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February 17, 2026

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2451
Baltimore, MD 21244-8016

Submitted electronically

Re: RIN 0938-AV87; CMS-3481-P
Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

The National Women's Law Center (NWLC) comments to express our strong opposition to the U.S. Department of Health and Human Services' (HHS) proposed rule targeting health care for transgender youth.[1] Since 1972, NWLC has fought for gender justice in the courts, in public policy, and in our society, spanning across core areas of people's lives—including health and reproductive rights, income security, employment, and education—with an emphasis on those who face multiple and compounding forms of discrimination. Dignity and equity for transgender people form an inextricable part of that mission, including our efforts to strengthen health equity, access to care, and coverage. Throughout those efforts, we have seen the profound impact that access to care has on transgender people's opportunity to thrive and the critical importance of laws and policies protecting this care.

HHS' Centers for Medicare and Medicaid (CMS), however, is now seeking to discard and undermine these laws and policies and replace them with a regulation threatening the health of transgender young people and their access to care. The proposed regulation would bar hospitals that provide essential care for transgender youth from participating in Medicaid and Medicare. This proposal is dangerous, unmoored from medical evidence, and contrary to legal requirements. It suffers from numerous substantive deficiencies that we outline throughout this comment, including its failure to account for the impacts of the rule on transgender youth and their families; its apparent reliance on pretextual rationales for an animus-based restriction; its misrepresentation of the scientific and clinical research supporting access to care; and its excess of statutory constraints. Given these incurable deficiencies, HHS must withdraw the proposed rule in its entirety.

[1] 90 Fed. Reg. 59463 (proposed Dec. 19, 2025) (to be codified at 42 C.F.R. pt. 482) (hereinafter "Proposed Rule").

I. Health care for transgender youth is safe, evidence-based, and essential.

Health care for transgender youth, often referred to as transition-related health care (TRH), is best practice care that is medically necessary for many young people. A robust body of research demonstrates the safety, effectiveness, and benefits of this care. The TRH standards of care, which provide for evidence-based, individualized, and age-appropriate care, have garnered widespread endorsement from the medical and scientific community, both in the United States and around the world. Major medical associations have repeatedly affirmed their support for these evidence-based standards of care and their opposition to political interference with its provision. Among many others, these include the American Academy of Child and Adolescent Psychiatry,[2] American Academy of Family Physicians,[3] American Academy of Nursing,[4] American Academy of Pediatrics,[5] American Medical Association,[6] American Psychological Association,[7] Endocrine Society[8] and Pediatric Endocrine Society.[9]

Extensive evidence shows that when transgender young people can access the care they need, their health, wellbeing, and quality of life improves significantly. In one of the most comprehensive reviews of the literature to date, researchers commissioned by the Utah state legislature assessed data from more than 28,000 youth with gender dysphoria (GD). Their conclusion was unambiguous. The researchers explained that "after having spent many months searching for, reading, and evaluating the available literature, it was impossible for [them] to avoid drawing some high-level conclusions. Namely, **the consensus of the evidence supports that the treatments**

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[2] American Academy of Child & Adolescent Psychiatry, *AACAP Statement Responding to Efforts to Ban Evidence-Based Care for Transgender and Gender Diverse Youth* (Nov. 8, 2019), https://www.aacap.org/AACAP/Latest_News/AACAP_Statement_Responding_to_Efforts-to_ban_Evidence-Based_Care_for_Transgender_and_Gender_Diverse.aspx.

[3] Press Release, American Academy of Family Physicians et al., Frontline Physicians Oppose Legislation that Interferes in or Penalizes Patient Care (Apr. 2, 2021), https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/equality/ST-G6-FrontlinePhysiciansOpposeLegislationThatInterferesInOrPenalizesPatientCare-040221.pdf.

[4] Carol A. Sedlak & Carol J. Boyd, *Health Care Services for Transgender Individuals: Position Statement*, 64 NURSING OUTLOOK 510 (Aug. 1, 2016), https://doi.org/10.1016/j.outlook.2016.07.002.

[5] *See, e.g.,* Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 PEDIATRICS e20182162 (Oct. 1, 2018), https://doi.org/10.1542/peds.2018-2162.

[6] *See, e.g.,* American Medical Association, Policy H-185.927, Clarification of Evidence-Based Gender-Affirming Care (adopted and reaffirmed 2024), https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml; American Medical Association, *Health Insurance Coverage for Gender-Affirming Care of Transgender Patients* (2019), https://www.ama-assn.org/system/files/transgender-coverage-issue-brief.pdf.

[7] *See, e.g.,* American Psychological Association, *APA Policy Statement on Affirming Evidence-Based Inclusive Care for Transgender, Gender Diverse, and Nonbinary Individuals, Addressing Misinformation, and the Role of Psychological Practice and Science* (Feb. 2024), https://www.apa.org/about/policy/transgender-nonbinary-inclusive-care.pdf.

[8] Endocrine Society & Pediatric Endocrine Society, *Transgender Health: Position Statement* (Dec. 2020), https://www.endocrine.org/-/media/endocrine/files/advocacy/position-statement/position_statement_transgender_health_pes.pdf.

[9] *Id*.

are effective in terms of mental health, psychological outcomes, and the induction of body changes consistent with the affirmed gender in pediatric GD patients."[10]

Examples of recent studies further illustrate the effectiveness and benefits of TRH:

- **TRH is associated with significant improvements in mental health outcomes among youth:** In a study that included nearly 12,000 transgender youth, those who were able to access hormone therapy were substantially less likely to experience depression and suicidality compared to youth who wanted but did not receive hormone therapy.[11] Another study similarly found that access to puberty-pausing medications and hormone therapy was associated with 60% lower odds of moderate or severe depression and 73% lower odds of suicidality in a 12-month follow-up.[12] Similarly, a retrospective study of 3,500 transgender youth found a reduction of over 40% in hospital admissions or emergency department visits for suicidality among those who received hormone therapy, compared to those who had not.[13]
- **Access to TRH can improve young people's overall wellness:** Transgender youth assessed two years after initiating hormone therapy experienced higher levels of life satisfaction and positive affect (experiences such as joy, gratitude, and contentment), as well as lower levels of depression and anxiety.[14] Young people accessing puberty-pausing medication and hormone therapy also expressed high rates of satisfaction with TRH 3–5 years after beginning care, with many participants reporting that their only regret was not beginning treatment earlier.[15]
- **Access to TRH in adolescence can impact transgender people's wellbeing throughout their lives:** In a study that compared transgender adults who began hormone therapy as youth with those who first accessed the care at 18 or older, the former had better mental health outcomes in the period immediately prior to taking the survey.[16]

Like its effectiveness and benefits, the safety of TRH for youth is well established. The medications prescribed as part of TRH have been safely used for decades to conditions such as precocious puberty,[17] and research has further demonstrated their safety when used to treat gender dysphoria. The study commissioned by the Utah state legislature reached the following conclusion:

