February 17, 2026

Via Electronic Submission (via Regulations.gov)

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2451-P
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments in Response to Request for Public Comment Regarding "Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children," Docket No. CMS-2451-P

Dear Administrator Oz:

The American Civil Liberties Union Foundation (ACLU) and Lambda Legal Defense & Education Fund, Inc. (Lambda Legal) submit these comments in response to the Centers for Medicare & Medicaid Services (CMS) proposed rule titled "Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children," Docket No. CMS-2451-P (hereinafter the Proposed Rule).

For more than 100 years, the ACLU has been our nation's guardian of liberty, working in courts, legislatures, and communities to defend and preserve the individual rights and liberties that the Constitution and laws of the United States guarantee to everyone in this country. With more than six million members, activists, and supporters, the ACLU is a nationwide, non-partisan public-interest organization that works across all 50 states, Puerto Rico, and Washington, D.C. to advance the principle that every individual's rights must be protected equally under the law, regardless of race, religion, gender, sexual orientation, gender identity or expression, disability, national origin, citizenship status, or record of arrest or conviction.

Founded in 1973, Lambda Legal is the oldest and largest national legal organization dedicated to achieving full recognition of the civil rights of lesbian, gay, bisexual, transgender, and queer (LGBTQ) people and everyone living with HIV through impact litigation, education, and policy advocacy. Lambda Legal has served as counsel of record or *amicus* in seminal cases regarding the rights of LGBTQ people and people living with HIV. Since its founding, Lambda Legal has sought to eliminate discriminatory barriers to health care for LGBTQ people.

The matters addressed in the Proposed Rule are of great concern to the ACLU and Lambda Legal because of our commitment to and long history of ensuring access to safe, effective medical care for transgender youth. For the following reasons, the ACLU and Lambda Legal respectfully submit that this attempt by CMS to restrict the provision of medically necessary gender-affirming medical care is unlawful on multiple grounds.

INTRODUCTION

The Proposed Rule seeks to withhold federal funding for necessary medical care for transgender adolescents who seek such care to treat their gender dysphoria. It would add new sections to the regulations for Medicaid and CHIP that would classify essential gender-affirming medical care services as "sex-rejecting procedures" and prohibit federal payment for these services for adolescents under the age of 18 in Medicaid and under the age of 19 in CHIP. If this proposal is finalized, many adolescents and young adults, including those in foster care and in low-income families, would be denied services their physicians prescribe in accordance with established professional guidelines.

The Proposed Rule is not grounded in neutral scientific analysis; it is driven by animus towards transgender individuals. It misrepresents the existing evidence showing that gender-affirming medical care is safe and effective for treating gender dysphoria, ignores widespread medical consensus supporting such care, and purports to solve a problem that does not exist. It is unlawful several times over.

First, the Proposed Rule exceeds CMS's authority under the Medicaid statute. Congress has not authorized CMS to determine what medical care is necessary or in the best interests of Medicaid and CHIP-eligible patients. Nor does the Constitution or any relevant federal statute give CMS discretion to impose sweeping new prohibitions on federal funds that Congress has authorized to be spent.

Second, and related, CMS's attempt to condition federal funds amounts to an unconstitutional infringement upon Congress's power of the purse in violation of the separation of powers.

Third, the Proposed Rule is inconsistent with the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) mandatory benefit, which provides children, adolescents, and young adults under 21 with comprehensive services under the Medicaid program. For many transgender adolescents, gender-affirming medical care is essential. As CMS has long recognized, decisions about when and how to treat a patient's medical needs require an individualized inquiry. CMS's proposed *categorical* prohibition on gender-affirming medical care is accordingly unlawful.

Fourth, the Proposed Rule violates the Medicaid Act's comparability requirement by discriminating on the basis of medical diagnosis. It would prohibit federal financial participation (FFP) for services needed to treat an adolescent's gender dysphoria while continuing to provide FFP for the same services provided for different purposes. The Medicaid Act prohibits such discrimination among those with equivalent medical needs.

Fifth, the Proposed Rule discriminates on the basis of sex and transgender status, in violation of Section 1557 of the Affordable Care Act (ACA) and the Equal Protection component of the Fifth Amendment. The Proposed Rule singles out gender-affirming medical care provided to transgender adolescents who seek care because they are transgender. "[D]iscrimination based on . . . transgender status necessarily entails discrimination based on sex."[1] Such discrimination is prohibited by Section 1557. Moreover, the Proposed Rule bears the hallmarks of animus against

[1] *Bostock v. Clayton County*, 590 U.S. 644, 669 (2020).

transgender individuals, a motive that cannot survive even rational-basis review under the Constitution's equal protection guarantee.

Finally, the Proposed Rule is arbitrary and capricious. CMS proposes to depart from its prior policy protecting gender-affirming medical care without adequately explaining the basis for its decision. Moreover, the Proposed Rule relies extensively on the flawed review by the U.S. Department of Health and Human Services (HHS) titled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" (the HHS Review). The HHS Review violates the Federal Advisory Committee Act (FACA), cherry-picks evidence favorable to its preordained conclusion, and fundamentally misunderstands and misrepresents the body of literature supporting gender-affirming medical care as a safe and effective treatment for gender dysphoria. Further, CMS failed to consider the reliance interests of patients, healthcare providers, and other stakeholders, as well as the societal costs of excluding hospitals from the Medicare and Medicaid programs. For all these reasons, CMS should withdraw the Proposed Rule and refrain from any further actions to prevent transgender adolescents from obtaining the medical care they depend on.

BACKGROUND

Gender identity is a person's internal sense of belonging to a particular sex, such as male or female.[2] Although most people are cisgender, meaning their gender identity matches their birth-assigned sex, transgender people have a gender identity that differs from their birth-assigned sex.[3] Being transgender is a natural variation of human development with a biological basis.[4]

A. Gender-Affirming Medical Care For Youth With Gender Dysphoria Is Evidence-Based, Safe, And Effective At Treating Gender Dysphoria.

Transgender people may experience gender dysphoria, a medical condition marked by clinically significant distress arising from any dissonance or "incongruence" between a person's gender identity and their birth-assigned sex.[5] The American Psychiatric Association codifies gender dysphoria as a diagnosis in the *Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revision* (DSM-5-TR).[6] To be diagnosed with gender dysphoria, this incongruence must have persisted for at least six months prior to the diagnosis and be accompanied by clinically significant distress or impairment in social, occupational, or other important areas of functioning.[7] Similarly, "gender incongruence" is codified as a diagnosis in the *International Classification of Diseases, 11th Version*, a globally used clinical diagnosis classification system:[8]

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[2] American Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 Am. Psychologist 832, 834 (2015).

[3] *Id.* at 832–833.

[4] *See* Natalia S. Fernández, et al., *Is There a Biological Component in Gender Identity?*, Anales de Pediatría 103(1), 503883 (2025).

[5] *See* American Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 511 (5th ed. 2022).

[6] *Id.*

[7] *Id.* at 512.

[8] World Health Org., *Gender Incongruence*, International Classification of Diseases (11th rev. 2018).

> Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual's experienced gender and the assigned sex, which often leads to a desire to "transition," in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender.[9]

Gender dysphoria is a serious medical condition that, if left untreated, can result in debilitating anxiety, severe depression, self-harm, and suicidality.[10] Doctors and other healthcare professionals may provide medical treatment for gender dysphoria to reduce or even eliminate clinically significant distress by helping a transgender person live in alignment with their gender identity.[11] This treatment is often referred to as "gender-affirming medical care."

As a Consensus Study Report by the National Academies of Science, Engineering, and Medicine states, physicians who provide gender-affirming medical care "are informed by expert evidence-based guidelines" that are based on "the best available data" and "intended to be flexible and holistic in application to individual people."[12] For example, the World Professional Association for Transgender Health (WPATH) and the Endocrine Society have published widely accepted guidelines for treating gender dysphoria.[13] The guidelines were developed using a transparent, rigorous, and methodologically sound process that included systematic reviews of evidence by leading healthcare professionals.[14] Each recommendation underwent extensive review and debate among members.[15] And WPATH's recommendations for adolescents comprehensively address the evidence-based benefits and risks of each recommendation to ensure that treating physicians can reliably weigh treatment options for their patients. These guidelines represent the consensus approach among healthcare professionals: Indeed, a "number of professional medical organizations have joined WPATH in recognizing that gender-affirming medical care is medically necessary for

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[9] *Id.*

[10] *See* Brayden N. Kameg & Donna G. Nativio, *Gender Dysphoria in Youth: An Overview for Primary Care Providers*, 30 J. Am. Ass'n Nurse Practitioners 493, 493 (2018) ("Because those with untreated gender dysphoria are at risk of a variety of negative outcomes, including mood symptomatology, suicidality, substance use disorders, and other psychosocial risk factors, it is critical that health care providers are adept in the provision of holistic, patient-centered care.").

[11] *Gender Incongruence*, *supra* n.8.

[12] National Acad. Sciences, Eng'g & Med., *Understanding the Well-Being of LGBTQI+ Populations* 361 (Patterson, Sepúlveda & White eds., 2020).

[13] Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 Int'l J. Transgender Health S1 (2022) (hereinafter WPATH SOC8); Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clinical Endocrinology & Metabolism 3869 (2017); *see also* UCSF Gender Affirming Health Program, *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* (Deutsch ed., 2d ed. 2016), https://transcare.ucsf.edu/guidelines (revision forthcoming).

[14] Brief for Clinical Practice Guideline Experts as Amici Curiae Supporting Petitioners at 6, *Skrmetti v. L.W.* (No. 23-477) (2024); *see also id.* at 8–14 (describing methodology for developing SOC8).

[15] *See id.* at 11–14.

transgender people because it reduces distress and promotes wellbeing, while withholding care increases distress and decreases wellbeing."[16]

Treating gender dysphoria for any individual depends on that person's specific needs, and the medical treatment guidelines differ based on whether the patient is an adolescent or an adult.[17] No medical treatment is recommended or necessary prior to the onset of puberty.[18] Additionally, and particularly as it pertains to adolescents, mental health counseling is an essential first step for treating gender dysphoria. All decisions about necessary medical or surgical intervention should be guided by a comprehensive biopsychosocial assessment by a qualified mental health professional.[19] Options for treatment after the onset of puberty include the use of gonadotropin-releasing hormone agonists (also known as GnRHa, puberty blockers, or puberty-delaying medications) to prevent progression of pubertal development; hormonal interventions such as testosterone and estrogen administration; and, on rare occasion, gender-affirming chest surgery for older adolescents.[20]

These treatment options are safe, effective, and supported by robust evidence. More than a dozen studies have evaluated the efficacy and effectiveness of GnRH agonists, hormone therapy, and gender-affirming surgery to treat adolescents with gender dysphoria.[21] Further longitudinal studies

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[16] National Acad. Sciences, Eng'g & Med., *supra* n.12, at 361 (noting acceptance by the American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse Midwives, American College of Obstetricians and Gynecologists, AMA, American Psychiatric Association, American Psychological Association, and the Endocrine Society).

[17] WPATH SOC8, *supra* n.13, at S6, S9.

[18] *Id.* at S111.

[19] *Id.* at S50–S51.

[20] *Id.* at S49; *see also id.* at S256 (Appendix D: Summary Criteria for Hormonal and Surgical Treatments for Adults and Adolescents).

[21] Regarding puberty-delaying medications, *see generally* Annelou L.C. de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. Sexual Med. 2276 (2011); Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12 J. Sexual Med. 2206 (2015); Jack L. Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145 Pediatrics e20191725 (2020); Anna I.R. van der Miesen et al., *Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers*, 66 J. Adolescent Health 699 (2020); Christal Achille et al., *Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results*, 8 Int'l J. Pediatric Endocrinology 1 (2020); Kerry McGregor et al., *Association of Pubertal Blockade at Tanner 2/3 with Psychosocial Benefits in Transgender and Gender Diverse Youth at Hormone Readiness Assessment*, 74 J. Adolescent Health 801 (2024).

Regarding hormone therapy, *see generally* Johanna Olson-Kennedy, et al., *Emotional Health of Transgender Youth 24 Months After Initiating Gender-Affirming Hormone Therapy*, 77 J. Adolescent Health 41 (2025); Luke R. Allen, et al. *Changes in Suicidality among Transgender Adolescents Following Hormone Therapy: An Extended Study*, 289 J. Pediatrics 114883 (2025); Priya Chelliah et al., *Changes in Gender Dysphoria, Interpersonal Minority Stress, and Mental Health Among Transgender Youth After One Year of Hormone Therapy*, 74 J. Adolescent Health 1106 (2024); Diane Chen et al., *Psychosocial Functioning in Transgender Youth After 2 Years of Hormones*, 388 N. Eng. J. Med. 240 (2023); Jack L. Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, 17 PLOS One e0287283 (2022); Inga Becker-Hebly et al., *Psychosocial Health in Adolescents and Young Adults with Gender Dysphoria Before and After Gender-Affirming Medical Interventions: A Descriptive Study from the Hamburg Gender Identity Service*, 30 Eur. Child & Adolescent Psychiatry 1755 (2020);

have examined mental health before and after interventions and found that patients' mental health improved after these treatments.[22] Controlled cross-sectional studies have also compared those who access treatment to those who desired, but did not access, treatment and found that those who accessed treatment had better mental health outcomes.[23] And decades of clinical experience from experts across the world also support the conclusion that gender-affirming medical treatments for adolescents with gender dysphoria are effective in treating gender dysphoria and are consistently linked to improved mental health.[24]

The types of observational studies that support gender-affirming medical care for adolescents are well-accepted in medical research and often relied upon when making treatment recommendations or creating clinical practice guidelines.[25] Reliance on observational studies or, if such studies are not available, expert consensus is the norm in pediatrics: 90% of the recommendations contained in the American Academy of Pediatrics' fourteen clinical practice guidelines are based on evidence other than randomized controlled trials (RCTs).[26]

Many medical organizations have also examined the science behind gender-affirming medical care and determined it is both medically necessary for treating gender dysphoria and clinically effective at doing so, including the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, and the Endocrine Society, among others.[27] And prior to the current administration, HHS followed the findings of

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Connor Grannis et al., *Testosterone Treatment, Internalizing Symptoms, and Body Image Dissatisfaction in Transgender Boys*, 132 Psychoneuroendocrinology 105358 (2021); Laura E. Kuper et al., *Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy*, 145 Pediatrics e20193006 (2020); Achille et al., *supra*; Diego López de Lara et al., *Psychosocial Assessment in Transgender Adolescents*, 93 Anales Pediatría (Eng. Edition) 41 (2020); Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7 Clinical Prac. Pediatric Psych. 302 (2019).

