

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 “Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children,” Docket No. CMS-3481-P

Dear Administrator Oz:

The American Civil Liberties Union Foundation (ACLU) and Lambda Legal Defense and Education Fund, Inc. (Lambda Legal) submit these comments in response to the Centers for Medicare & Medicaid Services (CMS) proposed rule titled “Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children,” Docket No. CMS-3481-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 prohibit hospitals from providing medically necessary gender-affirming medical care to individuals under the age of 18. It would add a new subpart to the regulations setting Conditions of Participation for Medicare and Medicaid-participating hospitals that would classify essential gender-affirming medical care services as “sex-rejecting procedures” and prohibit those hospitals from providing these services to any individual under the age of 18, including to adolescents outside the Medicaid or Medicare programs.

If finalized, the Proposed Rule will have significant deleterious effects. Hospitals could no longer provide gender-affirming medical care to *any* adolescent—regardless of whether the patient is a Medicaid or Medicare beneficiary—without risking expulsion from the Medicaid and Medicare programs. The Proposed Rule will consequently prevent thousands of people from obtaining medically necessary gender-affirming medical care from hospital providers.

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 Medicare or Medicaid Acts. The Proposed Rule is not authorized by Section 1871 of the of the Social Security Act (SSA) because the authority to “administer” Medicare does not authorize CMS to prohibit hospitals from providing medically necessary care, including for patients *outside* of the Medicare and Medicaid programs. And the Proposed Rule is not authorized by Section 1861(e)(9) because that provision allows CMS to implement conditions on *the manner in which* medical services are provided to patients, while the Proposed Rule attempts to proclaim *a category of* medical services may not be provided. Moreover, the Proposed Rule attempts to regulate the practice of medicine, an area traditionally left to the States. But Congress has not clearly authorized CMS to upset this federal-state balance—much less sanctioned the use of Conditions of Participation to bar whole categories of medical care. Because the Proposed Rule purports to do both, it exceeds CMS’s regulatory authority.

Second, the Proposed Rule contravenes multiple federal laws including the Medicare Act’s prohibition on federal interference with the practice of medicine. Congress has specifically *prohibited* CMS from exercising “any . . . control over the practice of medicine or the manner in which medical services are provided.”¹ CMS would ignore this congressional prohibition by redefining the meaning of “healthcare,” but its attempt is both unworkable and unauthorized under the Medicare statute. The Proposed Rule also violates the Medicaid Act’s free-choice-of-provider guarantee.² By disqualifying hospitals from participating in Medicare and Medicaid unless they agree to withhold gender-affirming medical care to transgender adolescents, the Proposed Rule prevents Medicaid beneficiaries from obtaining necessary medical care from their chosen provider. And the Proposed Rule violates the federal Noninterference Mandate, which prohibits the

¹ Social Security Act (SSA) § 1801.

² SSA § 1902(a)(23).

Secretary of Health and Human Services from, *inter alia*, impeding, interfering with, or creating barriers to “appropriate medical care.”³ The very purpose of the Proposed Rule is to do precisely that—interfere or impede access to gender-affirming medical care—by threatening providers of such treatment with expulsion from Medicaid and Medicare.

Third, 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 bars hospitals from offering medical care to transgender adolescents who seek medical care *because they are transgender*. “[D]iscrimination based on . . . transgender status necessarily entails discrimination based on sex.”⁴ Such discrimination is prohibited by Section 1557. Moreover, the Proposed Rule bears the hallmarks of animus against 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 gender, such as male or female.⁵ 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.⁶ Being transgender is a natural variation of human development with a strong biological basis.⁷

³ 42 U.S.C. § 18114.

⁴ *Bostock v. Clayton County*, 590 U.S. 644, 669 (2020).

⁵ American Psychological Ass’n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 Am. Psych. 832, 834 (2015).

⁶ *Id.* at 832–833.

⁷ See Natalia S. Fernández et al., *Is There a Biological Component in Gender Identity?*, 103 *Anales de Pediatría* 503883 (2025).