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[10] Joanne LaFleur, *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* 90 (Aug. 6, 2024), https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=287 (emphasis in original).
[11] Amy E. Green et al., *Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, 70 JOURNAL OF ADOLESCENT HEALTH 643 (Apr. 2022), https://doi.org/10.1016/j.jadohealth.2021.10.036.
[12] Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youth Receiving Gender-Affirming Care*, 5 JAMA Network Open e220978 (Feb. 2022), http://doi.org/10.1001/jamanetworkopen.2022.0978.
[13] Marissa Nunes-Moreno, *Mental Health Diagnosis and Suicidality Among Transgender Youth in Hospital Settings*, 12 LGBT HEALTH 20 (Jul. 17, 2024), https://doi.org/10.1089/lgbt.2023.0394.
[14] Diane Chen et al., *Psychosocial Functioning in Transgender Youth After 2 Years of Hormones*, 388 NEW ENGLAND JOURNAL OF MEDICINE 240 (Jan. 2023), http://doi.org/10.1056/NEJMoa2206297.
[15] Kirstina R. Olson et al., *Levels of Satisfaction and Regret with Gender-Affirming Medical Care in Adolescence*, 178 JAMA PEDIATRICS 1354 (Oct. 21, 2024), http://doi.org/10.1001/jamapediatrics.2024.4527.
[16] Jack L. Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, 17 PLOS ONE e0261039 (Jan. 12, 2022), https://doi.org/10.1371/journal.pone.0261039.
[17] *See, e.g.,* Erika L Zevin & Erica A. Eugster, *Central Precocious Puberty: A Review of Diagnosis, Treatment, and Outcomes*, 7 LANCET 886 (Dec. 2023), https://doi.org/10.1016/S2352-4642(23)00237-7.

> **The evidence also supports that treatments are safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer.** With regards to these safety outcomes, reviewed studies show that any patient-level changes are minimal, and that despite any small improvements or decrements in individual disease risk factors, the average patient's values remain within the bounds of normal, non-pathological ranges for human population.[18]

This body of evidence leads to a clear conclusion: TRH for youth is safe, effective, and even lifesaving. It demonstrates the need to preserve and strengthen young people's access to this medically necessary care and the dangers of policies that restrict such access.

II. CMS fails to account for the harm that would result from the proposed rule.

Disregarding the evidence supporting TRH, CMS seeks to undermine access to this care by prohibiting hospitals that participate in Medicaid and Medicare from providing TRH to transgender youth. The proposed rule would effectively coerce almost all hospitals from offering this care. Transgender youth who are unable to access TRH in hospital settings may find that their access to care is severely limited or in some cases eliminated entirely, jeopardizing their health, safety, and security. The harmful impacts of the proposed rule would extend to their families and providers, to intersex people, and to the transgender community broadly.

CMS offers only a cursory recognition of the harm its rule would cause. It dismisses some of the proposed rule's most dangerous consequences as negligible or refuses to acknowledge them entirely. CMS' failure to address the harm of its proposed rule, as well as its attempts to minimize or explain away that harm, strongly suggest it has disregarded crucially important evidence that it is obligated to consider.

a. The proposed rule would hinder or prevent transgender youth from accessing TRH.

If finalized, the proposed rule would force hospitals to deny best practice care for transgender youth or else be excluded from Medicaid and Medicare. In practice, this requirement would coerce the vast majority of hospitals into stopping this care, stripping them of their ability to serve transgender youth in accordance with the standards of care and their providers' professional judgment. Virtually all hospitals rely on Medicaid and Medicare funding, and nearly half (44%) of all spending on hospital care comes from Medicare and Medicaid payments.[19] The loss of such a significant portion of their funding can be catastrophic for hospitals, and many of those hospitals would likely conclude that exclusion from Medicaid and Medicare is not a viable option.

As a result, the proposed rule would largely prevent transgender young people from accessing TRH in hospital settings. Losing this source of care could make it far more difficult or even impossible for many transgender youth to receive TRH, especially given the significant number of youth who rely on hospital-based care as one of their few or only options. Those who do not have ready access to a non-hospital TRH provider may be forced to delay this often time-sensitive care as they seek another source or forgo it entirely if an alternative provider is not available. Young people currently receiving TRH in hospital settings may experience disruptions in their care or may be abruptly cut off from treatment, with significant risks to their physical and mental health.

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[18] LaFleur, *supra* note 10 at 90 (emphasis in original).
[19] Zachary Levinson et al., *Key Facts About Hospitals* (Feb. 19, 2025), https://www.kff.org/health-costs/key-facts-about-hospitals.

Even youth who receive TRH outside of hospitals could face interruptions in care, such as being denied routine puberty-pausing medications or hormone therapy during hospitalizations. As demonstrated in Section I of this comment, the ramifications for those who are unable to access care or whose ongoing treatments are cut off could be severe, including negative health outcomes such as higher rates of depression, anxiety, and suicidality.

The harm of preventing hospitals from providing TRH to youth would be far-reaching. A large proportion of TRH care for youth occurs in hospitals, including through hospital-based clinics. For example, one study indicates that 80% of multidisciplinary pediatric gender health clinics in the United States are housed in academic medical facilities like university hospitals or teaching hospital systems.[20] Hospitals have remained among the most common sources of TRH for youth even as ongoing state and federal actions discourage a growing number from providing this care, underscoring both the widespread impact the rule would have and the limited availability of non-hospital alternatives.

By suppressing or even eliminating hospital-based services, the proposed rule would exacerbate barriers that transgender youth already face to accessing TRH providers. The availability of such providers is already limited, particularly in states with laws criminalizing or otherwise targeting them.[21] These providers have become even fewer in number over the past year, as hostile federal actions—including baseless investigations, threats of criminal penalties, subpoenas for sensitive patient data, denial of funding, and harassment—have deterred or prevented them from maintaining care for transgender youth.[22] The vitriolic rhetoric and disinformation used to justify such actions have further accelerated this shift: TRH providers are increasingly fearful for their safety due to a dramatic rise in harassment and threats of violence, often spurred by statements by political leaders, government officials, and other public figures that erode confidence in medical professionals and scientific evidence.[23]

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[20] Aytch Denaro et al., *Lessons from Grassroots Efforts to Increase Gender-Affirming Medical Care for Transgender and Gender Diverse Youth in the Community Health Care Setting*, 8 TRANSGENDER HEALTH 207 (Jun. 1, 2023), http://doi.org/10.1089/trgh.2021.0092.

[21] *See* Isabelle C. Band et al., *An Analysis of Gender-Affirming Care Offerings on United States Pediatric Hospital Websites: Exploring the Impact of State Legislative Bans*, 12 LGBT HEALTH 458 (Feb. 17, 2025), https://doi.org/10.1089/lgbt.2024.0214.

[22] *See, e.g.,* Selena Simmons-Duffins, *Trump Pushes an End to Medical Care for Transgender Youth Nationally*, NPR (Oct. 30, 2025), https://www.npr.org/sections/shots-health-news/2025/10/30/nx-s1-5588655/transgender-trump-medicare-medicaid-gender-affirming-care; Theresa Gaffney, *Amid Federal Pressure, More Hospitals Stop Gender-Affirming Care for Minors*, STAT NEWS (Feb. 5, 2026), https://www.statnews.com/2026/02/05/hospitals-stop-gender-care-minors-trump-administration-pressure; Sam Levine, *DOJ Subpoenas Clinics and Doctors who Offer Gender-Affirming Care to Minors*, THE GUARDIAN (Jul. 9, 2025), https://www.theguardian.com/us-news/2025/jul/09/gender-affirming-care-minors; Orion Rummler, *Three Hospitals Are Under Investigation for Providing Gender-Affirming Care to Trans Youth*, THE 19TH (Jan. 7, 2026), https://19thnews.org/2026/01/gender-affirming-care-youth-hospitals.