Regarding gender-affirming surgery, *see generally* Elizabeth R. Boskey et al., *Prospective Evaluation of Psychosocial Changes After Chest Reconstruction in Transmasculine and Non-Binary Youth*, 73 J. Adolescent Health 503 (2023); Ascha Mona et al., *Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults*, 176 JAMA Pediatrics 1115 (2022); Annie Tang et al., *Gender-Affirming Mastectomy Trends and Surgical Outcomes in Adolescents*, 88 Annals Plastic Surgery S325 (2022); Johanna Olson-Kennedy, et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431 (2018).

[22] *See, e.g.*, Chen et al., *supra* n.21; Thomas D. Steensma et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696 (2014).

[23] *See, e.g.*, van der Miesen et al., *supra* n.21; Turban et al., *supra* n.21.

[24] *See* Terri A. Croteau et al., *Psychological and Physical Health Outcomes Associated with Gender-Affirming Medical Care for Transgender and Gender-Diverse Youth: A Critical Review*, 13 Healthcare 1659 (2025).

[25] *See, e.g.*, Andrea Gershon et al., *Informing Healthcare Decisions with Observational Research Assessing Causal Effect: An Official American Thoracic Society Research Statement*, 203 Am. J. Respiratory & Critical Care Med. 14, 15 (2021) (defining the central role of observational study in medicine).

[26] *See* Armand H. Antommaria et al., *Quality of Evidence and Strength of Recommendations in American Academy of Pediatrics' Guidelines*, 155 Pediatrics e2024067836 (2025).

[27] *See, e.g.*, American Acad. Child & Adolescent Psychiatry, *Statement Responding to Efforts to Ban Evidence-Based Care for Transgender and Gender Diverse Youth* (2019), https://www.aacap.org/AACAP/Latest_News/AACAP_Statement_Responding_to_Efforts-to_ban_Evidence-Based_Care_for_Transgender_and_Gender_Diverse.aspx; American Acad. Family Physicians, *Care for the*

these many expert organizations.[28] As we discuss in section VII, below, CMS's proposed policy is based on an inaccurate and deeply flawed characterization of the medical evidence and an equally flawed evidentiary review.

B. The Proposed Rule Is Not Based On Scientific Or Medical Evidence.

Despite the scientific and medical consensus supporting gender-affirming medical care, the Trump Administration has sought to eliminate medically necessary gender-affirming medical care as part of a campaign against transgender people. The Proposed Rule is the latest addition to a "constellation of close-in-time executive actions directed at transgender Americans that contain[ ] powerfully demeaning language,"[29] demonstrating the Administration's overt animus towards transgender individuals.

On the first day of President Trump's second term in office, he issued Executive Order 14168, titled "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" (the Gender Identity Order), to reverse existing protections for transgender individuals across the federal government and deny recognition of their existence.[30] Among other things, the Gender Identity Order disclaimed that a person might have a gender identity different

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Transgender and Nonbinary Patient (2020), www.aafp.org/about/policies/all/transgender-nonbinary.html; American Acad. Pediatrics, *Policy Statement Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents* (2018), https://publications.aap.org/pediatrics/article-pdf/142/4/e20182162/1529435/peds_20182162.pdf; American Coll. Obstetricians & Gynecologists, *Committee Opinion No. 823: Health Care for Transgender and Gender Diverse Individuals* (2021), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals (2024); American Med. Ass'n & GLMA, *Issue Brief: Health Insurance Coverage for Gender-Affirming of Transgender Patients* (2019), https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf; American Psychiatric Ass'n, *Position Statement on Access to Care for Transgender and Gender Diverse Individuals* (2018), https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-2018-Access-to-Care-for-Transgender-and-Gender-Diverse-Individuals.pdf; American Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 Am. Psych. 832 (2015); Hembree et al., *supra* n.13; Pediatric Endocrine Soc'y, *Pediatric Endocrine Society Opposes Bills That Harm Transgender Youth* (2021), https://www.pedsendo.org/news-announcements/the-pediatric-endocrine-society-opposes-bills-that-harm-transgender-youth-2; Pediatric Endocrine Soc'y, *Position Statement: Transgender Health* (2020), https://www.endocrine.org/-/media/a65106b6ae7f4d2394a1ebeba458591d.ashx; World Med. Ass'n, *WMA Statement on Transgender People* (2017), https://www.wma.net/policies-post/wma-statement-on-transgender-people; WPATH, *Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.* (2016), https://www.wpath.org/newsroom/medical-necessity-statement; *see also* Myles N. LaValley et al., *Making a Statement: Positions of Professional Medical Organizations Towards Gender-Affirming Care*, 2024 Annals Surgery 10.1097/SLA.0000000000006342; Lambda Legal, *Professional Organization Statements Supporting Transgender People in Health Care* (Sept. 18, 2018), https://www.lambdalegal.org/sites/default/files/publications/downloads/resource_trans-professional-statements_09-18-2018.pdf; Advocates For Trans Equality, *Medical Organization Statements*, https://transhealthproject.org/resources/medical-organization-statements (last visited Feb. 17, 2026).

[28] Office of Population Affs., *Gender-Affirming Care and Young People*, HHS (Mar. 2022), https://www.opa.hhs.gov/sites/default/files/2022-03/gender-affirming-care-young-people-march-2022.pdf.

[29] *Orr v. Trump*, 778 F. Supp. 3d 394, 417 (D. Mass. 2025).

[30] Exec. Order 14,168, *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8,615 (Jan. 20, 2025) (the Gender Identity Order).

from their birth-assigned sex, which the Order describes as a "false claim"[31]; mandated all agencies to interpret sex-based terms—including in government-issued identification documents and personnel records—as birth-assigned sex[32]; rescinded protections for LGBTQ+ people in the military and forbade transgender persons from serving in the military[33]; barred federal funding from being "used to promote gender ideology"[34]; and directed federal agencies to rescind guidance, forms, and policies acknowledging the existence of transgender people.[35]

A few days later, Executive Order 14187, entitled "Protecting Children from Chemical and Surgical Mutilation" (the Denial-of-Care Order), declared it the "policy of the United States" not to "support the so-called 'transition' of a child from one sex to another."[36] It disparaged gender-affirming medical care as "destructive" and "maiming,"[37] called being transgender a "radical and false claim,"[38] and dismissed the breadth of medical support for gender-affirming medical care as "junk science."[39] Section 3 of the Denial-of-Care Order instructed HHS to "publish a review of the existing literature" on gender-affirming medical care for minors with gender dysphoria, while Section 5(a) directed HHS to ''take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and subregulatory actions, which may involve . . . Medicare or Medicaid conditions of participation or conditions for coverage.''[40]

HHS immediately acted to implement the Administration's campaign against transgender people.[41] First, the Department hastily cobbled together a "Review of Evidence and Best Practices" to

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[31] Gender Identity Order § 2.

[32] *Id.* §§ 3(c)–(d).

[33] *Id.* § 7(b).

[34] *Id.* § 3(g).

[35] *Id.* §§ 3(e), 7(c).

[36] Exec. Order 14187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8,771 (Jan. 28, 2025) (the Denial-of-Care Order).

[37] Denial-of-Care Order § 1.

[38] *Id.*

[39] *Id.* § 3.

[40] *Id.* § 5.

[41] The National Institutes of Health (an HHS component) terminated hundreds of research grants relating to LGBTQ+ people because the research related to "transgender issues" and, according to the Administration, "research based on gender identity … do[es] nothing to enhance the health of many Americans" and "ignore[s] biological realities." *American Ass'n of Physicians for Hum. Rts., Inc. v. NIH*, 795 F. Supp. 3d 678, 688, 696–697 (D. Md. 2025). Other federal agencies have similarly implemented the Administration's campaign against transgender people. For example, the Department of Justice has targeted providers of gender-affirming medical care to transgender adolescents, including by seeking adolescent patients' medical records. These moves have been unanimously rebuffed by courts as motivated by animus toward transgender people and the gender-affirming medical care that enables transgender youth to live healthy lives. *See, e.g.*, *In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063, 2026 WL 33398, at *7 (D. Colo. Jan. 5, 2026); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069, 2025 WL 3724705, at *2 (W.D. Pa. Dec. 24, 2025); *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 237, 239 (D. Mass. 2025); *In re Subpoena No. 25-1431-014*, No. MC 25-39, 2025 WL 3252648, at *10 (E.D. Pa. Nov. 21, 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-MC-00041, 2025 WL 3562151, at *10–11 (W.D. Wash. Sept. 3, 2025).

effectuate Section 3 of the Denial-of-Care Order.[42] This HHS Review has been strongly criticized by major national medical organizations and medical experts for "misrepresent[ing] the current medical consensus and fail[ing] to reflect the realities of pediatric care.[43] These criticisms are correct: the HHS Review is a flawed, selective review of the literature regarding gender-affirming medical care. Contrary to the HHS Review's conclusions, multiple studies and systematic reviews have found gender-affirming medical care for adolescents to be evidence-based care for which there is low regret, low dissatisfaction, low side effects, and documented improvements in gender dysphoria and body satisfaction, as well as other mental health improvements.[44]

Notwithstanding the HHS Review's many flaws, HHS has relied on the Review to justify a series of actions targeting gender-affirming medical care, including the Proposed Rule. First, the agency notified healthcare providers of the Review's findings and requested detailed information about gender-affirming medical care for minors from providers.[45] Then in December 2025, HHS Secretary Kennedy went further and sought by fiat to unilaterally declare that *any* provision of gender-affirming care for minors is *per se* below the standard of care.[46] The next day, HHS published the instant Proposed Rule, as well as two others that would condition Medicaid and Medicare participation on the refusal to provide gender-affirming medical care for minors under the age of 18[47] and exclude gender dysphoria from disability-based antidiscrimination

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[42] HHS, *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).

[43] *See, e.g.*, Susan J. Kressly, *AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria*, Am. Acad. Pediatrics (May 1, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-hhs-report-treatment-for-pediatric-gender-dysphoria; *see also, e.g.*, G. Nic Rider, et al., *Scientific Integrity and Pediatric Gender Healthcare: Disputing the HHS Review*, Sexuality Rsch. and Soc. Pol'y (2025), https://doi.org/10.1007/s13178-025-01221-55 (condemning "the political motivations leading to the publication of the HHS review without consulting pediatric gender care experts and organizations" and "the review's misrepresentation of the evidence surrounding the benefits of supporting and affirming TGNB youth"); Nadia Dowshen, et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. of Adolescent Health 342–345 (2025), https://doi.org/10.1016/j.jadohealth.2025.06.002 ("The HHS report, with its extensive violations of scientific norms, misrepresentations of science, and wanton disregard of the expert standard of care for TGD youth, is a dangerous incursion of politics into science and medicine."); Phie Jacobs, *Researchers Slam HHS Report on Gender-Affirming Care for Youth*, Science (May 2, 2025), https://tinyurl.com/326md8yf.

[44] *See, e.g.*, Dopp, *infra* n.183; LaFleur *infra* n.185; Gianluca Tornese, et al., *Use Of Gonadotropin-releasing Hormone Agonists In Transgender And Gender Diverse Youth: A Systematic Review,* Front. Endocrinol. (2025).

[45] *See* HHS, *Urgent Review of Quality Standards and Gender Transition Procedures* (May 28, 2025), https://tinyurl.com/4j2bt2zd.

[46] *See* Decl. of Robert F. Kennedy, Jr., Sec'y, HHS, *Re: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents* (Dec. 18, 2025) (RFK Declaration), https://tinyurl.com/4uyrafyf. Subsequent testimony by an HHS official disclaimed that the RFK Declaration exercised any "specific statutory authority to determine that a treatment modality is not safe and effective," and that "the Declaration alone is not dispositive of 'professionally recognized standards of health care.'" Decl. of Robert M. Penezic ¶¶ 6-8, State of Oregon et al. v. Kennedy, Jr. et al., No. 6:25-cv-2409-MTK (D. Or. Filed Feb. 10, 2026) (ECF No. 75), https://tinyurl.com/3wyvemh6.

[47] *Medicare and Medicaid Programs; Hospital Conditions of Participation: Prohibiting Sex-Rejecting Procedures for Children*, 90 Fed. Reg. 59,463, 59,477 (Dec. 19, 2025).

protections.[48] CMS's Proposed Rule would adopt the Review's conclusions wholesale. The resulting Proposed Rule is contrary to the longstanding, overwhelming scientific and medical consensus supporting gender-affirming medical care.

THE PROPOSED RULE IS UNLAWFUL ON MULTIPLE GROUNDS

I. CMS Lacks Authority To Issue The Proposed Rule.

The Medicaid Act was designed to ensure that essential medical care would be available to individuals enrolled in the program. The Proposed Rule would do the opposite; it would deny medically necessary care to the very people the program was meant to support. The Proposed Rule is contrary to the Medicaid Act and cannot be supported by either the text of the law or CMS's own regulations.

A. Congress Vested The States With Authority To Determine Which Care and Services It Will Offer Under Their State Plans.

CMS is tasked with the "administration" of the Medicaid and Medicare programs while "States have traditionally exercised primary responsibility over . . . the regulation of the practice of medicine,"[49] and relatedly, the doctor-patient relationship. Accordingly, Congress created the Medicaid program as a federal-state partnership. Federal law tasks CMS with administering the funds directed to "State plans for medical assistance"[50] and, as part of the EPSDT benefit, requires State plans to cover all medically "necessary health care, diagnostic services, [and] treatment" for individuals under the age of 21.[51] In turn, Congress granted States, not CMS, authority to determine what types of care and services to cover under their plans.[52] As part of its approved plan, each State determines its own eligibility requirements, benefit coverage, provider reimbursement rates, and care delivery systems.[53]

The Medicaid statute thus reflects Congress's careful balance between the federal agency's administration of this health insurance program and the States' control over the practice of medicine, a balance reflecting the respect for States' rights under the Tenth Amendment. Courts will not assume that CMS may usurp "the historic police powers of the States" in this area "unless that was the clear and manifest purpose of Congress."[54]

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[48] *Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance*, 90 Fed. Reg. 59,478 (proposed Dec. 19, 2025) (to be codified at 45 C.F.R. pt. 84).