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.⁸ 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”).⁹ 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.¹⁰ Similarly, “gender incongruence” is codified as a diagnosis in the *International Classification of Diseases, 11th Version*, a globally used clinical diagnosis classification system:¹¹

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.¹²

Gender dysphoria is a serious medical condition that, if left untreated, can result in debilitating anxiety, severe depression, self-harm, and suicidality.¹³ 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.¹⁴ 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.”¹⁵ For example, the World Professional Association for Transgender Health (WPATH) and the Endocrine Society have published widely accepted guidelines

⁸ See American Psychiatric Ass’n, *Diagnostic and Statistical Manual of Mental Disorders* 511 (5th ed. 2022).

⁹ *Id.*

¹⁰ *Id.* at 512.

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

¹² *Id.*

¹³ 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.”).

¹⁴ *Gender Incongruence*, *supra* n.11.

¹⁵ National Acad. Sciences, Eng’g & Med., *Understanding the Well-Being of LGBTQI+ Populations* 361 (Patterson, Sepúlveda & White eds., 2020).

for treating gender dysphoria.¹⁶ The guidelines were developed using a transparent, rigorous, and methodologically sound process that included systematic reviews of evidence by leading healthcare professionals.¹⁷ Each recommendation underwent extensive review and debate among members.¹⁸ 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 transgender people because it reduces distress and promotes wellbeing, while withholding care increases distress and decreases wellbeing.”¹⁹

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.²⁰ No medical treatment is recommended or necessary prior to the onset of puberty.²¹ 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.²² 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.²³

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

¹⁶ 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).

¹⁷ Brief for Clinical Practice Guideline Experts as Amici Curiae Supporting Petitioners at 6, *Skremetti v. L.W.* (No. 23-477) (2024); see also *id.* at 8–14 (describing methodology for developing SOC8).

¹⁸ See *id.* at 11–14.

¹⁹ National Acad. Sciences, Eng’g & Med, *supra* n.15, 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).

²⁰ WPATH SOC8, *supra* n.16, at S6, S9.

²¹ *Id.* at S111.

²² *Id.* at S50–S51.

²³ *Id.*; see also *id.* at S256 (Appendix D: Summary Criteria for Hormonal and Surgical Treatments for Adults and Adolescents).

gender-affirming surgery to treat adolescents with gender dysphoria.²⁴ Further longitudinal studies have examined mental health before and after interventions and found that patients' mental health improved after these treatments.²⁵ 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.²⁶ 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.²⁷

²⁴ 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 41–50 (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); 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 41 (2020); Luke 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).

²⁵ See, e.g., Chen et al., *supra* n.24; Thomas D. Steensma et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696 (2014).

²⁶ See, e.g., van der Miesen et al., *supra* n.24; Turban et al., *supra* n.24.

²⁷ 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).

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.²⁸ 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).²⁹

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.³⁰ And prior to the current administration, HHS followed the findings of

²⁸ 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).

²⁹ See Armand H. Antommaria et al., *Quality of Evidence and Strength of Recommendations in American Academy of Pediatrics' Guidelines*, 155 Pediatrics e2024067836 (2025).

³⁰ 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 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>; American Med. Ass'n & GLMA, *Issue Brief: Health Insurance Coverage for Gender-Affirming Care 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.16; 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/a65106b6ae7f4d2394a1ebeb458591d.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).

these many expert organizations.³¹ As we discuss in section V, 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,” demonstrating the Administration’s overt animus towards transgender individuals.³²

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.³³ Among other things, the Gender Identity Order disclaimed that a person might have a gender identity different from their birth-assigned sex, which the Order describes as a “false claim”³⁴; mandated all agencies to interpret sex-based terms—including in government-issued identification documents and personnel records—as birth-assigned sex³⁵; rescinded protections for LGBTQ+ people in the military and forbade transgender persons from serving in the military³⁶; barred federal funding from being “used to promote gender ideology”³⁷; and directed federal agencies to rescind guidance, forms, and policies acknowledging the existence of transgender people.³⁸

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.”³⁹ It disparaged gender-affirming medical care as “destructive” and “maiming,”⁴⁰ called being transgender a “radical and false claim,”⁴¹ and dismissed the breadth of medical support for gender-affirming medical care as

³¹ Office 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>.

³² *Orr v. Trump*, 778 F. Supp. 3d 394, 417 (D. Mass. 2025).

