

**Congress of the United States**  
**Washington, DC 20515**

January 27, 2022

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

*RE: Proposed Rule: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 – RIN: 0938-AU65*

Dear Secretary Becerra,

We write in strong opposition to the U.S. Department of Health and Human Services' (HHS) proposed rule on *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023* published in the Federal Register on January 5, 2022.

First, we would like to express our concern and disapproval over the mere 22-day window to submit public comments on this 145-page proposed rule. For such a lengthy, complex, and important rule, the public should have a minimum of 30 days, if not 60 days, to provide input. Given the importance of the issues covered by this proposed rule, we request HHS extend the deadline for public comment to 60 days rather than trying to rush the rule through and cut the public out of the process.

Second, we would like to address the proposal to add sexual orientation and gender identity as protected classes in several non-discrimination prohibitions relating to insurance coverage. The stated purpose is to ensure that individuals receive “medically necessary care”, but HHS includes within that definition experimental procedures regarded as harmful by a growing body of medical studies.<sup>1</sup>

HHS proposes that it will be presumptively discriminatory if insurance plans do not cover experimental gender transition drugs and procedures, including puberty blockers, cross-sex hormones, and sex-reassignment surgeries, if they are covered for reasons other than gender dysphoria. Under the proposed rule, these procedures will be covered regardless of the individual determinations of physicians based on their clinical judgment, which are based on evidence-based practices, and without regard to conscience or religious objections of employers or the insured.

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<sup>1</sup> [Federal Register :: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023](#)

Mandating coverage of these services will harm patients as there is growing evidence that these gender transition procedures can be harmful, especially for minors.<sup>2</sup> Under the Obama Administration, the Centers for Medicare and Medicaid Services (CMS) stated that, “there is not enough evidence to determine whether gender reassignment surgery improves health outcomes for [patients] with gender dysphoria.”<sup>3</sup> As a result, CMS declined to issue a national coverage determination for such procedures under the Medicare program.<sup>4</sup>

Other countries have also found these procedures can lead to harmful health outcomes, especially for minors. A 2020 study commissioned by England’s National Institute for Health and Care Excellence found very low evidence for the effectiveness of puberty blockers and cross-sex hormones.<sup>5</sup> England’s High Court of Justice prohibited such treatments in young children due to the risks of permanent physical and psychological harm. (The decision was later reversed on procedural grounds, and is currently on further appeal).<sup>6</sup> Sweden’s leading medical research institute recently announced it is ending the practice of prescribing puberty blockers and cross-sex hormones to minors citing the highly uncertain risk/benefit ratio of hormonal interventions for minors.<sup>7</sup> Finland has also changed course and is focused on psychotherapy for minors.<sup>8</sup> Psychotherapists in Australia and New Zealand also emphasized the importance of mental health treatments before further procedure decisions are made.<sup>9</sup>

This growing body of research should put a pause on HHS’s decision to mandate coverage of experimental, harmful, sterilizing, and irreversible procedures. At a minimum, insurers should not be required to cover such procedures for minors. There is a growing number of individuals

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<sup>2</sup> [Summary of Studies Regarding Risks Associated With Transgender Medical Interventions — HHS Transgender Mandate](#)

<sup>3</sup> [Proposed Decision Memo for Gender Dysphoria and Gender Reassignment Surgery \(CAG-00446N\) \(cms.gov\)](#)

<sup>4</sup> Centers for Medicare and Medicaid Services, Decision Memo for GENDER Dysphoria and GENDER REASSIGNMENT SURGERY (CAG-00446N), August 30, 2016, <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282&CoverageSelection=National&Keyword=gender+reassignment+surgery&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAACAACAAAAA%3D%3D&>.

<sup>5</sup> National Institute for Health and Care Excellence (England), *Evidence Review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria* (11 March 2021), <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3ffrom%3d2020-01-01%26q%3dgender%2bdysphoria%26sp%3don%26to%3d2021-03-31>.

<sup>6</sup> Royal Courts of Justice, High Court of Justice Administrative Court, *Bell v. Tavistock*, January 1, 2020, (Case No: CO/60/2020), <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>.

<sup>7</sup> [Sweden’s Karolinska Ends All Use of Puberty Blockers and Cross-Sex Hormones for Minors Outside of Clinical Studies | SEGM. The Karolinska Institute is responsible for selecting the annual Nobel Prize winner for medicine.](#) <https://ki.se/en/about>.

<sup>8</sup> Summary of a recommendation by COHERE 16.6.2020 Finland. COHERE website: <https://palveluvalikoima.fi/en/frontpage>. The Council for Choices in Health Care in Finland (COHERE Finland) works in conjunction with the Ministry of Social Affairs and Health, [www.palveluvalikoima.fi](http://www.palveluvalikoima.fi).

<sup>9</sup> Becky McCall, Psychiatrists Shift Stance on Gender Dysphoria, Recommend Therapy. Medscape. October 7, 2021. <https://www.medscape.com/viewarticle/960390>.

who had irreversible procedures, which they later came to regret.<sup>10</sup> Introducing cross-sex hormones, destroying fertility, or removing healthy breasts, genitals, or reproductive organs in the case of a minor is irreversible.<sup>11</sup> And concerns about outcomes from these procedures has increased.<sup>12</sup> Puberty blockers negatively impact bone density, social and emotional maturation, other aspects of development, and can have mixed results on mental health.<sup>13</sup> A Swedish teen who underwent medical transition and then de-transitioned said, “they’re experimenting on young people...we’re guinea pigs.”<sup>14</sup>

Given the growing body of medical research that shows that these procedures are medically harmful, the final rule should remove the mandate on insurers to cover these. At a minimum, it should clarify whether an insurance company that regularly covers or pays for hysterectomy or

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<sup>10</sup> Littman, L. (2021). Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners. *Arch Sex Behav* 50, 3353–3369. <https://link.springer.com/article/10.1007/s10508-021-02163-w>.