[49] *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025) (cleaned up).

[50] SSA § 1901.

[51] SSA § 1905(r)(5).

[52] SSA § 1902; *id.* § 1905(a)(1)–(30) (listing types of "care and services" that State plans may cover); *id.* § 1902(a)(10) (establishing services the plans "must" provide); 42 C.F.R. § 440.230.

[53] Cong. Rsch. Serv., R43357, *Medicaid: An Overview* (Apr. 30, 2025), https://www.congress.gov/crs-product/R43357.

[54] *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (citation omitted).

The Proposed Rule infringes upon the States' power to determine the scope of their own State plans within the Social Security Act's (SSA's) statutory requirements by prohibiting federal funding for gender-affirming medical care for children under age 18 enrolled in Medicaid and under age 19 enrolled in CHIP. Because CMS points to no "clear and manifest" power authorizing this action, the agency has exceeded its statutory authority.

B. Congress Has Not Granted CMS The Power To Deny Federal Medicaid Funding For Health Care Determined By States To Be Medically Necessary.

It is a foundational principle of administrative law that agencies have no power to regulate unless they are authorized to do so by statute. CMS claims to enact the Proposed Rule as part of its "oversight [authority] of Medicaid State programs for consistency with the requirements of [SSA] sections 1902(a)(19) and 1902(a)(30)(A)," as well as its authority under Sections 2101(a) and 2107(3) to oversee the "effective and efficient administration of CHIP and coordination with other health care programs."[55] None of these provisions authorize CMS to interfere with the services included in a State plan in this way. And the "idea that Congress gave [CMS] such broad and unusual authority through an implicit delegation . . . is not sustainable."[56] Far from providing clear authorization to supplant States' authority in this area, Congress has explicitly prohibited CMS from doing so.[57] Within that broad framework, Congress left decisions about appropriate medical services and procedures to the States and their providers.

First, Sections 1902(a)(19) and 1902(a)(30)(A) do not authorize the Proposed Rule. Section 1902(a) sets out various requirements for State plans. For example, Section 1902(a)(19) requires that State plans provide "safeguards . . . to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." Section 1902(a)(30)(A) also requires plans to establish "methods and procedures" to ensure payment for care and services "as may be necessary to safeguard against unnecessary utilization of such care and services," to ensure "that payments are consistent with efficiency, economy, and quality of care," and are "sufficient to enlist enough providers so that care and services are available" to the general population in the relevant geographic area.

Neither Sections 1902(a)(19) nor 1902(a)(30)(A), support the Proposed Rule. Section 1902(a)(19) directs *States* to provide "safeguards" to ensure that care and services are administratively efficient and in "the best interests of the recipients." And Section 1902(a)(30)(A) likewise requires that *State* plans must "provide such *methods and procedures*" to ensure payments are "are consistent with efficiency, economy, and quality of care." Both sections refer to "safeguards," "methods," and "procedures" that *States*—not CMS—must establish related to the provision of care and services. CMS cannot usurp the role Congress assigned to States by statute. But even if CMS shared these responsibilities (it does not), the Proposed Rule goes far beyond these requirements. Rather than overseeing the "safeguards" put in place by States to efficiently provide care, the

[55] 90 Fed. Reg. at 59,442.

[56] *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006).

[57] SSA §§ 1801, 1902(a)(23); ACA § 1554.

Proposed Rule imposes new, substantive *restrictions* on care. Authority for such conduct is found nowhere in the statutory text.

Second, Section 1102 does not provide authority for CMS's actions. That provision allows the Secretary—acting through its delegate CMS—to promulgate rules as necessary to implement Medicaid. But that delegation is limited to regulations that are "necessary to the efficient administration of the functions with which [the Secretary] is charged" and "not inconsistent" with the Medicaid Act.[58] Far from being "necessary" to the "efficient administration"" of the Medicaid program, the Proposed Rule would categorically deny coverage for critical medical services and procedures for transgender young people and make a blanket determination about what medical care is necessary for patients—a dramatic, never-before-claimed expansion of CMS's authority. Nothing in the Medicaid Act authorizes CMS to impose such restrictions.

Third, Section 2101(a), which governs State CHIP plans, cannot vest CMS with the authority it now claims. Section 2101(a) explains that, in enacting the CHIP statute, Congress intended "to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner." Section 2101 is a general statement of congressional purpose. To the extent it invites CMS to act at all, it does not authorize the agency to promulgate substantive rules redefining what medical care is considered necessary for individuals under the age of 1919.

Moreover, under CMS's new interpretation, it is difficult to see any limits to CMS's power to terminate funding for essential medical care under the guise of "efficient" administration. The same logic behind the Proposed Rule would permit CMS to ban funding for medication to treat depression, determine that c-sections should not be covered, or restrict available chemotherapy and radiation oncology treatments. And the list goes on. Again: *all* medical procedures carry risk. The body of clinical evidence is continually evolving for all medical services. Clinical standards are reviewed by expert organizations and are revised periodically. When there are disputes about the standard of care, Medicaid's policy should be to cover essential care, as identified by the patients' physicians, not to ban care based on spurious conclusions from incomplete literature.

Simply put, CMS cannot call upon these authorities to support the Proposed Rule. This is likely why, until now, CMS has never interpreted Sections 1102, 1902(a)(19), 1902(a)(30)(A), or 2101(a) to confer such power. This is a "telling indication" that the expansive regulatory authority CMS now asserts in the Proposed Rule "extends beyond the agency's legitimate reach."[59]

Nor is the Proposed Rule similar to prior CMS rulemaking. CMS would liken the Proposed Rule to the prohibition on federal Medicaid coverage for the sterilization of individuals under the age of 21, but this compares apples to oranges.[60]

At issue there was a provision of the Medicaid statute authorizing family planning services but providing that "acceptance of family planning services . . . shall be voluntary on the part of the

[58] SSA § 1102(a).

[59] *National Fed'n of Indep. Bus. v. DOL*, 595 U.S. 109, 119 (2022).

[60] 90 Fed. Reg. at 59,454 (citing *Provision of Sterilization in Federally Assisted Programs of the Public Health Service*, 43 Fed. Reg. 52,146, 52,151–53 (Nov. 8, 1978)).

individual to whom such services are offered."[61] HHS initially promulgated a series of rules funding sterilizations of minors and the legally incompetent under certain circumstances,[62] but, advocacy organizations sued, arguing that the rule was inconsistent with the statute's voluntariness requirement.[63] After a federal district court agreed, HHS revised its rulemaking to prohibit sterilization of individuals who could not voluntarily consent, including "[p]ersons under 21, mentally incompetent persons, and institutionalized persons."[64] The revised rule and its restrictions on care for individuals under 21, therefore, directly effectuated the statutory requirement that treatment be "voluntary" by prohibiting treatment of individuals who could not give the necessary consent.

Here, in contrast, the Proposed Rule does not directly effectuate any statutory mandate contained in Sections 1102, 1902(a)(19), 1902(a)(30)(A), or 2101(a). Any grant of statutory authority contained in these provisions is directed to the States, not CMS. And the provisions say nothing—either directly, indirectly, or by stretch of the imagination—about treatment for gender dysphoria or the voluntariness of that treatment. Nor does CMS claim that the treatment and age limitations effectuate a voluntariness or consent requirement more broadly. The agency explicitly bases its concerns on "the effectiveness . . . and the plausible evidence of harm" from gender-affirming medical care, however misguided these concerns are.[65]

Thus, untethered to the statutory text, the Proposed Rule is nothing more than the agency's policy preference—but "major policy decisions" about the scope and limits of federal financial expenditures on medical care fall to Congress, not CMS, to resolve.[66] And here, Congress has given no indication it would resolve this "major policy decision" in line with the Proposed Rule. When Congress intends to impose categorical restrictions on federal Medicaid funding, it does so explicitly and only in narrow circumstances. For example, since the mid-1970s, Congress has limited the conditions under which federal funds may be used to reimburse the cost of abortions under the Medicaid program through a provision contained in the annual appropriations acts and commonly referred to as the Hyde Amendment.[67] Congress remains free to include additional limitations, but each year, it has elected not to do so. Given this history, there is "reason to hesitate before concluding that Congress meant to confer [the] authority" CMS claims.[68]

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[61] SSA 1905(a)(4)(C); *see also* Public Health Services Act, § 1001(a), 42 U.S.C. 300(a) (authorizing support for "voluntary family planning projects").

[62] *Sterilization Procedures*, 38 Fed. Reg. 26,459–60 (1973); *Sterilization of Persons by Federally Assisted Family Planning Projects*, 39 Fed. Reg. 4,730–33 (Feb. 6, 1974).

[63] *Relf v. Weinberger*, 372 F. Supp. 1196, 1202–03 (D.D.C. 1974), *vacated and remanded*, on remand *Relf v. Mathews*, 403 F. Supp. 1235 (D.D.C. 1975), *vacated as moot*, 565 F.2d 722 (1977).

[64] 43 Fed. Reg. 52,147.

[65] 90 Fed. Reg. at 59,454.

[66] *West Virginia*, 597 U.S. at 723.

[67] *See Harris v. McRae*, 448 U.S. 297, 302 (1980).

[68] *Biden v. Nebraska*, 600 U.S. 477, 501 (2023) (cleaned up).

The Proposed Rule would categorically prohibit federal funding for gender-affirming medical care for children under age 18 enrolled in Medicaid and under age 19 enrolled in CHIP, including virtually every youth in foster care, who rely solely on Medicaid for their health care. The rule would effectively deny necessary medical care to hundreds of thousands of children based on CMS's—not States'—assessment of medical necessity.

Congress did not grant CMS power to make this decision or to enforce limitations the Legislature itself chose not to impose, much less do so in a provision tasking CMS to "efficiently" administer the Social Security Act. This is especially true in this case, where CMS seeks to regulate in an area that is committed to State regulation both by statute and longstanding practice. We expect Congress to use "exceedingly clear language if it wishes to significantly alter the balance between federal and state power."[69] It did not do so here.

II. CMS's Proposed Rule Is Contrary to Law Because It Violates the Separation of Powers.

The Proposed Rule is contrary to law in that it usurps Congress's authority in another way as well: It seeks to wield the power of the purse by regulatory fiat. The Constitution vests Congress with the power to tax and spend.[70] It is Congress that determines when and how federal funds will be spent.[71] And it falls to Congress to set conditions and limitations on the recipients of those federal funds.

The Spending Clause restricts "the disbursing authority of the Executive department."[72] "Federal agencies and departments can spend, award, or suspend money based only on the power Congress has given to them—they have no other spending power."[73] Because "[t]he Constitution vests the spending powers in Congress, not the President," CMS cannot place extra-statutory, substantive restrictions on federal expenditures absent authorization from Congress.[74]

The Medicaid and CHIP Acts broadly authorize federal expenditures for necessary medical services provided through State Medicaid and CHIP plans, including for pharmaceutical and surgical interventions.[75] And while States must cover such necessary care, federal law leaves it up to the individual State to define what care is "necessary."[76] Many States recognize the critical need for gender-affirming medical care, deem this care "necessary," and therefore require the state plan

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[69] *Alabama Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2021) (quotation marks omitted).

[70] U.S. Const. art. I, § 8, cl. 1.

[71] U.S. Const. art. 1, § 9, cl. 7 ("No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law.").

[72] *Cincinnati Soap Co. v. United States*, 301 U.S. 308, 321 (1937).

[73] *New York v. Trump*, 769 F. Supp. 3d 119, 127 (D.R.I. 2025).

[74] *County of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 508 (N.D. Cal. 2017), *aff'd in relevant part City & Cnty. of San Francisco v. Garland*, 42 F.4th 1078 (9th Cir. 2022).

[75] SSA § 1905(a) (defining reimbursable "medical assistance"); *id.* § 1905(r)(5); *id.* § 2110(a) (defining reimbursable "child health assistance").

[76] *See Beal v. Doe*, 432 U.S. 438, 444–445 (1977).

to cover it.[77] So long as the State plan otherwise abides by the conditions outlined in the Medicaid and CHIP Acts, States are entitled to reimbursement for the federal share of this provided care.[78]

Congress has not imposed any conditions or restrictions on Medicaid expenditures used for gender-affirming medical care. Indeed, CMS has, until now, consistently provided payment for gender-affirming medical care for minors when those services are included in State plans.[79] What Congress has chosen not to do, CMS cannot do in its stead.

Rather than effectuate Congress's will, the Proposed Rule instead reflects the Executive Branch's policy objection to gender-affirming medical care. The Executive Branch ordered HHS to promulgate rules in line with the President's views on gender-affirming medical care,[80] and unsurprisingly, CMS has now effectuated that order in a Proposed Rule stating that gender-affirming medical care for minors is not in minors' best interests. That conclusion runs contrary to medical practice, as well enduring principles of parental autonomy to make decisions for their children's welfare, including with regard to medical care.[81] But even if CMS had science or logic in its corner, CMS cannot usurp Congress's power of the purse to impose its preferences and suspend federal funds for treatment options the agency dislikes.

If finalized, the Proposed Rule would also infringe on Congress's authority to enact law. By federal law and through the Medicaid and CHIP Acts, Congress has obligated CMS to "pay to each State" with an approved State plan the federal percentage of the cost of care.[82] No provision in either statute conditions the federal medical assistance percentage on whether *federal funds are used for treatment options CMS agrees with*. Congress has not authorized CMS to make these kinds of decisions. Yet this is exactly what CMS purports to do.