³³ 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).

³⁴ Gender Identity Order § 2.

³⁵ *Id.* §§ 3(c)–(d).

³⁶ *Id.* § 7(b).

³⁷ *Id.* § 3(g).

³⁸ *Id.* §§ 3(e), 7(c).

³⁹ Exec. Order 14187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8,771 (Jan. 28, 2025) (the Denial-of-Care Order).

⁴⁰ Denial-of-Care Order § 1.

⁴¹ *Id.*

“junk science,”⁴² 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.”⁴³

HHS immediately acted to implement the Administration’s campaign against transgender people.⁴⁴ First, the Department hastily cobbled together a “Review of Evidence and Best Practices” to effectuate Section 3 of the Denial-of-Care Order.⁴⁵ 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.”⁴⁶ 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.⁴⁷

⁴² *Id.* § 3.

⁴³ *Id.* § 5.

⁴⁴ 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).

⁴⁵ 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”).

⁴⁶ *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 *The Journal 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>.

⁴⁷ *See, e.g.,* Dopp, *infra* n.165; Joanne LaFleur, et al., *Univ. of Utah Coll. of Pharmacy, Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* (Nov. 2024), <https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=287>; Gianluca Tornese, et al., *Use Of Gonadotropin-*

Notwithstanding the HHS Review’s many flaws, HHS has relied on it 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 those providers.⁴⁸ 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.⁴⁹ The next day, HHS published the instant Proposed Rule, as well as two others that would ban federal financial participation for gender-affirming medical care for minors under the age of 18 in Medicaid and under the age of 19 in CHIP⁵⁰ and exclude gender dysphoria from disability-based antidiscrimination protections.⁵¹ CMS’s Proposed Rule would adopt the Review’s flawed 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.

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,”⁵² and relatedly, the doctor-patient relationship. The Medicaid and Medicare statutes reflect Congress’s careful balance between the federal agency’s administration of these health insurance programs and the States’ control over the practice of medicine, a balance reflecting the respect for States’ rights under the Tenth Amendment. Accordingly, 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.”⁵³

releasing Hormone Agonists In Transgender And Gender Diverse Youth: A Systematic Review, 16 *Front. Endocrinol.* (2025).

⁴⁸ See HHS, *Urgent Review of Quality Standards and Gender Transition Procedures* (May 28, 2025), <https://tinyurl.com/4j2bt2zd>.

⁴⁹ 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>.

⁵⁰ *Medicaid Program; Prohibition on Federal Medicaid and Children’s Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children*, 90 Fed. Reg. 59,441 (proposed Dec. 19, 2025) (to be codified at 42 C.F.R. pts. 441 and 457).

⁵¹ *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).

⁵² *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025) (cleaned up).

⁵³ *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 would impermissibly infringe upon the States’ inherent power to regulate the practice of medicine by barring gender-affirming medical care within those States’ borders—regardless of whether that State has authorized the same. Congress has not authorized CMS under Sections 1871(a)(1) and 1861(e)(9) to interfere with States’ regulation of the practice of medicine in this way. And the “idea that Congress gave [CMS] such broad and unusual authority through an implicit delegation . . . is not sustainable.”⁵⁴ Indeed, far from providing clear authorization to supplant States’ authority in this area, Congress has explicitly prohibited CMS from doing so.⁵⁵

A. Congress Has Not Authorized CMS To Use Conditions of Participation To Regulate The Practice of Medicine By Prohibiting Necessary Medical Treatments.

The power of a federal agency is grounded in the powers Congress confers upon the agency. But no provision in the Medicare or Medicaid Acts permits CMS to use federal Medicare and Medicaid eligibility to regulate the practice of medicine by strongarming hospitals into withdrawing medically necessary care.⁵⁶

CMS claims that Sections 1871(a)(1) and 1861(e)(9) authorize the Proposed Rule.⁵⁷ But neither provision authorizes CMS to use Conditions of Participation to categorically bar modes of treatment for patients inside or outside Medicaid or Medicare—much less provides the type of “clear statement” needed to justify such sweeping reform.⁵⁸