[23] Casey Parks, *Doctors Who Treat Trans Patients Say Threats Worsened After Trump's Orders*, WASHINGTON POST (Mar. 9, 2025), https://www.washingtonpost.com/nation/2025/03/09/doctors-transgender-safety-threats-trump. *See also* Landon D. Hughes et al., *Adolescent Providers' Experiences of Harassment Related to Delivering Gender-Affirming Care*, 73 JOURNAL OF ADOLESCENT MEDICINE 672 (Aug. 15, 2023), https://doi.org/10.1016/j.jadohealth.2023.06.024; Human Rights Campaign, *Online Harassment, Offline Violence: Unchecked Harassment of Gender-Affirming Care Providers and Children's Hospitals on Social Media and its Offline Violent Consequences* (Dec. 8, 2022), https://hrc-prod-requests.s3-us-west-2.amazonaws.com/HRCF-OnlineHarassmentOfflineViolence.pdf.

While existing barriers to accessing TRH providers impact young people across the country, those living in states that already restrict TRH are at an especially precarious baseline. Studies have found correlations between anti-transgender laws and the geographic distribution of pediatric TRH clinics, with the South and Midwest suffering from significantly fewer clinics relative to the transgender youth population in those regions.[24] In some states, bans on TRH for youth have eliminated in-state care entirely.[25] The decreasing availability of TRH providers has had a domino effect on access to care for all transgender people, as the remaining providers have become overwhelmed with more patients than they have capacity to accept.[26]

Many transgender youth can only access care if they travel long distances, often out of state. A May 2023 study demonstrated the travel burden many youth already face by comparing driving distance to the nearest TRH clinic before and after state-level restrictions were adopted. At the time the study was conducted, more than 25% of young people lived more than a one-day drive away from the nearest clinic, a sharp rise from the pre-restriction rate of 1.4%.[27] As TRH bans have continued to proliferate since 2023, this burden is likely even worse now. Forcing transgender youth and their families to travel for TRH can create a substantial barrier, especially as TRH often entails frequent, ongoing medical visits. For some transgender youth, the cost and logistical barriers of travel are prohibitive, turning the geographic isolation into an effective bar to care.[28] Transgender youth from low-income families, who disproportionately include youth of color, may face especially pronounced cost burdens and other barriers to travel, as would disabled youth.

The proposed rule would significantly worsen these barriers. Young people who already have limited options for TRH providers may be left with none. More families could be forced to travel long distances to access care, with some having no realistic sources of care even with extensive travel. The proposed rule would further worsen the cost burdens resulting from the lack of available providers: Some families may need to pay for frequent travel or rely on out-of-network providers, while those who cannot access TRH may bear costs related to the negative health outcomes transgender youth often experience when denied care. And the influx of displaced patients would strain the capacity of non-hospital providers even more, resulting in longer delays or more frequent denials of care for transgender youth broadly.

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[24] Tara Weixel & Beth Wildman, *Geographic Distribution of Clinical Care for Transgender and Gender-Diverse Youth*, 150 PEDIATRICS e2022057054 (Nov. 2022), https://doi.org/10.1542/peds.2022-057054

[25] Luca Borah et al., *State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth*, 330 JAMA 375, http://doi.org/10.1001/jama.2023.11299.

[26] *See, e.g.,* Abbie E. Goldberg & Elana Redfield, *The Experiences of Gender-Affirming Care Providers in States Without Laws Restricting Access to Care* (Apr. 2025), https://williamsinstitute.law.ucla.edu/publications/experiences-gac-providers (finding that state restrictions have led to an influx of patients and related pressures for TRH providers in other states); Tara Weixel & Beth Wildman, *Geographic Distribution of Clinical Care for Transgender and Gender-Diverse Youth*, 150 PEDIATRICS e2022057054 (Nov. 2022), https://doi.org/10.1542/peds.2022-057054 (finding substantially higher numbers of transgender youth per pediatric gender clinic in U.S. regions with less protective policies).

[27] Borah et al., *supra* note 25.

[28] Ellesse-Roselee L. Akré et al., *Structural Barriers to Accessing Gender-Affirming Care for Transgender and Gender Diverse (TGD) Individuals in the United States*, INTERNATIONAL JOURNAL OF TRANSGENDER HEALTH 1, https://doi.org/10.1080/26895269.2024.2431826.

b. The proposed rule's promotion of prejudice and disinformation harms transgender people broadly.

The harm of this proposed rule goes beyond its immediate impact on access to care: The prejudice and disinformation it relies on threatens the health and safety of transgender people, regardless of whether it would directly affect their access to TRH. The proposed rule wields the power of the federal government to further an aggressive, concerted effort to target the rights and dignity of transgender people. It stigmatizes transgender youth, dismisses the legitimacy of their experiences and needs, spreads myths about their care, and erodes public trust in the providers and families who support them.

These tactics are dangerous in and of themselves. Research on the impact of other anti-transgender and anti-LGBTQ+ policies and rhetoric illustrates numerous potential consequences:

- **Impacts on wellbeing and mental health:** A study of LGBTQ+ youth overall found that the overwhelming majority (90%) said their wellbeing was negatively impacted due to recent politics,[29] an experience also reported by 88% of transgender adults in second study.[30] The spread of anti-transgender policies has also been repeatedly linked to higher rates of depression, anxiety, and suicidality among transgender people.[31] The mental health impacts of policies like state TRH bans have also reached families[32] and providers,[33] who have reported higher levels of anxiety, fear, stress, and burnout.
- **Harassment and violence:** Government officials and politicians who spread anti-transgender disinformation often encourage and even implicitly legitimize interpersonal abuse. As the political attacks on transgender people have escalated, so have threats, harassment, and violence against them and their providers. Transgender youth reported high rates of such experiences within the year prior to a survey: As a result of anti-LGBTQ+

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[29] Ronita Nath et al., *2024 U.S. National Survey on the Mental Health of LGBTQ+ Young People* 11 (2024), https://www.thetrevorproject.org/survey-2024/assets/static/TTP_2024_National_Survey.pdf.

[30] Movement Advancement Project, *New Study Reveals Dramatic Changes for LGBTQ Adults Since November 2024* (Oct. 2025), https://www.mapresearch.org/2025-norc-survey-report.

[31] Lindsay Y. Dhanani & Rebecca R. Totton, *Have You Heard the News? The Effects of Exposure to News About Recent Transgender Legislation on Transgender Youth and Young Adults*, 20 SEXUALITY RESEARCH AND SOCIAL POLICY 1345 (Apr. 2023), https://doi.org/10.1007/s13178-023-00810-6; George B. Cunningham et al., *Anti-Transgender Rights Legislation and Internet Searches Pertaining to Depression and Suicide*, 17 PLOS ONE e0279420 (Dec. 22, 2022), https://doi.org/10.1371/journal.pone.0279420; Sharon G. Horne et al., *The Stench of Bathroom Bills and Anti-Transgender Legislation: Anxiety and Depression Among Transgender, Nonbinary, and Cisgender LGBQ People During a State Referendum*, 69 JOURNAL OF COUNSELING PSYCHOLOGY 1 (Jan. 2022), https://doi.org/10.1037/cou0000558; Amy Novotney, *'The Young People Feel It': A Look at the Mental Health Impact of Transgender Legislation* (Jun. 29, 2023), https://www.apa.org/topics/lgbtq/mental-health-anti-transgender-legislation.

