58-1-603

- (e) (i) "Hormonal transgender treatment" means administering, prescribing, or supplying for effectuating or facilitating an individual's attempted sex change:
- (A) to an individual whose biological sex at birth is female, a dose of testosterone or other androgens at levels above those normally found in an individual whose biological sex at birth is female;
- (B) to an individual whose biological sex at birth is male, a dose of estrogen or a synthetic compound with estrogenic activity or effect at levels above those normally found in an individual whose biological sex at birth is male; (C) a puberty inhibition drug.

#### o Sec. 4, § 58-67-102

- (22) (a) "Primary sex characteristic surgical procedure" means any of the following if done for the purpose of effectuating or facilitating an individual's attempted sex change:
  - (i) for an individual whose biological sex at birth is male, castration, orchiectomy, penectomy, vaginoplasty, or vulvoplasty;
  - (ii) for an individual whose biological sex at birth is female, hysterectomy, 566 oophorectomy, metoidioplasty, or phalloplasty; or
  - (iii) any surgical procedure that is related to or necessary for a procedure ... that would result in the sterilization of an individual who is not sterile.

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- (23) (a) "Secondary sex characteristic surgical procedure" means any of the following if done for the purpose of effectuating or facilitating an individual's attempted sex change:
  - (i) for an individual whose biological sex at birth is male, breast augmentation surgery, chest feminization surgery, or facial feminization surgery; or
  - (ii) for an individual whose biological sex at birth is female, mastectomy, breast reduction surgery, chest masculinization surgery, or facial masculinization surgery.

#### 26. West Virginia

West Virginia Code § 30-3-20, HB 2007 (2023),
<a href="https://www.wvlegislature.gov/bill\_status/bills\_text.cfm?billdoc=hb2007%20sub%20enr.htm&yr=2023&sesstype=RS&billtype=B&houseorig=H&i=2007">https://www.wvlegislature.gov/bill\_status/bills\_text.cfm?billdoc=hb2007%20sub%20enr.htm&yr=2023&sesstype=RS&billtype=B&houseorig=H&i=2007</a>

### o Art. 3, § 30-3-20

"Gender altering medication" means the prescribing or administering of the following for the purpose of assisting an individual with a gender transition:

- (1) Puberty blocking medication to stop or delay normal puberty;
- (2) Supraphysiologic doses of testosterone or other androgens to females; and
- (3) Supraphysiologic doses of estrogen to males.

"Gender transition" means the process in which a person goes from identifying with and living as a gender that corresponds to the person's biological sex to identifying with and living as a gender different from the person biological sex and may involve social, legal, or physical changes.

"Irreversible gender reassignment surgery" means a medical procedure performed for the purpose of assisting an individual with a gender transition, including any of the following:

- (1) Penectomy, orchiectomy, vaginoplasty, clitoroplasty, or vulvoplasty for biologically male patients or hysterectomy or ovariectomy for biologically female patients;
- (2) Metoidioplasty, phalloplasty, vaginectomy, scrotoplasty, or implantation of erection or testicular prostheses for biologically female patients; and
- (3) Augmentation mammoplasty for biological male patient and subcutaneous mastectomy for female patients.

### 27. Wyoming

- Wyoming Statutes § 35-4-1001, SF 99 (2024), https://www.wyoleg.gov/Legislation/2024/SF0099
- o Sec. 1, §35-4-1001
  - (b) Except as provided in subsection (c) of this section and for purposes of transitioning a child's biological sex as determined by the sex organs, chromosomes and endogenous profiles of the child or affirming the child's perception of the child's sex if that perception is inconsistent with the child's biological sex, no physician or health care provider shall:
    - (i) Perform a surgery that sterilizes the child, including castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty and vaginoplasty;
    - (ii) Perform a mastectomy;
    - (iii) Provide, administer, prescribe or dispense any of the following prescription drugs that induce transient or permanent infertility:
      - (A) Puberty suppression or blocking prescription drugs to stop or delay normal puberty;
      - (B) Supraphysiologic doses of testosterone to females;
      - (C) Supraphysiologic doses of estrogen to males.
    - (iv) Remove any otherwise healthy or nondiseased body part or tissue.