1. Section 1871 Does Not Authorize The Proposed Rule.

CMS first claims that section 1871 grants the agency the power it purports to exercise here.⁵⁹ Section 1871(a)(1) grants the HHS Secretary general rulemaking authority to “prescribe such regulations as may be necessary to carry out the administration” of the programs under the Act. That provision authorizes HHS—acting through its delegate CMS—to issue regulations related to “the practical management and direction” of Medicare and Medicaid.⁶⁰

The existing conditions of participation regulate participating hospitals’ health and safety standards. For example, CMS requires hospitals to “develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program,”⁶¹ and to “have in effect a utilization review (UR) plan.”⁶² Similarly, hospitals must “be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities

⁵⁴ *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006).

⁵⁵ See SSA §§ 1801, 1902(a)(23); ACA § 1554.

⁵⁶ See *West Virginia v. EPA*, 597 U.S. 697, 735 (2022) (“A decision of such magnitude and consequence rests with Congress itself, or an agency acting pursuant to a clear delegation from that representative body.”).

⁵⁷ 90 Fed. Reg. at 59,464.

⁵⁸ *West Virginia*, 597 U.S. at 724 (requiring clear statement of authority when agency “claim[s] to discover in a long-extant statute an unheralded power representing a transformative expansion in its regulatory authority”).

⁵⁹ 90 Fed. Reg. at 59,464.

⁶⁰ *Administration*, Black’s Law Dictionary 58 (3d ed. 1933).

⁶¹ 42 C.F.R. § 482.21.

⁶² 42 C.F.R. § 482.30.

for diagnosis and treatment and for special hospital services appropriate to the needs of the community.”⁶³ Other Conditions of Participation relate to staffing: Hospitals must have an organized and qualified medical staff and nursing service, as well as a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.⁶⁴ CMS likewise requires hospitals to maintain adequate diagnostic radiological, laboratory, and dietary services.⁶⁵

The Proposed Rule cannot be reasonably described as “practical management” or a health and safety standard. Unlike any other Condition of Participation, the Proposed Rule lacks any connection to the “practical management” of Medicare or Medicaid. It does not regulate operational standards but instead purports to bar hospitals from providing an entire category of safe, effective, and medically necessary care merely because the President disagrees with it. The authority to “administer” Medicare and Medicaid does not extend this far.

This is likely why CMS has never before interpreted the Social Security Act to grant it the authority to categorically ban certain healthcare services Medicare and Medicaid-participating hospitals may use to treat their patients’ medical needs. This is a “telling indication” that the expansive regulatory authority CMS now asserts in the Proposed Rule “extends beyond the agency’s legitimate reach.”⁶⁶

The scope of the Proposed Rule only confirms CMS has exceeded its authority. The Proposed Rule extends beyond Medicare and Medicaid by prohibiting hospitals from providing medically necessary gender-affirming medical care to adolescents *outside* the Medicare and Medicaid program. This CMS cannot do; the authority to “administer” Medicare and Medicaid does not authorize CMS to direct hospitals to cease providing certain categories of necessary medical care for patients *outside* of Medicare and Medicaid.

2. Section 1861(e)(9) Does Not Authorize The Proposed Rule.

CMS also invokes section 1861(e)(9), a provision specifying that for purposes of Medicare, “[t]he term ‘hospital’ . . . means an institution which . . . meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.” This provision does not confer sweeping authority to promulgate any regulation as long as the agency asserts (contrary to accepted medical standards) some purported interest in health or safety.

The whole of section 1861(e) confirms as much. Subsection (e)(9) is a catchall provision that falls at the end of a list of requirements for participating hospitals. The provisions that come before it describe structural and administrative standards that hospitals must meet to qualify for participation in Medicare. For example, hospitals must be “primarily engaged in providing, by or under the supervision of physicians, . . . diagnostic services and therapeutic services . . . or . . .

⁶³ 42 C.F.R. § 482.41.

⁶⁴ See 42 C.F.R. §§ 482.22, 482.23, 482.25.

⁶⁵ *Id.* §§ 482.26, 482.27, 482.28.