[32] Roberto L. Abreu et al., *"I Am Afrida for Those Kids Who Might Find Death Preferable": Parental Figures' Reactions and Coping Strategies to Bans on Gender Affirming Care for Transgender and Gender Diverse Youth*, 9 PSYCHOLOGY OF SEXUAL ORIENTATION AND GENDER DIVERSITY 500 (2022), https://psycnet.apa.org/doi/10.1037/sgd0000495; Richard A. Brandon-Friedman et al., *The Perspective of Gender-Diverse Youth and Caregivers Coping with Legislation Banning Gender-Affirming Medical Interventions*, 75 JOURNAL OF ADOLESCENT HEALTH S8 (2024), https://doi.org/10.1016/j.jadohealth.2023.11.033.

[33] Pranav Gupta et al., *Exploring the Impact of Legislation Aiming to Ban Gender-Affirming Care on Pediatric Endocrine Providers: A Mixed-Methods Analysis*, 7 JOURNAL OF THE ENDOCRINE SOCIETY bvad111 (Oct. 2023), https://doi.org/10.1210/jendso/bvad111; Landon D. Hughes et al., *"These Laws Will Be Devastating": Provider Perspectives on Legislation Banning Gender-Affirming Care for Transgender Adolescents*, 69 JOURNAL OF ADOLESCENT HEALTH 976 (Oct. 2021), https://doi.org/10.1016/j.jadohealth.2021.08.020.

policies and debates, 45% experienced cyberbullying and online harassment, 24% faced bullying at school, and one in ten experienced physical assault.[34] Analyses of Federal Bureau of Investigations also revealed a sharp rise in crimes targeting LGBTQ youth in K–12, correlating with the proliferation and distribution of anti-LGBTQ laws.[35] TRH providers have also faced a dramatic rise in violent threats and harassment, jeopardizing their personal safety and their medical practice.[36]

- **Avoidance of medical care:** Concerns about safety, privacy, and mistreatment have led transgender youth and their families to avoid or postpone health care, including both TRH and other forms of care.[37] For example, 29% of surveyed transgender youth said they did not feel safe seeking medical care when sick or injured as a result of anti-LGBTQ+ policies.[38] The resulting loss of care further threatens their health—especially as the spike in harassment, violence, and negative mental health outcomes has made their access to medical services more important than ever.
- **Displacement:** Political attacks have forced many transgender people and their families to move or consider moving to another state, even when uprooting their lives jeopardizes their personal and financial stability. Nearly half (45%) of transgender youth report that they or their family have considered moving to a different state due to anti-LGBTQ+ politics and laws.[39] A survey conducted in June 2025 found that just in the months since November 2024, nearly one in ten transgender people had in fact moved to a different state as a response to the hostile climate.[40]

The proposed rule and the incendiary claims HHS made to justify it have already compounded these impacts. Finalizing the rule would magnify the harm even further.

[34] Morning Consult & Trevor Project, *Issues Impacting LGBTQ Youth* 7 (Jan. 2023), https://www.thetrevorproject.org/wp-content/uploads/2023/01/Issues-Impacting-LGBTQ-Youth-MC-Poll_Public-2.pdf. *See also* Kirby Phares et al., *Anti-LGBTQ+ Policies and Rhetoric Are Harming LGBTQ+ Lives* 7 (Mar. 2024), https://www.filesforprogress.org/memos/Anti-LGBTQ-Policies-and-Rhetoric-Are-Harming-LGBTQ-Lives.pdf.

[35] The analysis found that an increase in hate crimes targeting LGBTQ+ people in K–12 schools correlated with the rise in anti-LGBTQ+ laws, with hate crimes more than quadrupling in states that enacted laws restricting LGBTQ+ students' rights. Laura Meckler et al., *In States With Laws Targeting LGBTQ Issues, School Hate Crimes Quadrupled*, WASHINGTON POST (Mar. 12, 2024), https://www.washingtonpost.com/education/2024/03/12/school-lgbtq-hate-crimes-incidents/?utm_campaign=news.

[36] *See, e.g.,* Casey Parks, *Doctors Who Treat Trans Patients Say Threats Worsened After Trump's Orders*, WASHINGTON POST (Mar. 9, 2025), https://www.washingtonpost.com/nation/2025/03/09/doctors-transgender-safety-threats-trump. *See also* Landon D. Hughes et al., *Adolescent Providers' Experiences of Harassment Related to Delivering Gender-Affirming Care*, 73 JOURNAL OF ADOLESCENT MEDICINE 672 (Aug. 15, 2023), https://doi.org/10.1016/j.jadohealth.2023.06.024; Human Rights Campaign, *supra* note 23; Goldberg & Redfield, *supra* note 26, https://williamsinstitute.law.ucla.edu/publications/experiences-gac-providers.

[37] Jessie Melina Garcia Gutiérrez et al., *A Narrative Synthesis Review of Legislation Banning Gender-Affirming Care*, 12 CURRENT PEDIATRICS REPORTS 44 (Jun. 2024), https://doi.org/10.1007/s40124-024-00320-y; Hughes et al., *supra* note 33; Novotney, *supra* note 31; Human Rights Watch, *"They're Ruining People's Lives": Bans on Gender-Affirming Care for Transgender Youth in the US* (Jun. 2025), https://www.hrw.org/report/2025/06/03/theyre-ruining-peoples-lives/bans-on-gender-affirming-care-for-transgender-youth.

[38] Morning Consult & Trevor Project, *supra* note 34.

[39] Nath et al., *supra* note 29 at 11.

[40] Movement Advancement Project, *supra* note 30.

c. The proposed rule risks intersex people's health and rights.

The proposed rule would also harm intersex people, including those who do not identify as transgender. The proposed rule allows for an exception when the young person has "a medically verifiable disorder of sexual development."[41] This carveout fails to shield intersex people from the barriers to care imposed by the rule, and in fact invites violations of their rights.

The core function of this exception is not to protect intersex youth and their access to medically necessary care: It is to permit and endorse the procedures frequently performed on intersex infants and young children without their consent. As HHS previously recognized, these procedures are almost never carried out to address a present medical need. Rather they are intended to conform an intersex child's physical traits to a specific sex category based on stereotypical ideas of how bodies should appear and function.[42] Most often performed before a child turns two years old, these procedures preemptively deprive intersex youth of the ability to participate in medical decision-making and often result in lasting and irreversible medical complications.[43] International bodies such as the United Nations and the World Health Organization have repeatedly described nonconsensual surgeries on intersex children as human rights violations,[44] and a growing number of medical associations and experts have called for the end of this practice.[45]

Nevertheless, many hospitals in the United States continue to perform nonconsensual procedures on intersex children.[46] But instead of intervening to curb this practice, CMS now seeks to explicitly allow for it to persist, disregarding the evidence of its harm and departing without explanation from the position HHS adopted as recently as January 2025.[47] This rule would constitute a tacit

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[41] Proposed Rule, 90 Fed. Reg. at 59463.