<sup>11</sup> Levine SB. Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria. *J Sex Marital Ther.* 2018 Jan 2;44(1):29-44. doi: 10.1080/0092623X.2017.1309482 <https://pubmed.ncbi.nlm.nih.gov/28332936/>. Epub 2017 Apr 19. PMID: 28332936. <https://pubmed.ncbi.nlm.nih.gov/28332936/>. Blog, “Gender-affirming hormone in children and adolescents,” *BMJ EBM Spotlight*. February 25, 2019. <https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/>. Clayton, A. The Gender Affirmative Treatment Model for Youth with Gender Dysphoria: A Medical Advance or Dangerous Medicine?. *Arch Sex Behav* (2021). <https://doi.org/10.1007/s10508-021-02232-0>.

<sup>12</sup> For example, see the following recent publications: Malone, W., D’Angelo, R., Beck, S., Mason, J., & Evans, M. (2021). Puberty blockers for gender dysphoria: the science is far from settled. *The Lancet Child & Adolescent Health*, 5(9), e33–e34. [https://doi.org/10.1016/S2352-4642\(21\)00235-2](https://doi.org/10.1016/S2352-4642(21)00235-2); Griffin, L., et al., supra n.5; Entwistle, K. (2020). Debate: Reality check – Detransitioners’ testimonies require us to rethink gender dysphoria. *Child and Adolescent Mental Health*, camh.12380, <https://doi.org/10.1111/camh.12380>; Hruz, P. W. (2020). Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *The Linacre Quarterly*, 87(1), 34–42. <https://doi.org/10.1177/0024363919873762>; Levine, S.B. (2021). Reflections on the Clinician’s Role with Individuals Who Self-identify as Transgender. *Arch Sex Behav* 50, 3527–3536, <https://doi.org/10.1007/s10508-021-02142-1>. Levine SB. Correction to: Reflections on the Clinicians Role with Individuals Who Self-identify as Transgender. *Archives of Sexual Behavior*. 2021 Nov;50(8):3537. DOI: 10.1007/s10508-021-02195-2. PMID: 34725753.

<sup>13</sup> National Institute for Health and Care Excellence (NICE), Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, NHS England, 11 March 2021. <https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate>. Puberty blockers have significant effects on bone density, during a time of important bone growth. Biggs, Michael. “Revisiting the effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria” *Journal of Pediatric Endocrinology and Metabolism*, vol. 34, no. 7, 2021, pp. 937-939. <https://doi.org/10.1515/jpem-2021-0180>. Carmichael, P., et al., supra n.7; de Vries ALC, Steensma TD, Doreleijers TAH, and Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med* 2011;8:2276–2283. [https://www.jssexmed.org/article/S1743-6095\(15\)33617-1/pdf](https://www.jssexmed.org/article/S1743-6095(15)33617-1/pdf). Abigail Shrier, “Top Trans Doctors Blow the Whistle on ‘Sloppy Care,’” *Common Sense*, October 4, 2021. <https://bariweiss.substack.com/p/top-trans-doctors-blow-the-whistle>; *Bell v. Tavistock and Portman Trust*, High Court of Justice, Royal Courts of Justice, January 12, 2020. [Bell -v- Tavistock judgment \(judiciary.uk\)](https://www.judiciary.uk).

<sup>14</sup> Mission: Investigate. *Trans Children* (“Trans Train 4”), November 26, 2021. <https://www.svtplay.se/video/33358590/uppdrag-granskning/mission-investigate-trans-children-avsnitt-1>.

mastectomy services for reasons unrelated to gender dysphoria is now required to cover and pay for such services to treat gender dysphoria or for sex-reassignment purposes.

Third, for decades, Congress has made consistent and clear attempts in federal law to protect rights of conscience and religious freedom for those in the health industry including for insurers, but while paying lip service to those protections, HHS has been systematically undermining religious freedom and conscience protections. Compliance and enforcement with the law improved when HHS established a Conscience and Religious Freedom Division within its Office for Civil Rights (OCR) in 2018. However, that Division has been eliminated and its work redelegated (if at all) from the career professionals to non-subject matter experts. In this proposed rule, there is one line that states, “[i]n enforcing the nondiscrimination provisions in the corresponding CMS regulations, HHS will comply with laws protecting the exercise of conscience and religion, including the Religious Freedom Restoration Act (42 U.S.C. 2000bb through 2000bb-4) and all other applicable legal requirements.”<sup>15</sup> HHS should provide clear and robust protections—as multiple courts have ruled are required—to insurance entities, employers, and individuals who have deeply held religious beliefs or other conscience objections to covering experimental and harmful procedures.

At a minimum, HHS should provide a clear process by which insurers and the insured can receive an up-front exemption when they have a religious or conscience objection to paying for a plan that covers experimental drugs and procedures that can prove harmful.

Sincerely,



Doug LaMalfa  
Member of Congress



Roger Marshall, M.D.  
U.S. Senator



Jeff Duncan  
Member of Congress



Cindy Hyde-Smith  
U.S. Senator

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<sup>15</sup> <https://www.federalregister.gov/documents/2022/01/05/2021-28317/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023>

Ralph Norman  
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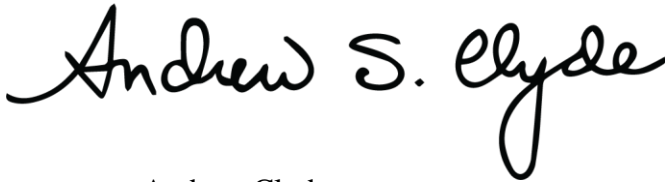
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