⁶⁶ *National Fed’n of Indep. Bus. v. DOL*, 595 U.S. 109, 119 (2022).

rehabilitation services” to inpatients.⁶⁷ Hospitals must maintain bylaws⁶⁸ and clinical records⁶⁹ and ensure that care is provided to patients by a physician or clinical psychologist.⁷⁰ Congress also requires hospitals to provide a 24-hour nursing service,⁷¹ maintain a utilization review plan,⁷² obtain State licensure where applicable,⁷³ and operate on a sufficient overall plan and budget.⁷⁴ These provisions provide context for and define the scope of CMS’s authority to promulgate further “health and safety” requirements.

When Congress required hospitals to meet “*such other* requirements as the Secretary finds necessary,”⁷⁵ it plainly referred to the preceding standards in subsection (e).⁷⁶ Here, the Proposed Rule is not remotely similar to the statute’s other enumerated conditions; the preceding conditions all concern *the manner in which* medical services are provided to patients, while the Proposed Rule attempts to proclaim *a category of* medical services may not be provided. None of the preceding requirements prohibit hospitals from providing particular medical items or services to their patients. Nor do they purport to set uniform federal standards for determining what medical care is appropriate. CMS cannot discover in the “catchall provision” of section 1861(e)(9) a brand-new authority to issue categorical bans on medical care that Congress has not chosen to enact.

* * *

The Proposed Rule thus exceeds CMS’s authority to “administer” Medicaid and Medicare under sections 1871(a)(1) and 1861(e)(9). The Proposed Rule would also set a dangerous precedent for the Executive Branch to make unilateral decisions about what medical care is appropriate for patients. Indeed, CMS’s interpretation would grant it unrestricted authority to dictate what types of health care hospitals can provide to *any and all* patients—from those covered by Medicare or Medicaid to those who are privately insured. By the same logic, CMS could prevent hospitals from providing vaccinations or offering behavioral and mental health care to their patients. “We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.”⁷⁷ Congress has not done so here.

⁶⁷ SSA § 1861(e)(1).

⁶⁸ *Id.* § 1861(e)(3).

⁶⁹ *Id.* § 1861(e)(2).

⁷⁰ *Id.* § 1861(e)(4).

⁷¹ *Id.* § 1861(e)(5).

⁷² *Id.* § 1861(e)(6).

⁷³ *Id.* § 1861(e)(7).

⁷⁴ *Id.* § 1861(e)(8).

⁷⁵ *Id.* § 1861(e)(9) (emphasis added).

⁷⁶ See *Bissonnette v. LePage Bakeries Park St., LLC*, 601 U.S. 246, 252 (2024) (explaining that the *ejusdem generis* canon instructs courts to “interpret a general or collective term at the end of a list of specific items in light of any common attributes shared by the specific items”) (cleaned up).

⁷⁷ *Alabama Ass’n of Realtors v. HHS*, 594 U.S. 758, 764 (2021) (quotation marks omitted).

II. The Proposed Rule Is Contrary To Federal Laws Prohibiting CMS From Interfering In The Practice Of Medicine.

A. The Proposed Rule Violates Section 1801 Of The Social Security Act.

Congress enacted section 1801 as a bulwark against federal encroachment into the practice of medicine and the doctor-patient relationship, areas that have historically fallen to the States to regulate under their traditional police powers.⁷⁸ Section 1801 accordingly bars CMS from “exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided.”⁷⁹ Indeed, as one of the chief architects of the Medicare Act explained, this provision was included in response to concerns that “Federal legislation would give Federal officials the opportunity and the right to interfere in the diagnosis and treatment of the individual.”⁸⁰

Yet this is precisely what the Proposed Rule aims to do. At least fourteen States and the District of Columbia have enacted laws protecting access to gender-affirming medical care and shielding healthcare professionals from suit or consequences relating simply to their provision of gender-affirming medical care.⁸¹ Many States also cover gender-affirming medical care for minors in their State Medicaid and CHIP plans.⁸² The Proposed Rule would negate this legislation by barring the provision of gender-affirming medical care and effectively sanctioning hospitals for providing the same.⁸³ Furthermore, the Proposed Rule would not merely obstruct Medicare and Medicaid patients’ access to medically necessary care, it would also prohibit hospitals that participate in Medicare and Medicaid from providing gender-affirming medical care to *any* adolescent, even outside the Medicare and Medicaid program.⁸⁴ The Proposed Rule thus infringes upon these States’ ability to regulate the practice of medicine.