[42] Department of Health and Human Services, *Advancing Health Equity for Intersex Individuals* 5 (Jan. 2025), https://interactadvocates.org/wp-content/uploads/2025/01/intersex-health-equity-report.pdf (hereinafter HHS Intersex Health Equity Report). *See also* Human Rights Watch & InterACT, *"I Want to Be Like Nature Made Me": Medically Unnecessary Surgeries on Intersex Children in the US* (Jul. 25, 2017), https://www.hrw.org/report/2017/07/25/i-want-be-nature-made-me/medically-unnecessary-surgeries-intersex-children-us.

[43] HHS Intersex Health Equity Report, *supra* note 42 at 5.

[44] United Nations Human Rights Council, Re. 55/14, Combatting Discrimination, Violence and Harmful Practices Against Intersex Persons, U.N. Doc. A/HRC/RES/55/14 (Apr. 4, 2024), https://digitallibrary.un.org/record/4045699?ln=en&v=pdf; United Nations Office of the High Commissioner for Human Rights, *Background Note on Human Rights Violations Against Intersex People* (2019), https://www.ohchr.org/sites/default/files/BackgroundNoteHumanRightsViolationsagainstIntersexPeople.pdf; Human Rights Council Juan E. Méndez (Special Rapporteur), *Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment* 18–19, UN Doc. A/HRC/22/53 (2013), https://www.ohchr.org/sites/default/files/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf; World Health Organization, *Eliminating Forced, Coercive and Otherwise Involuntary Sterilization: An Interagency Statement (OHCHR, UN Women, UNAIDS, UNDP, UNFPA, UNICEF, and WHO)* 13 (2014), https://iris.who.int/server/api/core/bitstreams/f32e6f52-8cd4-45a5-8b19-6aecd9c71575/content;

[45] The Brussels Collaboration on Bodily Integrity, *Genital Modifications in Prepubescent Minors: When May Clinicians Ethically Proceed?*, 25 AMERICAN JOURNAL OF BIOETHICS 53 (Jul. 17, 2024), https://doi.org/10.1080/15265161.2024.2353823; Luke Muschialli et al., *Perspectives on Conducting "Sex-Normalising" Intersex Surgeries Conducted in Infancy: A Systematic Review*, 4 PLOS GLOBAL PUBLIC HEALTH e0003568 (Aug. 28, 2024), https://doi.org/10.1371/journal.pgph.0003568.

[46] Barbara Rodriguez & Kate Sosin, *Hospitals that Paused Youth Gender-Affirming Care Continued Controversial Intersex Surgeries, Group Says*, THE 19TH (Mar. 10, 2025), https://19thnews.org/2025/03/hospitals-intersex-surgery-gender-affirming-care-youth.

[47] HHS previously recognized the harms of nonconsensual procedures on intersex children in *Advancing Health Equity for Intersex Individuals*, a landmark report published January 17, 2025. While HHS later removed the report

endorsement of such procedures, undermining progress made towards their eradication and perpetuating their negative impacts on intersex people.

The endorsement of these procedures stands in stark contrast with the proposed rule's attitude towards TRH coverage for transgender people. Care for transgender adolescents is medically necessary, evidence-based, and effective. Per the well-established standards of care for TRH, its course of treatment is determined through shared medical decision-making that ensures that all parties, including the patient who initiated the care, are fully informed and consenting.[48] By contrast, the procedures endorsed in proposed rule's exception are conducted long before the intersex individual can participate in decision-making, they are not guided by medical necessity or recognized standards of care, and significant evidence demonstrates their harms and marginal benefits. This contrast underscores the true thrust of this proposed rule: not to protect children or follow scientific evidence, but to target health care based on ideological preconceptions and sex stereotypes.

Meanwhile, the exception fails to adequately protect intersex adolescents who seek consensual, patient-initiated care that may otherwise be affected by the proposed rule. For example, hospitals may be unaware of the exception, putting the onus on intersex youth and their families to provide the often-inaccessible legal evidence before they can receive care. Hospitals who are aware of the exception may require documentation of a young person's intersex traits out of fear of noncompliance with the proposed rule. This problem may particularly arise when an individual's intersex traits are not explicitly reflected in their medical history or in contexts where the hospital does not have immediate access to the individual's complete medical records. Such documentation requirements can be deeply invasive and, in some cases, can result in delays or denials of care. Yet another complication may result from the requirement that intersex traits be "medically verifiable." This ambiguous term has no medical, scientific, or legal basis. As a result, hospitals may not understand this phrase or impose an overly restrictive interpretation, while intersex individuals and their families may have difficulty determining what evidence must be provided to show they qualify for the exemption.

d. A likely chilling effect would further magnify the proposed rule's impact.

For many hospitals, exclusion from Medicaid and Medicare would jeopardize their ability to operate. Faced with a penalty of this severity, some may be fearful of even being perceived as violating the rule. This fear would not be surprising: HHS has already targeted hospitals with aggressive investigations, intimidation tactics, and funding denials, often based on baseless claims and misconstructions of the law.[49] The proposed rule would likely result in a chilling effect that would pressure hospitals and even non-hospital providers to deny care to transgender youth even in circumstances that the rule would not reach.

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from its website without explanation, it is archived at https://interactadvocates.org/wp-content/uploads/2025/01/intersex-health-equity-report.pdf.

[48] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INTERNATIONAL JOURNAL OF TRANSGENDER HEALTH S1 (Sep. 15, 2022), https://doi.org/10.1080/26895269.2022.2100644; Wylie C. Hebree et al., *Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM 3869 (Sep. 13, 2017), https://doi.org/10.1210/jc.2017-01658.

[49] *See, e.g.,* Gaffney, *supra* note 22; Levine, *supra* note 22; Rummler, *supra* note 22.

The likelihood of overcompliance is not theoretical. Federal pressure and overreaching enforcement have already prompted numerous hospitals and other providers to stop offering TRH for young people, even when not required to do so. In the period since President Trump signed his executive order targeting TRH,[50] more than 40 hospitals have discontinued this care for youth; many explicitly noted that they made the decision in response to federal actions, despite their continued recognition that TRH is best practice care.[51] The proposed rule itself has stoked this mass exodus even before it has been finalized, with at least nine hospitals stopping the provision of TRH for youth since the rule was announced in late December.[52] Even some providers of TRH for transgender adults or those not affiliated with hospitals have decided to suspend their services in response to federal actions.

Finalizing this proposed rule would aggravate this chilling effect, likely leading to denials of care that go even beyond its far-reaching scope. For example, non-hospital providers may be concerned that offering TRH for youth would open them up to investigations, or they may stop care in anticipation of future regulations targeting a wider range of medical entities. Others, particularly providers or clinics who have some level of affiliation with hospitals, may be uncertain about whether the rule applies to them. Meanwhile, hospitals may deny care to minimize their legal risks even when it is permitted under the rule. Some may stop providing TRH to transgender people of all ages, deny access to mental health counseling, or construe the exceptions to the rule more narrowly than intended. Hospitals may even avoid treating transgender youth for other conditions out of confusion or an overabundance of caution. For instance, hospitals may worry even if a transgender patient is receiving TRH from an outside source, treating them for a different condition can require the hospital's providers to factor in the patient's TRH in order to ensure continuous and effective care. The proposed rule could also lead to delays in care if hospitals must navigate the legality of care for specific patients or resolve ambiguities in the regulatory language. The rule would also exacerbate—and in fact has already exacerbated—the climate of fear that has pressured providers to desist from offering TRH, both by creating a new enforcement lever to target those providers and by promoting the disinformation that has previously put their safety at risk.