The Proposed Rule attempts to unilaterally amend these federal laws; this CMS cannot do.[83] Indeed, CMS could not amend federal law even if Congress unambiguously authorized it to. The Constitution requires more: Any modification or amendment to a duly enacted statute must be passed by both houses of Congress and presented to the President.[84] The Proposed Rule thus violates the separation of powers enshrined in the Constitution and is unlawful.

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[77] Such States include Maine, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, Maryland, Delaware, Virginia, District of Columbia, Wisconsin, Illinois, Michigan, Minnesota, Colorado, New Mexico, Nevada, Washington, Oregon, California, and Alaska. *See* Movement Advancement Project, *Medicaid Coverage of Transgender-Related Healthcare*, https://www.lgbtmap.org/equality-maps/medicaid (last visited Feb. 17, 2026); *see also* California (Cal. Ins. Code § 10140); District of Columbia (D.C. Code § 31-2231.11(c)); Maine (Me. Rev. Stat. Ann. tit. 22 § 3174-MMM (Supp. 2025)); Maryland (Md. H.B. 283 (2023)); Minnesota (Minn. Stat. § 62Q.585); New Jersey (N.J. Stat. Ann. § 30:4D-9.1); Oregon (H.B. 2002 (2023)); Vermont (Vt. Agency of Human Servs., Health Care Administrative Rules § 4.238).

[78] SSA §§ 1903, 2105.

[79] *See, e.g.*, Compl. ¶¶ 58–60, *State of Oregon et al. v. Kennedy et al.*, No. 6:25-cv-02409 (D. Or. filed Dec. 23, 2025).

[80] Denial-of-Care Order § 5.

[81] *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

[82] SSA §§ 1903(a) (Medicaid), 2105(a)(1) (CHIP).

[83] *Clinton v. City of New York*, 524 U.S. 417, 448 (1998).

[84] U.S. Const. art. I, § 7, cl. 2.

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Transgender adolescents—like all citizens—have a "vital interest" in the "liberty which the separation of powers seeks to secure."[85] When "the decision to spend [is] determined by the Executive alone, without adequate control by a citizen's Representatives in Congress, liberty is threatened."[86] CMS, through this Proposed Rule, claims the unilateral "ability to hurt a group that is a visible target"—transgender children.[87] The separation of powers forbids this result.

III. CMS's Proposed Rule Denies Medically Necessary Treatment to Children, In Violation Of The Early And Periodic Screening, Diagnostic And Treatment Services Benefit.

The Proposed Rule is also inconsistent with the Medicaid Act's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) mandatory benefit.[88] Under this benefit, state plans must cover "care and services" of "early and periodic screening, diagnostic, and treatment services" for eligible individuals under the age of 21.[89] CMS is obligated to reimburse States for this care;[90] the statute does not vest CMS with the authority to deny federal funding for healthcare services and procedures determined by the State to be medically necessary.

A. The EPSDT Benefit Requires State Plans To Cover Any Medically Necessary Care, Which Is Determined On A Patient-By-Patient Basis.

The EPSDT benefit specifically requires States to provide eligible children, adolescents, and young adults under the age of 21 with comprehensive Medicaid coverage for medically "necessary health care, diagnostic services, and treatment . . . to correct or ameliorate defects and physical and mental illnesses and conditions . . . whether or not such services are covered under the State plan." The fundamental purpose of these requirements is to ensure that Medicaid recipients under age 21 receive the health care they need when they need it. Millions of children—including those with disabilities, in foster care, and from low-income families—depend on EPSDT for their medical care.[91] CMS itself has described the EPSDT benefit as "a cornerstone of the Medicaid program" designed to "ensure that individual eligible children get the health care they need, when they need it, in the most appropriate setting."[92]

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[85] *Clinton*, 524 U.S. at 452 (Kennedy, J., concurring).

[86] *Id.* at 451.

[87] *Id.*

[88] SSA § 1905(r).

[89] SSA § 1905(a), (a)(4)(B).

[90] SSA §§ 1902(a)(10)(A); 1903(a); 1905(a)(4)(B).

[91] Jane Perkins & Sarah Somers, *Medicaid's Gold Standard Coverage for Children and Youth: Past, Present, and Future*, 30 Annals Health L. 153, 154–156 (2021), https://lawecommons.luc.edu/annals/vol30/iss2/5.

[92] CMS, State Health Official Letter #24-005, *Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements* 1 (Sept. 26, 2024), https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf.

EPSDT is the gold standard for healthcare coverage for children, adolescents, and young adults under 21.[93] Congress has consistently emphasized its commitment to ensuring that such young people—who make up forty percent of all Medicaid enrollees[94]—obtain the broadest levels of coverage for their medical needs. Indeed, Congress has amended the SSA several times to maximize the EPSDT benefit and override efforts to limit the program's scope.[95]

Through the EPSDT requirements, Congress enacted a comprehensive system for identifying and treating the mental and physical conditions of children, adolescents, and young adults under 21 enrolled in Medicaid. To comply with the Act, States have an affirmative obligation to ensure that families are informed about the benefit; that qualified healthcare professionals screen children, adolescents, and young adults under 21 in regularly scheduled examinations; and that such young people receive all available medically necessary treatment for any health conditions identified.[96]

The Medicaid Act plainly demonstrates congressional intent to create special protections for adolescents and young adults under 21. Unlike the broader Medicaid program, which is structured as a "mere 'vendor payment' program," States cannot simply sit back and wait for eligible claims to be submitted for payment.[97] Rather, Congress recognized that time is of the essence for at risk young people; the EPSDT benefit therefore *entitles* children, adolescents, and young adults under 21 to coverage of early detection and comprehensive treatment and prohibits States from delaying or limiting coverage for critical care.[98]

There is only one question under EPSDT when it comes to health care for beneficiaries under 21: Is the service or procedure necessary for the treatment of an illness or condition? If the answer is *yes*, the service or procedure *must be covered*.[99] And the Act adopts a more expansive definition of medical necessity under EPSDT than for ordinary Medicaid: Treatment is covered any time it is "necessary . . . to correct *or ameliorate* defects and physical and mental illnesses and conditions."[100] CMS has broadly defined treatment as "ameliorative"—and therefore covered—if it will "maintain or improve a child's current health condition" or "prevent a condition from worsening or . . . [the] development of additional health problems."[101] And CMS has long emphasized that "[t]he determination of whether a service is medically necessary for an individual child must be made on a case-by-case basis, taking into account the particular needs of the child."[102] Indeed, CMS has explained that because medical necessity decisions are "individualized" by

[93] *See* Perkins & Somers, *supra* n.91, at 153.

[94] *Id.* at 154.

[95] *Id.* at 160–162.

[96] *See* Medicaid & CHIP Payment Access Comm'n, *EPSDT in Medicaid* (Jan. 11, 2021), https://www.macpac.gov/subtopic/epsdt-in-medicaid.

[97] *See* Perkins & Somers, *supra* n.91, at 160.

[98] *See* Medicaid & CHIP Payment Access Comm'n, *supra* n.96.

[99] SSA § 1905(r)(5).

[100] *Id.* (emphasis added); *see also* Perkins & Somers, *supra* n.91, at 13–14.

[101] *See* State Health Official Letter #24-005, *supra* n.92, at 6.

[102] CMS, *EPSDT-A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents*, 23 (June 2014), https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf.

nature, "flat limits or hard limits" are inconsistent with EPSDT requirements.[103] When and how best to treat a minor's physical and mental health conditions—including gender dysphoria—is a decision the Medicaid Act leaves primarily to families and their treating physicians.

Although section 1902 gives States discretion to adopt standards for the extent of medical assistance provided under State plans, those standards must be "reasonable" and "consistent with the objectives of the Act."[104] Recognizing the critical importance of the EPSDT benefit, CMS has informed States that even "tentative limits" on medical assistance must give way when additional services are "medically necessary to correct or ameliorate a diagnosed condition."[105] States "cannot say 'never' when it comes to medically necessary treatments" for children.[106] The Medicaid Act prohibits States from imposing categorical restrictions on what medical treatments are considered necessary.[107] The same goes for CMS.

B. The Proposed Rule Violates The EPSDT's Medical Necessity Requirement.

Categorically denying coverage "for a specific, medically necessary procedure . . . contravenes the purposes of Title XIX" to provide "medical treatment to needy persons whose income and resources are insufficient to meet the cost of *necessary medical services.*"[108] Yet this is exactly what the Proposed Rule purports to do. The Proposed Rule would prevent EPSDT-eligible transgender children from obtaining medically "necessary health care" treatment for their gender dysphoria, in direct violation of the EPSDT requirements. In fact, CMS concedes that the Proposed Rule would apply in "circumstances in which a provider may determine that a sex-rejecting procedure is medically necessary for a child diagnosed with gender dysphoria."[109] That concession is fatal.

CMS would nevertheless justify the Proposed Rule based on the *possibility* that gender-affirming medical care "*may* pose a risk of harm."[110] This suggestion goes against the overwhelming weight of medical and scientific authority demonstrating that such care is safe, effective, and medically necessary in appropriate circumstances. Moreover, the EPSDT benefit does not hinge on CMS's risk-reward assessment, but whether treatment is "necessary . . . to correct or ameliorate defects and physical and mental illnesses and conditions."[111] To the extent CMS intends to adopt a risk-reward standard for EPSDT benefits, the agency does not acknowledge—much less explain—its

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[103] EPSDT-A Guide for States, *supra* n.102, at 23.

[104] *Beal*, 432 U.S. at 444 (internal quotation omitted).

[105] EPSDT-A Guide for States, *supra* n.102, at 23–24.

[106] *Cruz v. Zucker*, 195 F. Supp. 3d 554, 571 (S.D.N.Y. 2016).

[107] *Id.*

[108] *Hern v. Beye*, 57 F.3d 906, 911 (10th Cir. 1995) (quotation marks omitted).

[109] 90 Fed. Reg. at 59,451.

[110] 90 Fed. Reg. at 59,452. By that logic, CMS could ban federal funding for *any* medical treatment based on little more than its say-so. Nearly all medical procedures come with some risk. But such an interpretation would eviscerate the EPSDT benefit. Unsurprisingly, this is not the standard Congress enacted. *See* SSA § 1905(r)(5), 90 Fed. Reg. at 59,452.

[111] SSA § 1905(r)(5) (emphasis added).

abrupt departure from its decades-long interpretation of the requirements for making medical necessity decisions, nor provide a reasonable explanation for its interpretation of the statutory text. Nor does CMS attempt to reconcile its categorical determination that treatment is inappropriate with the statutory demand that medical necessity is determined based on the individualized needs of EPSDT-eligible children.

* * *

The Medicaid Act is clear: When gender-affirming medical care is medically necessary for adolescents and young adults under 21, States must cover it—and CMS must share the cost.[112] CMS's attempt to unilaterally withdraw federal funding for medically necessary services violates the statute's plain terms. The Proposed Rule accordingly violates the EPSDT provisions of the Medicaid statute and is unlawful.

IV. CMS's Proposed Rule Violates The Medicaid Act's Comparability Requirement.

Section 1902(a)(10)(B) requires all Medicaid participants be provided with medical assistance equal in "amount, duration, or scope," regardless of diagnosis. Existing CMS regulations implementing this requirement forbid "arbitrarily deny[ing] or reduc[ing] the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition."[113] Put another way, the Medicaid Act "prohibits discrimination among individuals with the same medical needs stemming from different medical conditions."[114] A beneficiary need not show that their medical needs are *identical* to those of the beneficiaries who are receiving coverage; rather, a showing that their medical needs are *equivalent* is sufficient.[115]

Medicaid programs routinely cover hormone therapy, such as testosterone and estrogen, and puberty-delaying medications because they are medically accepted indications for various health conditions, including treatment of gender dysphoria. The comparability requirement thus requires Medicaid to cover the same services for the treatment of gender dysphoria if a beneficiary needs it.[116]

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[112] SSA §§ 1902(a)(43), 1905(r)(5).

[113] 42 C.F.R. § 440.230(c); *see also* 42 C.F.R. § 440.240(b) (comparability regulation).

[114] *Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016).

[115] *Id.*

[116] The Proposed Rule also violates Section 1927, which requires States to cover all FDA-approved drugs when they are prescribed for a "medically accepted indication," subject to certain limited unrelated exceptions. SSA § 1927; 42 U.S.C. §§ 1396r-8(k)(2), 1396r-8(d)(1)(B). A "medically accepted indication" is a use that is FDA-approved or "supported by one or more citations included or approved for inclusion in any of the compendia" listed in the Medicaid Act. SSA § 1927(k)(6); 42 U.S.C. § 1396r8(k)(6). The three approved compendia include the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. Relevant here, DRUGDEX supports the use of forms of testosterone, estrogen, and puberty-delaying medications to treat gender dysphoria. *See, e.g.*, *Estradiol*, DrugDex® Information System (Feb. 5, 2026); *Goserelin*, DrugDex® Information System (Jan. 8, 2026); *Leuprolide*, DrugDex® Information System (Jan. 16, 2026); *Testosterone*, DrugDex® Information System (Feb. 5, 2026); *Triptorelin*, DrugDex® Information System (Jan. 8, 2026).

Yet, the Proposed Rule blatantly violates the comparability requirement by imposing a regime that fails to provide "comparable services for individuals with comparable needs."[117] The Proposed Rule would prevent federal Medicaid dollars from covering medically necessary treatment for gender dysphoria but fund the very same services when used to treat conditions like delayed or precocious puberty or certain metabolism disorders. Were this incongruity not apparent enough, the Proposed Rule denies coverage "for an illness suffered only" by transgender youth.[118] Such a disparate result plainly violates the Medicaid comparability provision.