CMS attempts to circumvent the Medicare Act’s clear prohibition on interfering with the practice of medicine by declaring that gender-affirming medical care is “not healthcare and hence . . . not subsumed under the term of the ‘practice of medicine.’”⁸⁵ CMS proposes to define “the practice

⁷⁸ See *Linder v. United States*, 268 U.S. 5, 18 (1925).

⁷⁹ SSA § 1801.

⁸⁰ Wilbur Cohen, *Reflections on the Enactment of Medicare and Medicaid*, Health Care Financing Rev. 8 (Dec. 1985), <https://pmc.ncbi.nlm.nih.gov/articles/PMC4195078/pdf/hcfr-85-suppl-003.pdf>.

⁸¹ See Movement Advancement Project, *Healthcare Laws and Policies: “Shield” or “Refuge” Laws Protecting Access to Transgender Health Care 3* (Jan. 1, 2026), <https://www.lgbtmap.org/img/maps/citations-trans-shield-laws.pdf>.

⁸² See Movement Advancement Project, *Medicaid Coverage of Transgender-Related Healthcare*, <https://www.lgbtmap.org/equality-maps/medicaid> (last visited Feb. 17, 2026).

⁸³ 90 Fed. Reg. at 59,477.

⁸⁴ *Id.*

⁸⁵ *Id.* at 59,471. In addition to its many other flaws, CMS’s claim that gender-affirming medical care is not health care is inconsistent with its own regulations. In another proposed rule the agency published on the very same day, CMS acknowledges that its plan to withhold federal financial participation under Medicaid and CHIP for gender-affirming medical care for minors “may prevent or delay individuals from receiving these *healthcare services*.” See Medicaid Program; *Prohibition on Federal Medicaid and Children’s Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children*, 90 Fed. Reg. 59,441, 59,459 (Dec. 19, 2025) (emphasis added). And the HHS Review repeatedly refers to gender-affirming medical care as a “*field of medicine*” that “treats children and adolescents

of medicine” to exclude services that pose, in CMS’s view alone, an unreasonable risk of harm, as well as any services that would alter organs or tissue “operating according to their biological functions.”⁸⁶

CMS’s novel interpretation of the “practice of medicine” is untenable for several reasons. For one thing, declaring that gender-affirming medical care is not health care piles unauthorized action on top of unauthorized action. CMS cites no statutory basis for its asserted authority to decide that gender-affirming medical care is not health care. Nor could it—the Medicare and Medicaid Acts contain no such provision.

Second, CMS’s definition also has no basis in the ordinary meaning of the terms *medicine* or *health care*. “Medicine” means “the science and art of dealing with the maintenance of health and the prevention, alleviation, or cure of disease.”⁸⁷ Similarly, “health care” refers to “efforts made to maintain, restore, or promote someone’s physical, mental, or emotional well-being especially when performed by trained and licensed professionals.”⁸⁸ Treatment for gender dysphoria plainly falls within the ordinary meaning of the practice of medicine. Gender dysphoria is a recognized diagnosis in the DSM-5-TR, is treated in accordance with well-established standards of care, and is supported by robust evidence. Moreover, CMS’s broad statement that a person’s body and organs are “either healthy or unhealthy” based only on whether “they are operating according to their biological functions,”⁸⁹ ignores that patients often need medical treatment to respond to mental health conditions as well as physical ones, as the Medicare and Medicaid Acts repeatedly acknowledge.⁹⁰

Third, CMS’s new interpretation has no discernible limits. By its logic, CMS could declare that chemotherapy is not health care because the side-effect risks may outweigh the benefits. Or it

with [gender dysphoria], sometimes with medical interventions.” HHS Review, *supra* n.45, at 22–23, 40 (emphasis added).