III. The rationale proffered in the proposed rule appears to be a pretext for anti-transgender animus.

The primary rationale that CMS provides for the proposed rule is its belief that TRH is unsafe and unproven. As detailed in the following section, this belief is incompatible with the evidence and grounded in distortions and disinformation. The incongruity between this rationale and the factual basis is so extensive that it is difficult to explain it away as a mere misunderstanding of the scientific evidence. Rather, it raises serious questions about whether CMS has reverse-engineered its claims about the safety and effectiveness of TRH in service of a different motive. The proposed

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[50] *See* Exec. Order No. 14187, 90 Fed. Reg. 8771 (Feb. 3, 2025).

[51] Gaffney, *supra* note 22. Among other examples, Children's Hospital Los Angeles cited the "increasingly severe impacts of federal administrative actions and proposed policies" when announcing it had "no viable alternative" to ending their provision of TRH care for youth. Sonja Sharp, *Children's Hospital Los Angeles Halts Transgender Care Under Pressure from Trump*, LA TIMES (Jun. 12, 2025), https://www.latimes.com/california/story/2025-06-12/childrens-hospital-of-los-angeles-transgender-care. Children's National Hospital similarly pointed to "escalating legal and regulatory risks to Children's National, our providers, and the families we serve." Andrea Swalec, *Children's National Hospital to Stop Prescribing Gender-Affirming Medication*, NBC WASHINGTON (Jul. 21, 2025), https://www.nbcwashington.com/news/local/childrens-national-hospital-to-stop-prescribing-gender-affirming-medication/3961133.

[52] Gaffney, *supra* note 22.

rule's development and language strongly suggest such a motive: an ideological opposition to transgender people and the care they may need. Taken together, the evidence of animus and the patent flaws in CMS' purported rationale strongly suggest that the rationale is pretextual. When a rule suffers from this type of disconnect between the actual impetus for agency action and the reasons provided in the preamble, it cannot survive review under the Administrative Procedure Act (APA).[53]

a. Evidence strongly suggests the rule is motivated by animus.

Numerous sources indicate that the proposed rule is based in anti-transgender ideology, including the executive order that mandated the proposed rule, the regulatory language, and the justifications that HHS officials have relied on. Cumulatively, this evidence strongly points to animus as being the primary and potentially only true motive for this rule.

The proposed rule emerged out of the president's week-one executive order on TRH, which called on HHS to take regulatory and subregulatory action "to end the chemical and surgical mutilation of children," including by changing hospital conditions of participation to fit that objective.[54] The executive order makes no effort to hide its bias. It claims, for example, that TRH represents "a stain on our Nation's history"; that "the so-called 'transition' of a child" is "destructive" and a "tragedy"; and that it driven by health providers who "are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex."[55] On its own, the development of a proposed rule out of a presidential directive or an administration's political priorities is not evidence of impropriety. But the executive order's anti-transgender prejudice is so strident, baseless, and overt that it casts doubt on the motives of policies it generates. HHS does not try to dispel those doubts in the context of this proposed rule: In fact, it explicitly credited the executive order as both the source of authority and a guiding principle for the rule and offered a full-throated endorsement of its contents.[56] HHS' reliance on the executive order thus offers an initial sign that the proposed rule is motivated by animus.

The proposed rule itself offers further indications of animus. For example, HHS has chosen to refer to TRH as "sex-rejecting procedures," an ideologically laden term that has no medical or legal basis. This term appears to have been developed by an extremist think tank with the explicit intent of persuading a broader audience to adopt its anti-transgender positions, maximizing restrictions on care, and precluding nondiscrimination arguments.[57] A recent report by the think tank urged HHS to discard the term "sex-trait modification," the language HHS had been using in previous regulations and policies targeting TRH.[58] The report argued that the term "sex-rejecting procedures" better rebuts the suggestion that TRH is legitimate care and "more effectively

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[53] *See Department of Commerce v. New York*, 588 U.S. 752, 785 (2019).
[54] Exec. Order No. 14187, § 5, 90 Fed. Reg. 8771, 8772 (Feb. 3, 2025).
[55] Exec. Order No. 14187, § 1.
[56] *See, e.g.,* Department of Health and Human Services, *Protecting Children*, at 10:23 (YouTube, Dec. 18, 2025), https://www.youtube.com/live/aY1XfN6Tt0Q?si=S9rRPs4tKv28IACL&t=3993.
[57] Eric Kniffin et al., *Terminology and Definition: Replacing "Gender-Affirming Care" with "Sex-Rejecting Procedures"* (May 9, 2025), https://eppc.org/publication/terminology-and-definition-replacing-gender-affirming-care-with-sex-rejecting-procedures; Walker Bragman, *HHS Has Been Using Anti-Trans Language From a Christian Right Think Tank*, IMPORTANT CONTEXT (Feb. 9, 2026), https://www.importantcontext.news/p/hhs-is-using-anti-trans-language.
[58] *See, e.g.,* Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 Fed. Reg. 27074, 27152 (Jun. 25, 2025).

communicates the unnatural and disruptive nature of the targeted procedures."[59] While HHS itself does not provide an explanation for its decision to change its terminology, the clearly hostile connotations of the phrase "sex-rejecting procedures," as well as the rationale expressed by its developers, further show the role that animus has likely played this proposed rule.

A third source of evidence of animus is in the justifications HHS officials have given for this proposed rule. The press event where HHS announced the rule featured a lengthy string of inflammatory falsehoods and accusations about transgender people, their care, and their providers, including the following examples:

- HHS Secretary Robert F. Kennedy Jr. asserted that "the American Medical Association and the American Academy of Pediatrics peddled a lie…that sex can be changed."[60] He alleged that they maliciously conspired to spread this lie in the service of "big money interests,"[61] like hospitals who "rake in millions of dollars by convincing boys and girls" that access to TRH is "the only way to achieve true happiness and belonging in life."[62]
- Administrator Oz similarly referred to TRH providers as "charlatans"[63] who have engaged in "predatory actions"[64] and "shameful[ly]…profiteered" off of "a pathology that has afflicted the medical profession."[65]
- Demonstrating disdain for both transgender youth and providers who support them, Administrator Oz added that a medical professional supporting a transgender young person has turned them into "an opportunity" and "a victim"[66] by exploiting a "decision they might have wandered into mistakenly in a whimsical moment."[67]
- In reference to other actions announced at the press event, HHS officials variously referred to the provision of TRH as "barbaric,"[68] an attempt to "blackmail" parents,[69] and a "sorry episode that will go down in medical history of how the power of enthrallment to a false science can damage and harm lives."[70] One official maligned transgender people generally, claiming that recognizing their existence represents "a denial of fundamental truths" that "can destroy natures from within," that is it "at the root of the evils we face," and that it demonstrates "a hatred for nature as God designed it and for life as it was meant to be lived."[71]

These statements, coming from the highest ranks of the agency, were explicitly offered as justifications for the anti-transgender actions announced in the press event, including this proposed rule. As such, they provide direct insight into the motives behind the rule. Together, those

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[59] Kniffin et al., *supra* note 57.
[60] Department of Health and Human Services, *Protecting Children*, at 2:23 (YouTube, Dec. 18, 2025), https://www.youtube.com/live/aY1XfN6Tt0Q?si=S9rRPs4tKv28IACL&t=3993.
[61] *Id*. at 7:44.
[62] *Id*. at 8:17.
[63] *Id*. at 11:37.
[64] *Id*. at 11:13.
[65] *Id*. at 16:50.
[66] *Id*. at 13:20.
[67] *Id*. at 14:21.
[68] *Id*. at 18:39.
[69] *Id*. at 33:01.
[70] *Id*. at 36:15.
[71] *Id*. at 37:06.

statements, the language of the proposed rule, and the executive order that spawned it all strongly indicate that the rule is based in anti-transgender animus.

b. A rule whose rationales are pretextual cannot survive under the APA.