CMS's contrary interpretation of the comparability provision is unworkable. For purpose of the comparability requirement, it makes no difference that the treatments are prescribed for different diagnoses. "[F]ederal law prohibits a state from denying or reducing a Medicaid-eligible patient's required services 'solely because of the diagnosis, type of illness, or condition.'"[119] The comparability provision does not "defer[]" to a regulation's "definition of the 'purpose' of any given service."[120] "Medical services are always, by nature, diagnosis-specific, and rarely are two diagnoses or medical histories exactly alike."[121] This is precisely why the comparability provision exists: to protect Medicaid beneficiaries with different diagnoses who have "*equivalent medical needs*."[122] Thus, just as States "cannot get around the comparability requirement by defining the relevant services as services aimed at treating only some medical conditions," neither can CMS.[123]

Nor can CMS justify its disparate treatment based on the claim that "different uses of these procedures" have different benefits and risks. 90 Fed. Reg. at 59,452. On that basis, it purports to distinguish between procedures to "align a child's physical appearance or body with an . . . identity that differs from the child's sex" from those same procedures when used for any other purposes. 90 Fed. Reg. at 59,463. The fact that the same treatment may be used for different purposes and under different circumstances is immaterial. Permitting the federal government to "deny medical benefits to some categorically needy individuals that it provides to others with the exact same medical needs by defining such services—however arbitrarily—as aimed at treating only some medical conditions would risk swallowing the comparability provision whole."[124]

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[117] *Cota v. Maxwell-Jolly*, 688 F. Supp. 2d 980, 933 (N.D. Cal. 2010).

[118] *Dekker v. Weida*, 679 F. Supp. 3d 1271, 1299 (N.D. Fla. 2023).

[119] *Id.* at 1298 (quoting 42 C.F.R. § 440.230(c)).

[120] *Davis*, 821 F.3d at 257.

[121] *Id.* at 258.

[122] *Id.* (emphasis added).

[123] *Kadel*, 100 F.4th at 163.

[124] *Davis*, 821 F.3d at 257. Taken to its logical conclusion, CMS could justify denying a prosthetic for eligible individuals "who lose limbs through amputation" merely by "defin[ing] the purpose of a prosthetic leg as enhancing mobility in disabled individuals born without limbs." *Id.* Such a conclusion "surely . . . would violate the comparability requirement" because it denies equivalent services to eligible individuals "who have the same indisputable medical needs." *Id.*

The comparability requirement prohibits States and CMS from declining coverage based on diagnosis or treatment purpose. The Proposed Rule explicitly makes such problematic distinctions and violates federal law in the process.

V. CMS's Proposed Rule Discriminates On The Basis Of Sex In Violation of Section 1557 Of The Affordable Care Act.

Section 1557 of the Affordable Care Act (ACA) guarantees that "an individual shall not . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity" receiving federal funds on the basis of any "ground prohibited under . . . title IX of the Education Amendments of 1972."[125] Title IX, in turn, prohibits discrimination based on sex.[126] Courts generally "construe Title IX's protections consistently with those of Title VII,"[127] and in *Bostock v. Clayton County*, the Supreme Court held that "discrimination based on . . . transgender status necessarily entails discrimination based on sex" under Title VII.[128] Accordingly, Section 1557 prohibits covered health programs from treating transgender patients differently from cisgender patients because of their sex or transgender status.

Yet this is precisely what the Proposed Rule seeks to accomplish. The Proposed Rule adopts a "policy against [gender-affirming medical care] to treat gender dysphoria—a condition inextricably related to a person's sex."[129] The Proposed Rule would authorize federal funding for young people to access medically necessary puberty-delaying medication, hormone therapy, and surgical interventions—except when those young people are seeking that medically necessary care *because they are transgender*. Whether federal funding is available for an individual's medically necessary treatment would accordingly turn on whether that person's gender identity matches their birth-assigned sex. *Bostock* forbids this result.[130]

The Proposed Rule also relies on impermissible sex stereotyping for the same reason.[131] By its terms, federal funding eligibility would turn on whether a young person seeks treatment that is "sex-rejecting"—treatment that would "intentionally alter[ ] [their] physical appearance or body" to "align" with their birth-assigned sex.[132] The Proposed Rule would effectively require all transgender youth who rely on Medicaid to refrain from "rejecting" physical characteristics of their birth-assigned sex and would "entrench[ ] the belief that transgender individuals must preserve the genitalia and other physical attributes of their natal sex over not just personal

[125] 42 U.S.C. § 18116(a).

[126] 20 U.S.C. § 1681(a).

[127] *Doe v. Snyder*, 28 F.4th 103, 114 (9th Cir. 2022).

[128] 590 U.S. at 669.

[129] *Hammons v. University of Md. Med. Sys. Corp.*, 649 F. Supp. 3d 104, 113 (D. Md. 2023).

[130] *See* 590 U.S. at 660–661 (explaining that "transgender status [is] inextricably bound up with sex").

[131] *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989).

[132] 90 Fed. Reg. at 59,454.

preference, but specific medical and psychological recommendations to the contrary"—a "form of sex stereotyping" that "trigger[s] the protections of . . . the ACA's anti-discrimination provision."[133]

The Supreme Court's decision in *Skrmetti*, on which the Proposed Rule relies, is not to the contrary. Unlike the statute at issue in *Skrmetti*, which the Court found to classify only based on age and medical use, the Proposed Rule here is expressly couched in terms of sex.[134] Furthermore, *Skrmetti* was decided on constitutional grounds; the case is silent as to statutory sex discrimination claims.[135] Even if *Skrmetti*'s constitutional holdings were relevant, the Court acknowledged that "invidious discrimination" against transgender individuals *may* violate the Equal Protection Clause.[136] The Proposed Rule, part and parcel of the Administration's explicit and unremitting campaign targeting transgender people, evinces the Administration's invidious discrimination. Finally, and apart from any constitutional concerns, Congress through the ACA set a higher standard for sex discrimination than that contained in the Equal Protection Clause. Under that standard, the Proposed Rule clearly discriminates on the basis of sex.

* * *

The Proposed Rule is contrary to law because it discriminates based on sex and transgender status, in violation of Section 1557 of the ACA. Even if the Proposed Rule were deemed to discriminate solely based on diagnosis, such discrimination is pretextual and motivated by a purpose to discriminate against transgender people more generally.

VI. CMS's Proposed Rule Violates The Equal Protection Clause.

The Proposed Rule also discriminates on the basis of sex and transgender status in violation of the Constitution's equal protection guarantee. "[T]he Due Process Clause of the Fifth Amendment contains an equal protection component prohibiting the United States from invidiously discriminating between individuals or groups."[137] Gender identity is a protected characteristic under the equal protection guarantee and is subject to heightened scrutiny.[138] To pass muster, the Proposed Rule must be "substantially related to a sufficiently important government interest."[139] Desire "to harm a politically unpopular group" can never satisfy this standard.[140]

The proposed rule, which styles itself as a prohibition on coverage for "sex-rejecting procedures," expressly determines coverage on the basis of sex and transgender status. The Proposed Rule does not focus on any particular medical treatment but on the particular motive for seeking or providing

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[133] *Boyden v. Conlin*, 341 F. Supp. 3d 979, 997 (W.D. Wis. 2018).

[134] *Compare United States v. Skrmetti*, 605 U.S. 495, 511 (2025), *with* 90 Fed. Reg. at 59,463.

[135] *See Doe by Doe v. South Carolina*, No. 25-1787, 2025 WL 2375386, at *10 (4th Cir. Aug. 15, 2025) (Diaz, C.J., concurring), *stay denied*, No. 25A234, 2025 WL 2610400, at *1 (U.S. Sept. 10, 2025) ("*Skrmetti* said nothing whatsoever to cause doubt as to the vitality of [the Fourth Circuit's] Title IX holding.").

[136] *Skrmetti*, 605 U.S. at 518.

[137] *Washington v. Davis*, 462 U.S. 229, 239 (1976).

[138] *See Flack v. Wisconsin Dep't of Health Servs.*, 328 F. Supp. 3d 931, 952–953 (W.D. Wis. 2018).

[139] *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 441 (1985).

[140] *United States v. Windsor*, 570 U.S. 744, 770 (2013).

treatment—whether one "rejects" their "biological classification as either male or female"—which is inextricably linked with the characteristic of being transgender. Regulations that extend beyond particular "medical treatments" and instead seek to "regulate[ ] a class of *persons* identified on the basis of a specified characteristic" are impermissible.[141] By its terms, the Proposed Rule therefore classifies on the basis of sex and transgender status and is subject to heightened scrutiny.

Even if the Proposed Rule did not facially classify on the basis of sex or transgender status, heightened scrutiny would still apply. Facially neutral regulations merit heightened scrutiny when they are a mere "pretext[ ] designed to effect invidious discrimination against transgender individuals."[142] Not only is the Proposed Rule an "unusual deviation" into an area statutorily committed to State regulation, but it also "operates to deprive" only transgender adolescents from obtaining necessary medical care from hospital providers—providing "strong evidence" that the Proposed Rule "ha[s] the purpose and effect of disapproval of that class."[143] Moreover, as explained, the Proposed Rule is part of a "flurry of government actions directed at transgender persons—denying them everything from necessary medical care to access to homeless shelters."[144] "The Administration has been explicit about its disapproval of the transgender community and its aim to end [gender-affirming medical care]."[145] And as "part of a coordinated and rapid rollback of rights and protections previously afforded to transgender Americans,"[146] the Proposed Rule is merely the next step in this wide-ranging attempt to target transgender people as a class and to unlawfully interfere with their access to medical care.

CMS, for its part, has not (and cannot) offer an "exceedingly persuasive justification" for the Proposed Rule nor a close "means-end fit."[147] CMS claims that gender-affirming medical care is "inconsistent" with the "best interests and with quality of care" for Medicaid-eligible adolescents and "inconsistent" with providing health care to CHIP-eligible children "in an effective and efficient manner."[148] As explained herein, neither suffice to justify this regulatory action.

First, as discussed below, the Proposed Rule *undermines* CMS's asserted interest in "quality of care." The Proposed Rule takes an entirely one-sided approach to gender-affirming medical care by acknowledging only the potential risks (common to most medical interventions) without considering their benefit. The relevant medical studies and clinical practice guidelines are more than sufficient to demonstrate that, despite CMS's assertions to the contrary, gender-affirming medical care for transgender adolescents with gender dysphoria is far more likely to help rather than harm.

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[141] *Skrmetti*, 605 U.S. at 519 n.3.

[142] *Id.* at 497.

[143] *Windsor*, 570 U.S. at 770.

[144] *Talbott v. United States*, 775 F. Supp. 3d 283, 331 (D.D.C. 2025).

[145] *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239.

[146] *Orr*, 778 F. Supp. 3d at 417–418.

[147] *Sessions v. Morales-Santana*, 582 U.S. 47, 58, 68 (2017).

[148] 90 Fed. Reg, at 59,450.

The Proposed Rule also does not account for risks of *denying* or *interrupting* transgender youth with gender dysphoria's access to care. For transgender adolescents with gender dysphoria for whom medical treatment is clinically indicated, lack of access to that care is likely to increase anxiety, depression, severe distress, self-harm, and suicidality.[149] The risk of denying such patients medically necessary care under these circumstances is extreme. Indeed, as noted in a recent systematic review of the evidence on interventions for gender dysphoria in transgender youth, "[e]vidence-based policymaking decisions about banning or restricting gender dysphoria interventions for youth ought to consider the certainty of whether the policy is preventing harm that exceeds the potential harm of withholding clinical standards of care."[150]

Second, as discussed below, CMS overstates the risks with which it purports to be concerned. No medical treatment is without potential risks and side effects, but the potential side effects of gender-affirming medical care do not outweigh the overwhelming and well-documented benefits from receiving gender-affirming medical care. Indeed, the Proposed Rule demonstrates as much by maintaining coverage for the same medical interventions performed on cisgender youth. CMS's assertions about "quality of care" fall flat when the agency greenlights the same medical treatments for *cisgender* youth—even though the risks would be at least comparable, if not identical.

The mismatch between CMS's asserted interest in protecting minors from "risk" and the targeted means it has chosen to deny federal funding for medical care sought only by transgender adolescents demonstrates that the Proposed Rule is motivated by animus against transgender individuals. The Proposed Rule accordingly could not survive even rational-basis review.

VII. The Proposed Rule Is Arbitrary, Capricious, And Against the Weight of Scientific Evidence.

CMS's decision to withhold federal funding for gender-affirming medical care for adolescents under the age of 18 in Medicare and under the age of 19 in CHIP is also arbitrary and capricious under the Administrative Procedure Act.[151] Agency actions are arbitrary and capricious when they reverse previous policies without sufficient explanation, rely on flawed evidence, disregard important evidence, and fail to account for serious reliance interests.[152] All three of these deficiencies exist here.

A. The Proposed Rule Reverses CMS's Prior Policy Without Sufficient Justification.

Previously, HHS has interpreted Section 1557's prohibition on discrimination "on the basis of sex" to include discrimination on the basis of "gender identity."[153] Indeed, the agency stated that "evidence suggests that when patients are protected on the basis of sex in health care programs, quality of care improves."[154] And the agency went on to note that "individuals who are

[149] *See infra* n.207 and accompanying text.

[150] Dopp, *infra* n.183, at 35.

[151] *See* 5 U.S.C. § 706(2).

[152] *See, e.g.*, *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–222 (2016).

[153] *Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg. 31,376, 31,472 (May 18, 2016); *see also Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522, 37,701 (May 6, 2024).

[154] 89 Fed. Reg. at 37,575.

experiencing gender dysphoria . . . have a clinically significant decrease in distress if they have access to medically necessary care."[155] CMS now seeks to reverse course entirely and deny federal funding to transgender youth for gender-affirming medical care the agency previously recognized as safe, effective, and evidence-based. And it has neither acknowledged nor adequately explained that change in position. CMS's lack of "awareness that it is changing position" is arbitrary and capricious.[156]

B. The Proposed Rule Relies On Flawed Evidence And Disregards The Weight of Scientific Evidence.

CMS's Proposed Rule is also arbitrary and capricious because it is based on HHS's fundamentally flawed publication entitled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices."[157] The HHS Review does not provide a well-founded justification for barring federal financial participation for medically necessary gender-affirming medical care for adolescents. Commissioned in violation of the Federal Advisory Committee Act, the HHS Review offers a non-representative account of the literature and cherry-picks studies critiquing gender-affirming medical care without engaging in the full breadth of the scientific literature, and its conclusions thus fail to account for the research supporting gender-affirming medical care. CMS's near-determinative reliance on the HHS Review is thus arbitrary and capricious.[158]

1. The HHS Review Violated The Federal Advisory Committee Act.

The HHS Review was procedurally deficient from the beginning. The Review was commissioned pursuant to the Denial-of-Care Order, which declared gender-affirming medical care a "dangerous trend" that "must end."[159] The HHS Review was accordingly commissioned with a pre-determined outcome (undermining gender-affirming medical care for minors) and purpose (ending that care nationally).

The Review also violated the Federal Advisory Committee Act (FACA) and its disclosure mandates for committees advising federal agencies.[160] FACA authorizes federal agencies to utilize "advisory committees" to furnish "expert advice, ideas, and diverse opinions," though "new

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[155] *Id.*

[156] *Encino Motorcars*, 579 U.S. at 221–222.

[157] HHS, *Supplement to Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices: Peer Reviews and Replies* 5 (Nov. 19, 2025), https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report-supplement.pdf.

[158] *See Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency rule is arbitrary and capricious when it "runs counter to the evidence before the agency").

[159] Denial-of-Care Order, §§ 1, 2(c).

[160] 5 U.S.C. § 1001 *et seq*. The FACA defines "advisory committee" as "a committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof . . . that is established or utilized to obtain advice or recommendations for the President or one or more agencies or officers of the Federal Government and that is— . . . (ii) established or utilized by the President; or (iii) established or utilized by one or more agencies." 5 U.S.C. § 1001(2)(A). The HHS Review was established by the President and/or HHS and utilized by HHS to justify the proposed rule, among other executive branch activities. It is therefore subject to the FACA. *See, e.g., Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 16 (1st Cir. 2020); *Heartwood, Inc. v. USFS.*, 431 F. Supp. 2d 28, 34–35 (D.D.C. 2006).

advisory committees should be established only when they are determined to be essential" and requires that those committees satisfy the statute's transparency and membership requirements.[161] These include establishing a charter and holding meetings open to the public. Advisory committees must also be "fairly balanced in terms of the points of view represented and the functions to be performed."[162] To this end, advisory committees must submit a written plan "identif[ying] the points of view that would promote a fairly balanced advisory committee" and recruit members "with demonstrated professional or personal qualifications and experience relevant" to the function of the committee."[163]

The HHS Review committee satisfied none of these statutory mandates. First, it appears that HHS created a "new" committee without justification. HHS maintains an existing advisory committee—the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)—that provides CMS with an "unbiased and current deliberation of 'state of the art' technology and science."[164] But HHS did not rely on MEDCAC to draft the HHS Review. Nor did it explain why a new committee was "essential."

Second, the HHS Review committee failed to satisfy FACA's procedural requirements: The committee has no publicly-available charter, failed to hold any public meeting on its findings, and filed no written plan highlighting members' "balanced" perspectives.[165] Rather than assemble a committee of balanced experts, HHS appears to have done the opposite and selected contributors based on their prior publications criticizing gender-affirming medical care. None of the contributors are experts in the diagnosis and treatment of gender dysphoria or research regarding the safety and efficacy of gender-affirming medical care—but nonetheless, all have publicly spoken out against these services.

For example, contributor Evgenia Abbruzzese is a self-described "researcher" who co-founded the "Society for Evidenced-Based Gender Medicine," an organization that staunchly opposes gender-affirming medical care for transgender youth.[166] Alex Byrne is a philosopher, not a doctor, but has authored a "polemic" book characterizing "transgender healthcare" as an "inflammatory social and political issue[]."[167] After it was revealed that Byrne helped draft the HHS Review,[168] his own colleagues argued that he had violated the rules of professional ethics by participating in the Review despite lacking the requisite expertise on gender-affirming medical care for transgender

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[161] 5 U.S.C. § 1002(a).

[162] 5 U.S.C. 1004(b)(2), (c).

[163] 41 C.F.R. § 102-3.60(b)(1), (2).

[164] CMS, *Medicare Evidence Development & Coverage Advisory Committee*, https://www.cms.gov/medicare/regulations-guidance/advisory-committees/evidence-development-coverage (last visited Feb. 17, 2026).

[165] *See* 5 U.S.C. §§ 1008–09.

[166] Society for Evidence-Based Gender Med., *What Does SEGM Do?*, https://segm.org/about_us (last visited Feb. 17, 2026).

[167] Alex Byrne, *Trouble with Gender* vii (Polity Press; 2024), http://www.alexbyrne.org/trouble-with-gender.html.

[168] Justin Weinberg, *Philosopher's Apparent Role in Government's "Treatment for Pediatric Gender Dysphoria" Report Revealed by Metadata*, Daily Nous (May 5, 2025), https://dailynous.com/2025/05/05/philosophers-apparent-role-in-governments-treatment-for-pediatric-gender-dysphoria-report-revealed-by-metadata/.

youth.[169] Similarly, neither Moti Gorin nor Leor Sapir are medical professionals—but both have published extensive opinion pieces on their opposition to gender-affirming medical care.[170] Farr Curlin, Kristopher Kaliebe, and Michael Laidlaw have never treated minors with gender dysphoria—despite repeatedly attempting to serve as "experts" opposing the provision of gender-affirming medical care in litigation[171]—though all three have made statements opposing gender-affirming medical care.[172]

Similar bias and imbalance extended to HHS's post-review solicitation of "peer reviews." The peer reviews supporting the HHS Review were largely solicited from people who had already publicly voiced opposition to the provision of gender-affirming medical care for minors.[173] HHS's disregard of FACA and its protections for balanced decision-making fatally undermines the reliability of the HHS Review. The proposed rule's reliance on the illegally assembled report is inherently arbitrary and capricious.

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[169] Dear Professor Alex Byrne (June 26, 2025), https://dearprofessorbyrne.wordpress.com/.

[170] *See Moti Gorin*, Colorado State Univ., https://www.libarts.colostate.edu/people/mgorin/ (last visited Feb. 11, 2026); *Leor Sapir*, Manhattan Institute, https://manhattan.institute/person/leor-sapir?top=false&limit=10&page-number=6&people%5B%5D=46760&dates= (last visited Feb. 17, 2026); *see also, e.g.*, M. Gorin, *Gender, Pediatric Care, and Evidence*, 54 Hastings Ctr. Rep. 34 (2024).

[171] *See, e.g.*, *K.C. v. Individual Members of Med. Licensing Bd. of Indiana*, 677 F. Supp. 3d 802, 811 (S.D. Ind. 2023) (Kristopher Kaliebe designated as expert for defendants), *rev'd and remanded*, 121 F.4th 604 (7th Cir. 2024); Dkt. No. 37 at Exhibit E, Expert Declaration of Dr. Farr Curlin, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025) (Farr Curlin designated as expert for defendant); *Koe v. Noggle*, 688 F. Supp. 3d 1321, 1337 (N.D. Ga. 2023) (Michael Laidlaw designated as expert for defendant).

[172] Curlin has expressed opposition to gender-affirming medical care for adults as contradicting the purposes of medicine. Kaliebe opposes gender affirmation. *See* Dkt. No. 139, Plaintiffs' Memorandum of Law In Support Of Motion To Exclude Exprt Testimony Of Dr. Kristopher Kaliebe, at 14, *Dekker v. Weida*, No. 4:22-cv-00325-RH-MAF (N.D. Fl. 2023), https://storage.courtlistener.com/recap/gov.uscourts.flnd.443916/gov.uscourts.flnd.443916.139.0.pdf. And Laidlaw has gone so far as to oppose affirmation of a transgender person's identity *in any circumstances*. *See* Dkt. No. 119, Plaintiffs' Motion To Exclude Expert Testimony of Michael K. Laidlaw, M.D., at 14, *L.B. et al. v. Premera Blue Cross*, No. 2:23-cv-00953-TSZ (W. D. Wa. 2025), https://storage.courtlistener.com/recap/gov.uscourts.wawd.323685/gov.uscourts.wawd.323685.119.0_1.pdf.

[173] *See, e.g.*, J.C. Bester, *Minors Lack the Autonomy to Consent to Gender-Affirming Care: Best Interests Must Be Primary*, 54 Hastings Ctr. Rep. 57 (2024), https://doi.org/10.1002/hast.1600; Karleen Gribble, "The Desexing of Language in Women's Health Research and Care: A Story of Marginalization of Science, Cultural Imperialism, and Abuse of Power" in *The War on Science* (Lawrence Krauss ed., Post Hill Press 2024); P. Vankrunkelsven, K. Casteels & J. De Vleminck, *How to Provide the Best Care for Young People with Gender Dysphoria*, 27 Belgian J. Paediatrics 35 (2025), https://belgjpaediatrics.com/index.php/bjp/article/view/340; Jilles Smids & Patrik Vankrunkelsven, Uncertainties Around the Current Gender Care: Five Problems with the Clinical Lesson 'Youth with Gender Incongruence', 167 Ned. Tijdschr. Geneeskd. (2023), https://www.ntvg.nl/artikelen/onzekerheden-rond-de-huidige-genderzorg; HHS Review Supplement at 36 (noting that Dr. Lane Strathearn had attempted to publish an article about gender dysphoria that was rejected following peer review).

2. The HHS Review Ignores A Large Body Of Scientific Literature Regarding Gender-Affirming Medical Care.

The HHS Review is, at best, a highly selective review of the treatment for gender dysphoria.[174] The Review claims to "summarize[], synthesize[], and critically evaluate[] the existing literature on best practices" for treating gender dysphoria, but only relied upon studies discounting the safety and efficacy of gender-affirming medical care.[175] And even the Review's cherry-picked studies are open to significant critique.

For example, the HHS Review relies heavily on the "Cass Review," a study out of the United Kingdom regarding gender identity in adolescents. The Cass Review—which was led by a retired English pediatrician with no prior knowledge of gender dysphoria, no experience treating gender dysphoria, and no experience working with transgender youth—generally concluded that there was limited evidence for gender-affirming medical care.[176] But the Cass Review has been extensively criticized by clinical and academic medical practitioners for a wide range of shortcomings, including, but not limited to: (1) excluding the perspectives of transgender youth and those experienced in transgender youth care; (2) misusing data and violating its own evidentiary standards by resting many conclusions on speculation; (3) disregarding multiple relevant studies both in the Report and in its underlying reviews; and (4) disregarding the entirety of the data pointing to positive effects from both puberty blockers and gender-affirming hormones.[177]

In fact, the British Medical Association (BMA) has "call[ed] for a pause to the implementation of the Cass Review's recommendations" while it further investigates the Cass Review's many flaws, including "weaknesses in the methodologies used in the Review and problems arising from the implementation of some of the recommendations."[178] The BMA also reiterated its belief that "transgender and gender-diverse patients should continue to receive specialist health care, regardless of their age," its criticisms of "proposals to ban the prescribing of puberty blockers to

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[174] *See* Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. Adolescent Health 342 (2025); G. Nic Rider et al., *Scientific Integrity and Pediatric Gender Healthcare: Disputing the HHS Review*, Sexuality Rsch. & Soc. Pol'y (2025).

[175] HHS Review at 11.

[176] Cal Horton, *The Cass Review: Cis-Supremacy in the UKs' Approach to Healthcare for Trans Children*, Int'l J. Transgender Health 1 (2024).

[177] *See, e.g.*, Meredithe McNamara et al., *An Evidence-Based Critique of "The Cass Review" on Gender-Affirming Care for Adolescent Gender Dysphoria* (2024), https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf; Chris Noone et al., *Critically Appraising the Cass Report: Methodological Flaws and Unsupported Claims*, 25 BMC Med. Rsch. Methodology 128 (2025); Horton, *supra* n.176; WPATH & USPATH, *WPATH and USPATH Comment on the Cass Review* (May 17, 2024), https://wpath.org/wp-content/uploads/2024/11/17.05.24-Response-Cass-Review-FINAL-with-ed-note.pdf. *See generally* Dkt. No. 6, Expert Declaration of Dr. Armand Antommaria, at 19-21, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

[178] BMA Media Team, *BMA to Undertake an Evaluation of the Cass Review on Gender Identity Services for Children and Young* People, British Med. Ass'n (July 31, 2024), https://www.bma.org.uk/bma-media-centre/bma-to-undertake-an-evaluation-of-the-cass-review-on-gender-identity-services-for-children-and-young-people.

children and young people with gender dysphoria," and its belief that "clinicians, patients and families should make decisions about treatment on the best available evidence, not politicians."[179]

In relying on the Cass Report, the HHS Review dismissed the wealth of studies finding gender-affirming medical care to be a safe and effective treatment for gender dysphoria. For example, in 2023, the Louisiana Department of Health released a study focused on the "risks associated with gender reassignment procedures on minors."[180] The study concluded that for adolescents who received gender-affirming medical care, "[p]sychiatric or mental health outcomes (e.g. depression, suicidal ideation) improved after treatment" when compared to individuals not treated," and that "[r]egret or retransition in youth is rare (1% or less)."[181]

The HHS Review also failed to adequately consider more recent clinical practice guidelines from France and Germany endorsing gender-affirming medical care for adolescents,[182] as well as a 2024 systemic review from RAND finding that gender-affirming medical care was associated with reduced gender dysphoria, improved body satisfaction, and improved mental health incomes.[183] The RAND report reviewed studies from 1990 to 2023 evaluating interventions for youth with gender dysphoria. Its "findings indicat[ed] low regret, low dissatisfaction levels, and low side effects and complications" from gender-affirming medical care. At the same time, the review found that "gender identity and expression change efforts," such as conversion therapy, were "associated with increases in suicidality (low certainty) and increases or no change in mental health symptoms (very low certainty)."[184] The HHS Review did not provide principled reasons for elevating analyses like the Cass Review over other sources; the only consistent criterion appears to be whether the source supported providing gender-affirming medical care to adolescents or not.