The APA does not permit rulemaking where the justifications offered in the proposed rule are pretextual. A recent case before the Supreme Court involved rulemaking with facts similar to this proposed rule: Several indications suggested that an agency predetermined the desired outcome of its rule before it reviewed the evidence and that the rationale its proposed rule relied on was merely a cover for an unstated motive. The Supreme Court rejected the rule as arbitrary and capricious under the APA, pointing to "a significant mismatch between the decision the Secretary made and the rationale he provided."[72] The justification in the rule appeared "contrived"[73] and "more of a distraction" than a reasoned explanation for agency action.[74]

This proposed rule seems to demonstrate a similar "disconnect between the decision made and the explanation given."[75] The rationales offered in the proposed rule all stem from CMS' assertion that TRH is neither safe nor effective. But this groundless assertion does not appear to be based on CMS' genuine assessment of the data, but rather on an attempt to distort the evidence to fit a forgone conclusion. As detailed in Section IV of this comment, the proposed rule's counterfactual claims about TRH seem to be driven not by evidence but by anti-transgender ideology, undercutting CMS' assertion that the proposed rule emerged out of its scientific analysis. Together with the indications of prejudice presented above, the evidence strongly suggests that the reasons outlined in the preamble are *post hoc* rationalizations for an animus-based restriction—a flaw that would render the rule arbitrary and capricious.

IV. CMS relies on a gross misrepresentation of the evidence supporting TRH.

The central justification that CMS provides for the proposed rule is its belief that TRH is dangerous and unsupported by medical evidence. This belief is not grounded in data: As demonstrated in Section I of this comment, the widely accepted evidence demonstrates that TRH is safe, effective, and necessary for the health and wellbeing of many transgender youth. Rather, CMS' rationale is based on skewed data, disinformation, and ideologically driven preconceptions.

In the absence of peer-reviewed data to support its position, CMS relies primarily on HHS' own review of the evidence.[76] Yet medical and scientific experts have widely criticized the HHS report for both its misrepresentation of the evidence and its scientifically unsound process.[77] HHS' report is selective and biased: the review elevates contested, flawed, and discredited studies while dismissing the robust body of research contradicting its claims. Instead of grappling with studies

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[72] *Department of Commerce v. New York*, 588 U.S. 752, 783 (2019).
[73] *Id*. at 784.
[74] *Id*. at 785.
[75] *See id*. at 785.
[76] Department of Health and Human Services, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (Nov. 19, 2025), https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf (hereinafter HHS Review).
[77] *See, e.g.,* Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 JOURNAL OF ADOLESCENT HEALTH 342 (Sep. 2025), https://doi.org/10.1016/j.jadohealth.2025.06.002; G. Nic Rider et al., *Scientific Integrity and Pediatric Gender Healthcare: Disputing the HHS Review*, SEXUALITY RESEARCH AND SOCIAL POLICY (Oct. 13, 2025), https://doi.org/10.1007/s13178-025-01221-5.

that show the safety and effectiveness of TRH for youth, the review falls back on misleading assertions that the research is low quality and unreliable or even resorts to ad hominem attacks against medical associations and experts. With so few studies supporting its claim, HHS draws heavily on non-scientific and anecdotal sources in its report, with lay press articles, blogs, or social media posts constituting more than 20% of its references.[78] HHS' rushed, shoddy review stands in sharp contrast to the widely accepted World Professional Association for Transgender Health (WPATH) standards of care: Maintained since 1972, the WPATH standards of care, now in their eighth edition, relied on more than 70 systematic reviews, consensus recommendations from more than 100 experts in transgender health, and nearly a decade's worth of development.[79]

HHS' report recommends that these widely endorsed clinical standards be replaced with treatment restricted to psychotherapy alone. This position forms the core of the proposed rule: CMS draws directly on the report's recommendation and attempts to turn it into a bar on the provision of other forms of care. The methodological flaws underlying this psychotherapy-only stance are therefore pertinent to assessing the basis of this proposed rule.

HHS asserts that there is no evidence of harm resulting from a psychotherapy-only approach. The few studies it cites for this claim, however, do not provide evidence that this approach is harmless, nor did they attempt to.[80] While HHS recognizes elsewhere in the report that "the absence of evidence of harms in published studies is not equivalent to evidence of absence of harms,"[81] it raises this point solely to discredit systematic reviews of TRH. Even more broadly, HHS itself concedes that there is "no evidence on the effect of psychotherapy" on gender dysphoria when provided in isolation.[82] But instead of shaping its recommendation according to the data, the report redirects to an unsubstantiated claim that this "dearth of evidence"[83] results from widespread bias in the scientific and medical community.[84]

In particular, the report hypothesizes that researchers have refused to study psychotherapy-only approaches because they conflate it with conversion therapy. Decades of research reveals the dangers of conversion therapy, linking it with higher rates of post-traumatic stress disorder, depression, and suicidality, as well as with isolation from community, damaged family relationships, and higher rates of poverty throughout adulthood.[85] HHS disregards the well-

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[78] Dowshen et al., *supra* note 77.
[79] *Id*.
[80] HHS relies on a handful of studies on psychosocial interventions (such as social transition and counseling) and claims that "no harms were reported" as a result of psychotherapy. HHS Review, *supra* note 76 at 93. However, none of those studies evaluated the outcomes of restricting TRH to psychotherapy alone. Even disregarding the fact that some examined therapy in combination with social transition (such as name changes, changes to legal gender markers, and access to activities and settings like sports and restrooms), their assessment was related to the impact of psychotherapy access—which is not synonymous with the impact of permitting only psychotherapy and barring access to other care. Therefore, these studies provide no relevant evidence for HHS' recommendation. *See* Alex R. Dopp et al., *Interventions for Gender Dysphoria and Related Health Problems in Transgender and Gender-Expansive Youth* 20 (Nov. 26, 2024), https://www.rand.org/pubs/research_reports/RRA3223-1.html.
[81] HHS Review, *supra* note 76 at 101.
[82] *Id*. at 94.
[83] *Id*. at 260.
[84] *Id*. at 262–263.
[85] *See, e.g.,* Nguyen K. Tran et al., *Conversion Practice Recall and Mental Health Symptoms in Sexual and Gender Minority Adults in the USA: A Cross-Sectional Study*, 11 LANCET 879 (Nov. 2024), https://doi.org/10.1016/S2215-0366(24)00251-7; Amy Przeworski et al., *A Systematic Review of the Efficacy, Harmful Effects, and Ethical Issues*

documented harm of conversion therapy, and in fact it tries to recharacterize it as a favorable effort to "help children and adolescents come to terms with their bodies"[86] for the purpose of "the resolution of GD."[87] HHS persists in recommending that TRH for youth should be limited to psychotherapy alone, in spite of its own suggestion that this practice overlaps with conversion therapy and its own acknowledgement that no evidence supports its preferred policy. In doing so, HHS further demonstrates that its psychotherapy-only position is based on ideology rather than fact and thus cannot serve as a factual basis for CMS' rulemaking. Indeed, the proposed rule's reliance on the report may indicate that the regulatory carveout for mental health counseling is itself motivated in part by a desire to promote conversion therapy.