The Proposed Rule makes a similar error by disregarding a 2025 systemic review out of the University of Utah's Drug Regimen Review Center analyzing gender-affirming medical care for minors with gender dysphoria (the Utah Review). The Utah Review concluded that, contrary to the "conventional wisdom among non-experts [that] there are limited data on the use of [gender-affirming hormone therapy] in pediatric patients with [gender dysphoria] . . . results from our exhaustive literature searches have led us to the opposite conclusion."[185] The authors went on to

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[179] *Id.*

[180] S. Amanda Dumas et al., La. Dep't of Health, Bureau of Health Servs. Fin., *Study on Gender Reassignment Procedures for Minors: Response to HR 158 of the 2022 Regular Session* 3 (Mar. 2023)

[181] *Id.* at 5.

[182] *See generally* German Soc'y for Child & Adolescent Psychiatry, Psychosomatics & Psychotherapy (DGKJP), *S2k Guideline: Gender Incongruence and Gender Dysphoria in Childhood and Adolescence: Diagnosis and Treatment*, AWMF Reg. No. 028-014, Version 1.0 (2025), https://register.awmf.org/de/leitlinien/detail/028-014; François Brezin et al., *Endocrine Management of Transgender Adolescents: Expert Consensus of the French Society of Pediatric Endocrinology and Diabetology Working Group*, Archives de Pédiatrie (2024).

[183] Alex R. Dopp et al., RAND Corp., *Interventions for Gender Dysphoria and Related Health Problems in Transgender and Gender-Expansive Youth: A Systematic Review of Benefits and Risks to Inform Practice, Policy, and Research* (RRA3223-1, 2024).

[184] *Id.* at vi.

[185] Joanne LaFleur et al., Drug Regimen Rev. Ctr., Univ. of Utah Coll. of Pharmacy, *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* 90 (Aug. 6, 2024).

conclude that "[t]he consensus of the evidence supports" that gender-affirming medical care treatments "are effective in terms of mental health [and] psychosocial outcomes" and "safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer."[186] Finally, the Utah Review found there is "virtually no regret associated with receiving treatments," even among those who stop taking them.[187]

3. The HHS Review's Selective Evidentiary Review Led To Incorrect Factual Conclusions Regarding The Safety and Efficacy Of Gender-Affirming Medical Care.

The HHS Review fails to engage with studies supporting the safety and efficacy of gender-affirming medical care, and consequently makes a series of incorrect evidentiary conclusions that wrongfully discount the "overwhelming weight of medical authority" supporting gender-affirming medical care as an effective and safe treatment for gender dysphoria.[188] By adopting the HHS Review, the Proposed Rule makes identical errors which leads to an arbitrary and capricious result.[189]

First, the HHS Review's claim that gender-affirming medical care is based on "low quality evidence" does not hold up.[190] As already explained, a robust body of evidence demonstrates that gender-affirming medical care for adolescents with gender dysphoria is a safe and effective treatment for gender dysphoria. This body of evidence is comparable to that supporting other medical treatments, especially those in pediatrics.[191] For example, experts in the field have explained that the quality of evidence supporting the use of GnRHa for central precocious puberty is the same as the quality of evidence supporting the use of GnRHa for gender dysphoria.[192] And the most recent systematic reviews of the scientific literature found multiple studies regarding the efficacy of hormones and GnRHa to be of moderate to high quality.[193]

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[186] *Id.*

[187] *Id.* at 91.

[188] *Dekker*, 679 F. Supp. 3d at 1285.

[189] *State Farm*, 463 U.S. at 43 (agency rule is arbitrary and capricious when it offers an explanation that "runs counter to the evidence" or "fail[s] to consider an important aspect of the problem").

[190] *See, e.g.*, HHS Review at 71, 74, 91, 97.

[191] Dkt. No. 6, Expert Declaration of Dr. Armand Antommaria, at ¶¶ 6, 20-41, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

[192] *Id.* at ¶¶ 37-38.

[193] The York reviews commissioned for the Cass Report found that 34 of the 53 reviewed studies assessing outcomes of youth with gender dysphoria treated with gender-affirming hormones were of moderate or high (one study) quality evidence using the Newcastle-Ottawa Scale, and that there were 26 studies of moderate to high quality assessing outcomes of youth with gender dysphoria treated with GnRHa medications. *See* Jo Taylor et al., *Interventions to Suppress Puberty in Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, 109 Archives Disease Childhood Supp. 2, S33 (2024); Jo Taylor et al., *Masculinising and Feminising Hormone Interventions for Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, 109 Archives Disease Childhood Supp. 2, S48 (2024). Another review looking at GnRHa as treatment found that of the 51 studies it reviewed, that 22 were rated as moderate to high-quality evidence, concluding that "GnRHa is effective in halting puberty and improving mental health in TGD adolescents." Tornese, *supra* n.44, at 2.

HHS was wrong to claim that the lack of "randomized controlled trials" involving gender-affirming medical care indicated a "lack of methodologically rigorous studies."[194] Randomized, or placebo-controlled, trials are very rare in pediatrics because it is unethical to subject children to placebos when the existing evidence demonstrates that pharmacological treatment is superior. The same is true for gender-affirming medical care; researchers cannot ethically subject transgender youth—especially those experiencing clinically-significant distress from their gender dysphoria like suicidality—to a placebo treatment when the existing body of evidence instructs that the pharmacological alternative is superior.

Meanwhile, HHS failed to identify "high quality" evidence demonstrating that gender-affirming medical care for minors causes *any* of the alleged harms that CMS purports to be concerned about.[195] In fact, the HHS Review acknowledges that "[e]vidence for harms associated with pediatric medical transition in systematic reviews is also sparse," yet maintains that "the absence of evidence of harms in published studies is not equivalent to evidence of absence of harms."[196] This analysis is backwards: The substantial evidence of benefit for the overwhelming majority of adolescents, when coupled with the evidence that negative outcomes are rare, supports gender-affirming medical care as a safe and effective intervention where clinically indicated.[197]

Second, the HHS Review's claim that gender-affirming medical care has "unique" diagnostic criteria overlooks that the objected-to characteristics are typical of medical treatments writ large. For instance, the Review claims that gender dysphoria diagnoses are "exceptional" because diagnosis is "based entirely on subjective self-reports and behavioral observations, without any objective physical, imaging, or laboratory markers."[198] However, *all* psychiatric conditions are diagnosed based on self-reporting and behavioral observations.[199] So are medical conditions like migraines. But HHS did not single out depression, anxiety, or migraine diagnoses as "exceptional" or problematic.

The Review relatedly asserts that physicians do not agree whether the "the fundamental goal of treatment" is to "manage gender dysphoria," "manage common comorbidities like depression, anxiety, and suicidal ideation," or "help individuals realize their 'embodiment goals' (i.e., cosmetic desires)."[200] This is not unique to gender-affirming medical care. Physicians routinely offer identical medical treatments with different goals for different patients. Adderall may be prescribed to reduce hyperactivity, but it is also prescribed for youths with narcolepsy for the *opposite* purpose—to induce wakefulness and activity. Spironolactone is given to children to manage high blood pressure, but it is also prescribed for youths with cystic acne, a condition that may cause depression or anxiety.

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[194] *See, e.g.*, HHS Review at 92.

[195] HHS Review, *supra* n.42, at 85.

[196] *Id.* at 13, 101.

[197] Expert Declaration of Hilary Mabel, JD, HEC-C, at ¶¶ 30, 33, 46, *Soe v. Louisiana State Bd. of Med. Examiners*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

[198] HHS Review, *supra* n.42, at 22.

[199] *See* Dkt. No. 52, Expert Rebuttal Declaration of Dr. Jack Turban, at 5, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

[200] HHS Review, *supra* n.42, at 22.

Treatment for acne-prone youths simultaneously addresses the underlying condition, aligns with youths' "cosmetic desires," and alleviates "common comorbidities like depression." That a treatment may be prescribed for multiple purposes does not detract from its value.

Third, the HHS Review's conclusion that gender-affirming medical care is unjustifiably risky did not account for the broader context of risks associated with medical treatment in general. For instance, chapter 7 of the HHS Review, titled "Evidence from Basic Science and Physiology," purports to discuss the medical risks of puberty-delaying medications and hormone therapy. However, the report fails to contextualize that *any* medical intervention involves potential risks. Patients and families who choose a medical intervention to treat gender dysphoria are counseled on anticipated risks along with expected benefits, and they choose the treatment where their risk/benefit analysis favors the benefits. This is no different than any medical intervention.[201]

The proof that gender-affirming medical care is safe and effective is borne out by the lived experiences of transgender people. One study using data from the 2015 U.S. Transgender Survey of over 20,000 transgender adults compared those who received pubertal blocking treatment as adolescents with those who were unable to access that care and found that those who received puberty blocking care had a 70% lower chance of suicidal thoughts than those who did not.[202] In medicine, treatment with an improvement rate of 70% is considered a very powerful intervention.[203] A follow-up analysis examining access to gender-affirming hormone therapy similarly found that access to hormone therapy in adolescence was associated with reductions in suicidal ideation.[204] This improvement rate places hormone therapy for adolescents well within the commonly accepted range for safe and effective medical care.

By insisting that gender-affirming medical care causes serious and irreversible harm, HHS ignores the significant risks of *not* treating gender dysphoria.[205] Denying adolescent patients gender-affirming medical care may cause irreversible changes to a patient's body that may not align with their gender identity in adulthood.[206] These youths are then at high risk of suicidality, self-harm,

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[201] *See, e.g.*, Dkt. No. 5, Expert Declaration of Dr. Sarah Corathers, at ¶¶ 63–73, *Loe v. Kansas*, No. DG-2025-CV-000241 (Kan. Dist. Ct. 2025); Dkt. No. 6, Expert Declaration of Dr. Armand Antommaria, at ¶¶ 47–62, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025); Expert Declaration of Dr. Daniel Shumer, at ¶¶ 69, 91, *Soe v. Louisiana State Bd. of Med. Exam'rs*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

[202] Jack L. Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145 Pediatrics e20191725 (2020).

[203] For context, atorvastatin is a widely prescribed cholesterol-lowering medication and is considered safe based on a 36% improvement rate. *See, e.g.*, Stephen P. Adams, et al., *Atorvastatin for Lowering Lipids (Review)*, Cochrane Database of Systematic Revs. 3 (2015).

[204] Turban, et al., *supra* n.21, at e0287283; *see also* Luke R. Allen, et al., *supra* n.21; 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 J. Adolescent Health 643 (2022).

[205] *See* Dkt. No. 6, Expert Declaration of Dr. Armand Antommaria, at 24, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

[206] *See* Expert Declaration of Dr. Jennifer Creedon, at ¶¶ 76–77, *Soe v. Louisiana State Bd. of Med. Examiners*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

depression, and anxiety compared to their peers.[207] Lack of access to gender-affirming medical care therefore directly contributes to poorer mental health outcomes for transgender people.[208]

Fourth, the HHS Review's mangled discussion of "regret" overlooks that the vast majority of adolescents do not regret their treatment or later "detransition." "Regret" refers to patients' perception of treatment options, treatment outcomes, conflicting treatment plans, and other variable issues, and patients undergoing any treatment may experience some level of regret based on their past medical decision-making.[209] "Detransition," unlike regret, refers to ceasing treatment or undoing "social, medical, and/or administrative changes achieved" through gender transition.[210] Regret may be a reason to detransition, but detransition is not necessarily prompted by regret. Many of those who detransition choose to do so because of external factors, such as "facing too much harassment or discrimination after transitioning (31%), having trouble getting a job (29%), or pressure from a parent (36%), spouse (18%), or other family members (26%)."[211]

The existing body of literature indicates that few patients experience regret when gender-affirming medical care is provided in accordance with clinical guidelines. Regret of any kind is rare (0.6% in transgender women and 0.3% in transgender men).[212] And when regret due to lack of social or familial acceptance is excluded, the data reflects an even smaller percentage of individuals who report regret (approximately half this group, roughly 0.3% in transgender women and 0.15% in transgender men).[213] To the contrary, studies report "overwhelmingly positive" results from gender-affirming medical care "compared with other medical and nonmedical decisions."[214]

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[207] *See* Kameg & Nativio, *supra* n.10, at 493.

[208] Ashli A.Owen-Smith et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J. Sexual Med. 591 (2018).

[209] *See* Mireille Chehade et al., *Patient-Related Decisional Regret: An Evolutionary Concept Analysis*, 33 J. Clinical Nursing 4484 (2024).

[210] Pablo Expósito-Campos et al., *Gender Detransition: A Critical Review of the Literature, Gender Detransition: A Critical Review of the Literature,* 51 Actas Españolas Psiquiatría 98 (2023).

[211] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey*, Nat'l Ctr. Transgender Equality (2016), https://www.transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.

[212] *See* Chantal M. Wiepjes et al., *The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets*, 15 J. Sexual Med. 582, 585, 587 (2018). (classifying transgender women as having "social regrets" when they still identified as women, but reported feeling "ignored by surroundings" or they regretted loss of relatives, and classified "true regrets" as those experienced by individuals who "thought gender affirming treatment would be a 'solution' for, for example, homosexuality or [lack of] personal acceptance, but, in retrospect, regretted the diagnosis and treatment"); *see also* Lauren Bruce et al., *Long-Term Regret and Satisfaction with Decision Following Gender-Affirming Mastectomy*, 158 JAMA Surgery 1070 (2023); Sasha Karan Narayan et al., *Guiding the Conversation—Types of Regret After Gender-Affirming Surgery and Their Associated Etiologies*, 9 Annals Translational Med. 605 (2021).

[213] *See generally* de Vries et al., *supra* n.21; Maria Anna Theodora Catharina van der Loos et al., *Continuation of Gender-Affirming Hormones in Transgender People Starting Puberty Suppression in Adolescence: A Cohort Study in the Netherlands*, 6 Lancet Child & Adolescent Health 869 (2022); Wiepjes et al., *supra* n.212; Johanna Olson-Kennedy et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts*, 172 JAMA Pediatrics 431 (2018).

[214] Bruce et al., *supra* n.212, at E5.

This research shows that while regret occurs with virtually every type of medical intervention, recipients of gender-affirming medical care report regret at far lower rates than patients undergoing other medical treatments. For instance, a 2023 literature review found approximately 10% of patients who undergo joint replacement regret their decision,[215] and another 2024 study revealed almost half of patients who had undergone weight loss surgeries expressed some level of regret postoperatively.[216] Despite the high levels of reported regret, minors are routinely encouraged to undergo weight loss surgery.[217]

The scientific literature also shows that detransition as a result of reidentification with their birth-assigned sex is very rare. For example, in a study looking at 552 youth who were referred to a pediatric gender clinic between 2014 and 2020, only two patients (0.36%) reidentified with their birth-assigned sex (i.e., no longer identified as transgender) after starting puberty delaying medications.[218] Similarly, in a longitudinal study in the Netherlands looking at twenty years of data, only 2% of the patients who started GnRHa treatment discontinued treatment or did not go on to hormones because of remission of gender dysphoria.[219]

The HHS Review's focus on regret, detransition, and other purported negative outcomes does not account for the vast majority of people who benefit from and do not regret the care. Existing research demonstrates that gender-affirming medical treatments for adolescents with gender dysphoria are consistently linked to improved mental health.[220] Peer-reviewed and cross-sectional studies demonstrate an association between pubertal suppression and improved mental health outcomes.[221] Longitudinal studies show similar results.[222] The same is true for gender-affirming hormone therapy.[223]

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[215] Michael J. DeFrance & Giles R. Scuderi, *Are 20% of Patients Actually Dissatisfied Following Total Knee Arthroplasty? A Systematic Review of the Literature*, 38 J. Arthroplasty 594 (2023).

[216] Phillip J. Dijkhorst et al., *Factors Associated with Decision Regret After Bariatric Surgery*, 14 C, 14 Clinical Obesity e12597 (2024).

[217] *See* Maurizio De Luca et al., *Scientific Evidence for the Updated Guidelines on Indications For Metabolic and Bariatric Surgery*, 34 Obesity Surgery 3963 (2024).

[218] Blake S. Cavve et al., *Reidentification With Birth-Registered Sex in a Western Australian Pediatric Gender Clinic Cohort*, 178 JAMA Pediatrics 446 (2024).

[219] van der Loos et al., *supra* n.213, at 869.

[220] *See* Dkt. No. 7, Expert Declaration of Dr. Armand Antommaria, at ¶¶ 16–24, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025); Expert Declaration of Dr. Daniel Shumer, at ¶¶ 91–99, *Soe v. Louisiana State Bd. of Med. Examiners*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025); Expert Declaration of Dr. Kate Millington, at ¶¶ 65–81, *Soe v. Louisiana State Bd. of Med. Examiners*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

[221] *See, e.g.*, de Vries et al., *supra* n.21; Turban et al., *supra* n.202, at e20191725; van der Miesen et al, *supra* n.21; Achille et al., *supra* n.21.

[222] *See, e.g.*, Annelou L.C. de Vries et al., *Young Adult Psychological Outcome after Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696 (2014); Costa et al., *supra* n.21.

[223] *See, e.g.*, Diane Chen et al., *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*, 388 New Eng. J. Med. 240 (2023); Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth after Gender-Affirming Hormones*, 7 Clinical Prac. Pediatric Psych. 302 (2019); Achille et al., *supra* n.21; and Diego López de Lara et al., *supra* n.21.

Fifth, the HHS Review misapprehends the role of psychotherapy in gender-affirming medical care. Chapter 14, titled "Psychotherapy," appears to recommend that psychotherapy be considered as an alternative treatment for gender dysphoria instead of medical interventions. But psychotherapy is *already* a cornerstone of gender-affirming medical care for adolescents, as part of diagnosing gender dysphoria and to address potential co-occurring conditions like depression or anxiety.[224] And there is no evidence-based talk therapy to treat gender dysphoria and no evidence that psychotherapy alone can treat gender dysphoria where medical treatment is clinically indicated.[225]

It is also unethical to use psychotherapy to encourage transgender persons to change their gender identity to match their birth-assigned sex. So-called "gender identity change efforts" are harmful; existing research links this therapy to adverse mental health outcomes like suicide attempts.[226] As a result, leading medical and mental health organizations, including the American Medical Association, the American Psychiatric Association, the American Academy of Child & Adolescent Psychiatry, and the American Psychological Association, each have issued clear statements that psychotherapeutic practices meant to encourage transgender persons to change their gender identity to match their birth-assigned sex are discredited, harmful, and ineffective.[227]

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[224] WPATH SOC8, *supra* n.13, at S50-51.

[225] *See* Dkt. No. 7, Expert Declaration of Dr. Jack Turban, at ¶¶ 25-27, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

[226] A 2023 report by the Substance Abuse and Mental Health Services Administration (SAMHSA) found that "the evidence is strong that [sexual orientation and gender identity] change efforts are harmful to the health of people of diverse sexual orientation and/or gender identity, including children and adolescents." Substance Abuse & Mental Health Servs. Admin. (SAMHSA), HHS, *Moving Beyond Change Efforts: Evidence and Action to Support and Affirm LGBTQI+ Youth*, SAMHSA Pub. No. PEP22-03-12-001 (2023), https://archive.org/details/httpsstore.samhsa.govsitesdefaultfilespep22-03-12-001. Similarly, the RAND Corporation systematic review looking at the effectiveness of interventions for gender dysphoria in transgender and gender expansive (TGE) youth found that "[t]here was an association between [gender identity and expression change efforts (GIECE)] and increases in likelihood of suicidal ideation, likelihood, and frequency of suicide attempts (both immediately and long term after GIECE)." Dopp et al., *supra* n.183, at 33; *see also* Jack L. Turban et al., *Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults*, 77 JAMA Psychiatry 68 (2020); Amy E. Green et al., *Self-Reported Conversion Efforts and Suicidality Among US LGBTQ Youths and Young Adults, 2018*, 110 Am. J. Pub. Health 1221 (2018); Shelley L. Craig et al., *Fighting for Survival: The Experiences of Lesbian, Gay, Bisexual, Transgender, and Questioning Students in Religious Colleges and Universities*, 29 J. Gay & Lesbian Soc. Servs. 1 (2017). The HHS Review makes no mention of these reports.

[227] American Acad. of Child & Adolescent Psychiatry, *Policy Statement: Conversion Therapy* (2018), https://www.aacap.org/aacap/Policy_Statements/2018/Conversion_Therapy.aspx; Am. Med. Ass'n & GLMA: Health Professionals Advancing LGBTQ Equality, *Issue Brief: Sexual Orientation and Gender Identity Change Efforts (So-Called "Conversion Therapy")* (2022), https://www.ama-assn.org/system/files/conversion-therapy-issue-brief.pdf; American Psychiatric Ass'n, *Position Statement on Conversion Therapy and LGBTQ+ Patients* (2024), https://www.psychiatry.org/getattachment/3d23f2f4-1497-4537-b4de-fe32fe8761bf/Position-Conversion-Therapy.pdf; American Psychological Ass'n, *APA Resolution on Gender Identity Change Efforts* (Feb. 2021), https://www.apa.org/about/policy/resolution-gender-identity-change-efforts.pdf; *see also* WPATH SOC8, *supra* n.13, at S53.

4. Even if the HHS Report's Methodology And Conclusions Were Sound (They Are Not), That Does Not Justify Barring Federal Funding For Medically Necessary Gender-Affirming Medical Care.

Even if the HHS Review were sound, the Proposed Rule would still be arbitrary and capricious because the HHS Review does not provide a well-founded justification for denying federal funding for medically necessary gender-affirming medical care for adolescents.[228] An agency must provide "a satisfactory explanation for its action, including a rational connection between the facts found and the choice made."[229] No such rational connection exists here.

First, the Review itself acknowledges it "is not a clinical practice guideline" and recommends that "[w]hen evidence for benefit is lacking or of very low certainty, regulatory frameworks should focus on ongoing evaluation, risk mitigation, and the collection of more robust data before allowing broad implementation."[230] To the extent CMS relied on the HHS Review, the Review itself therefore suggests further research rather than "broad implementation."

Moreover, the Review's mischaracterization of gender-affirming medical care for minors as "experimental" does not provide a "sound medical or ethical basis" for excluding providers of gender-affirming medical care from participation in the Medicaid and Medicare programs.[231] States have broad flexibility to design their Medicaid and Medicare programs with benefits in addition to those mandated by federal law, including coverage for experimental treatments. The assertion that the experimental nature of a treatment renders it dangerous enough to justify the Proposed Rule is at odds with the federal mandate that States cover routine costs associated with participation in clinical trials for experimental treatments.[232]

And, finally, the Cass Review, on which the HHS Review heavily relies, likewise recognizes that gender-affirming medical care may be appropriate for some transgender adolescents with gender dysphoria.[233] Thus, even if the HHS Review's interpretation of the evidence were correct, the HHS Review still would not support the Proposed Rule's broad ban on gender-affirming medical care.

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In short, the HHS Review does not provide a well-founded justification for denying federal funding for medically necessary gender-affirming medical care for adolescents. The Review is procedurally deficient, fails to fully engage with the scientific literature, and does not even purport to support the Proposed Rule's broad ban on gender-affirming medical care.

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[228] *State Farm*, 463 U.S. at 43 (quotation marks omitted).

[229] *Ohio v. EPA*, 603 U.S. 279, 292 (2024) (quoting *State Farm*, 463 U.S. at 43).

[230] HHS Review, *supra* n.42, at 3–4, 85.

[231] HHS Review, *supra* n.42, at 9, 64, 151; *see also* Dkt. No. 6, Expert Declaration of Dr. Armand Antommaria, at 4, 9, 36, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025); Expert Declaration of Hilary Mabel, JD, HEC-C, at ¶¶ 52-53, *Soe v. Louisiana State Bd. of Med. Exam'rs*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

[232] 42 U.S.C. § 1396d(a)(30).

[233] *See* Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report* 30, 35, 180, 197 (Apr. 2024).

CMS has failed to meaningfully acknowledge and consider harms to transgender and nonbinary young people who will be unable to receive care if the Proposed Rule goes into effect. The Proposed Rule contains a mere four sentences discussing the harms that denying gender-affirming medical care will cause to transgender and nonbinary youth; the agency's purported "concern" over the "difficulties these minors may experience" rings hollow.[234]

C. The Proposed Rule Fails To Consider Serious Reliance Interests And The Downstream Costs Of Barring Coverage For Gender-Affirming Medical Care.

The Proposed Rule is also arbitrary and capricious because it fails to acknowledge relevant stakeholders' reliance interests in providing or obtaining gender-affirming medical care as well as the downstream effects of withholding federal funding for this care.[235]

Multiple stakeholders rely on Medicaid's coverage of gender-affirming medical care. This includes patients and their families who selected healthcare providers and decided where to live based on access to this care; health care systems who made staffing and training investments to account for gender-affirming medical care; and States whose funding and investment decisions may have relied on Medicaid coverage of gender-affirming medical care to meet the healthcare needs of transgender young people. The Proposed Rule does not acknowledge any of these reliance interests, nor does it make any effort to "incorporate[e] measures to limit the harm to the relying parties" as is required.[236]

The Proposed Rule also fails to consider increased costs to States, individuals, healthcare systems, and providers from enforcement of the proposed rule. For example, the Proposed Rule recognizes that it will not prevent States from providing coverage for gender-affirming medical care with State-only funds,[237] but does not acknowledge the increased financial burden to States from doing so.[238]

Similarly, the Proposed Rule recognizes that some transgender patients will be forced to seek alternative coverage,[239] but does not acknowledge the additional societal and financial costs to this switch. If patients currently covered by Medicaid can find alternative coverage—and frequently, no other coverage is available or affordable for Medicaid patients—changing coverage could force patients and their families to abandon trusted healthcare providers to seek treatment elsewhere—assuming they can find accessible treatment at all. Indeed, for the 300,000 young people in foster care who receive health care solely through Medicaid, finding alternative coverage is simply not

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[234] 90 Fed. Reg. 59,449.

[235] *See, e.g., DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020) (explaining it is arbitrary and capricious to ignore reliance interests).

[236] *Solar Energy Indus. Ass'n v. FERC*, 80 F.4th 956, 981 (9th Cir. 2023).

[237] 90 Fed. Reg. at 59,443.

[238] *Id.* at 59,458–59.

[239] *Id.* at 59,449, 59,458–59.

an option.[240] The Proposed Rule will essentially end access to gender-affirming medical care for youth in the foster system.

As for patients able to find alternative providers, those physicians may experience increased demand for services already provided at a financial loss. Physicians will also "be forced to provide increasingly difficult treatment for LGBTQ patients who arrive with more acute conditions, either because they refrain from being fully transparent with their external providers given their heightened fears of discrimination, or because such apprehension causes them to delay seeking necessary care entirely."[241] This "delayed provision of care—from either increased demand or patients' deferring such care and arriving with worsened conditions" will increase costs, frustrate the provision of health care, and strain the resources of alternative providers.[242] The Proposed Rule considers none of these costs.

CONCLUSION

If CMS were to finalize its Proposed Rule for withholding federal financial participation under Medicaid and CHIP for gender-affirming medical care for adolescents, it will jeopardize the wellbeing of transgender children across the nation. Transgender children depend on Medicaid and CHIP for essential medical treatment. The Proposed Rule is unconstitutional, exceeds CMS's authority, violates the EPSDT benefit, violates the Medicaid Comparability requirement, violates anti-discrimination law, and is arbitrary and capricious in light of the robust scientific and medical evidence supporting gender-affirming medical care. If CMS proceeds with this action, it will face immediate and multi-pronged challenges in court, and it will lose.

[240] HHS, *Adoption and Foster Care Analysis and Reporting System* (Sept. 5, 2025),https://acf.gov/cb/research-data-technology/statistics-research/afcars (counting 328,947 children and youth in foster care on September 30, 2024); Children's Bureau, HHS, *Health-Care Coverage for Children and Youth in Foster Care—and After* (Jan. 2022), https://www.govinfo.gov/content/pkg/GOVPUB-HE23_1200-PURL-gpo223677/pdf/GOVPUB-HE23_1200-PURL-gpo223677.pdf.

[241] *Whitman-Walker Clinic, Inc. v. HHS.*, 485 F. Supp. 3d 1, 56 (D.D.C. 2020).

[242] *Id.* at 56.

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