The origins of the report further demonstrate that its conclusion was predetermined and politically motivated rather than a result of neutral scientific inquiry. The HHS report was developed in response to a direct mandate from Executive Order 14187.[88] That executive order was unambiguous about the purpose of the HHS report: to reveal "the blatant harm done to children by chemical and surgical mutilation" and "end[] reliance on junk science," specifically in opposition to the WPATH standards.[89] This report was commissioned in service of executive order's overall objective of ending any federal support for TRH and ultimately eradicating TRH entirely.[90] Indeed, the executive order made clear that the report would discredit the very legitimacy of transgender people's experiences.[91] The HHS report delivered on this mandate, skewing data and relying on discredited theories to fit the conclusion it was trying to reach, disparaging medical experts who disagreed with its claims, and denigrating transgender youth and their loved ones.

CMS' reliance on this fatally flawed review casts serious doubts about the validity of its core justifications for the proposed rule. Indeed, echoing the unsound methods of the HHS report, CMS dismisses the large body of research contradicting the assumptions underlying its proposed rule, relies on irrelevant or methodologically weak studies to support its views, and misrepresents both the nature of TRH and the experiences of the transgender community as a whole.

V. The proposed rule exceeds limits on CMS' authority to regulate conditions of participation.

CMS seeks to adopt the proposed rule under its general authority to regulate the conditions hospitals must meet to participate in Medicaid and Medicare, relying on § 1861(e)(9) of the Social Security Act. As part of a subsection that enumerates a range of conditions of participation for hospitals, § 1861(e)(9) provides that these conditions include "such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution."[92]

While this provision offers CMS significant discretion, that discretion is not unfettered. It is hornbook law that even when a statute grants an agency broad rulemaking authority, "an agency

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Related to Sexual Orientation Change Efforts, 28 CLINICAL PSYCHOLOGY: SCIENCE AND PRACTICE 81 (2021), https://doi.org/10.1111/cpsp.12377.

[86] HHS Review, *supra* note 76 at 262.

[87] *Id*. at 93.

[88] Exec. Order No. 14187, § 3(ii).

[89] *Id*. at § 3.

[90] *Id*. at § 1.

[91] *Id*. at § 3(ii).

[92] 42 U.S.C 1395x(e)(9).

must cogently explain why it has exercised its discretion in a given manner."[93] A statute granting agency flexibility in rulemaking expands the considerations an agency can rely on, but it does not insulate the agency from their obligation to provide a reasoned justification. CMS fails to meet this requirement: As detailed throughout this comment, CMS' rationale for the proposed rule is contrary to the evidence and potentially pretextual and it disregards the impact of its rule on numerous stakeholders.

Another constraint on CMS' rulemaking powers lies in the statute itself. The Supreme Court has clarified that even when a statute uses open-ended terms to permit agency action, the agency must exercise its authority in accordance with other provisions in the statute.[94] Language allowing for agency discretion "is not a roving license to ignore the statutory text" but rather "a direction to exercise discretion within defined statutory limits."[95]

The scope of CMS' authority under § 1861(e)(9) must therefore be understood in the context of § 1861(e) as a whole. This section lists specific conditions for hospitals, such as ensuring patients are under the care of a physician, providing 24-hour nursing services, implementing discharge processes individualized to patients' health needs, and complying with licensing requirements.[96] When considered together, the enumerated conditions show the crux of this provision: establishing operational requirements that protect patients' rights and welfare. They regulate *how* services can be performed; they do not address which services can be provided. The same is true for conditions of participation applying to non-hospital health care entities under § 1861 more broadly. The provision allowing CMS to adopt "such other requirements" for participating hospitals is not a blank check for the agency to impose any condition it desires, but rather a directive to further effectuate the essence and purpose of § 1861(e).

The existing regulations promulgated under § 1861(e)(9) generally fall within these bounds. Like the statutory conditions of participation, the regulations focus on the manner in which care is provided, primarily operational and administrative requirements that protect patients and the quality of their care. For example, the rules set standards for patient rights, privacy, emergency preparedness, compliance with federal and state laws, and transparent and effective governance.[97] The rule that CMS now proposes deviates sharply from this long-standing practice. Rather than regulating operations and procedures to ensure quality health services, CMS seeks to appropriate the conditions of participation to prohibit a specific form of medically necessary care. Doing so would be unprecedented: There are no previous examples of CMS using these standards to bar licensed providers from administering best practice care for a discrete minority. The proposed rule is not only inconsistent with the conditions of participation in the statue and existing regulations; it actively undermines the purpose of the conditions of participation, making it more difficult for patients to receive quality care rather than protecting their access to it.

VI. The rule exceeds limits on CMS' authority to regulate the practice of medicine.

Section 1801 of the Social Security Act provides that federal officials and agencies may not "exercise any supervision or control over the practice of medicine or the manner in which medical

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[93] *Motor Vehicle Manufacturers Associations of the United States v. State Farm Automobile Insurance Company*,
[94] *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497, 533 (2007).
[95] *Id*.
[96] 42 U.S.C. § 1395x(e).
[97] *See generally* 42 C.F.R. pt. 482.

services are provided."[98] The proposed rule violates this express prohibition on federal interference: By limiting the medical care that hospitals participating in Medicaid and Medicare can provide, it is regulating the manner in which services are provided.

CMS does not dispute that barring hospitals from providing certain forms of medical care as a condition of participation would constitute interference in the practice of medicine. Rather, it asserts that the proposed rule does not violate the prohibition on federal interference because TRH "is not healthcare and hence…not subsumed under the term of 'the practice of medicine.'"[99] The evidence that CMS offers for this claim is circular and self-contradictory. The proposed rule repeatedly and explicitly describes TRH as medical intervention. Even its own misleading portrayal of how the care is provided bears all the standard hallmarks of medical care. CMS argues that the "risk/benefit profile" of TRH precludes it from being considered medical care.[100] But the potential risks or side effects of treatments do not determine whether they are considered medical care. Even if CMS' characterization of the impacts of TRH were not so fundamentally flawed, the risks or benefits of TRH do not provide a basis for CMS' claim that it is excluded from "the practice of medicine."

VII. Conclusion

CMS' proposed rule would jeopardize the health of transgender youth and impose unwarranted hardships on their families; it appears to rely on pretextual rationales to disguise anti-transgender animus; it rejects and misrepresents the large body of scientific and medical evidence regarding their care; and it exceeds its statutory authority. Rather than a reflection of law, science, or ethics, this rule represents a baseless and dangerous attempt to restrict access to care, in furtherance of an anti-transgender ideology that cannot form a valid basis for rulemaking. The proposed rule must be withdrawn.

We request that the supporting documentation we have made available through direct links in our citations be considered as part of the formal administrative record for purposes of the Administrative Procedure Act. If CMS does not intend to consider these materials part of the record as requested, we ask that you notify us and provide us with an opportunity to submit copies of the studies and articles into the record.

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[98] 42 U.S.C. § 1395.
[99] Proposed Rule, 90 Fed. Reg. at 39471.
[100] *Id*.