What’s more, on the same day that CMS issued the Proposed Rule, the HHS Secretary issued a declaration similarly purportedly declaring that “[s]ex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors, and therefore, fail to meet professional recognized standards of health care.” See RFK Declaration, *supra* n.49. However, just a few days ago, HHS clarified that “‘professionally recognized standards of health care’ addresses situations in which HHS or a component agency *has exercised specific statutory authority* to determine that a treatment modality is not safe and effective,” and that “[t]he Declaration does not purport to exercise such specific statutory authority.” Decl. of Robert M. Penezic, Dkt. No. 75, *Oregon v. Kennedy*, No. 6:25-cv-2409 (filed Feb. 10, 2026) (emphasis added).

⁸⁶ 90 Fed. Reg. at 59471.

⁸⁷ *Medicine*, Merriam-Webster.com Dictionary (Jan. 10, 2026), <https://www.merriam-webster.com/dictionary/medicine>.

⁸⁸ *Health Care*, Merriam-Webster.com Dictionary (Jan. 14, 2026), <https://www.merriam-webster.com/dictionary/healthcare>.

⁸⁹ 90 Fed. Reg. at 59,471.

⁹⁰ See, e.g., SSA § 1812(c) (Medicare Part A benefit for inpatients of psychiatric hospitals); *id.* § 1832(a)(2)(J) (Medicare Part B benefit for partial hospitalization and intensive outpatient services provided by community mental health centers); § 1905(r) (comprehensive assessment of mental health development in Medicaid early and periodic screening, diagnostic, and treatment benefit for minors).

could ban hospitals participating in Medicaid and Medicare from offering heart surgery—widely considered a high-risk procedure. Indeed, *all* medical interventions carry risk. Section 1801 makes clear that individualized decisions about how to balance those risks belong to physicians and their patients.⁹¹ CMS’s asserted authority to unilaterally redefine the “practice of medicine” would render Section 1801 a dead letter.

Fourth, under CMS’s new interpretation of health care, a vast swath of common medical procedures would be excluded. CMS suggests that intentionally destroying healthy biological functions is *per se* not health care,⁹² but physicians may destroy healthy tissue for any number of legitimate reasons, including but certainly not limited to gender-affirming medical care. To take CMS’s own example, physicians may treat breast cancer by removing cancerous and healthy tissue; they also may remove healthy tissue to prevent breast cancer from developing in patients at high risk for breast cancer or to prevent cancer from spreading. Doctors might also prescribe anticoagulants—commonly called blood thinners—even though they will decrease ordinary clot formation and increase the risk of bleeding to limit the greater risk of a stroke. Or a patient might need surgery to remove a perfectly healthy spleen to manage the symptoms of a genetic disorder affecting the shape of red blood cells.

CMS’s suggestion that surgeries addressing psychological distress are inappropriate is also untenable.⁹³ Healthcare professionals frequently conduct surgeries precisely to alleviate patients’ psychological distress. Take plastic surgeons who conduct skin grafts to minimize the appearance of scars. Breast surgeons perform reconstructive surgery after cancer treatment. Otolaryngologists perform rhinoplasties to align a patient’s nose with their ideal facial shape after accidents. CMS’s distinction between treatment to “restore bodily health” and treatment to reduce “psychological distress” thus has no basis in the reality of medical practice.

Finally, CMS’s appeal to the physicians’ Hippocratic Oath—often simplified as “first, do no harm”—cannot justify the agency’s violation of federal law.⁹⁴ CMS claims that gender-affirming medical care causes a “unique set of iatrogenic harms” because “the risk-benefit profile of [gender-affirming medical care] for children is extremely poor.”⁹⁵ There is more than a little irony in that. The Hippocratic Oath is the *physician*’s oath—it instructs *physicians* to evaluate the risks and benefits of treatment in light of their individual patient. Yet CMS’s Proposed Rule usurps this responsibility and vests *CMS* with the power to determine what treatment is appropriate for transgender adolescents. In doing so, CMS emphasizes the potential risks of treatment (common to most medical interventions) while ignoring all documented benefits, to categorically conclude that *any* physician who provides gender-affirming medical care to a transgender adolescent is “do[ing] . . . harm.”

⁹¹ See SSA § 1801 (prohibiting “any Federal officer or employee to exercise any supervision or control over the practice of medicine”).

⁹² 90 Fed. Reg. at 59,471.

⁹³ *Id.*

⁹⁴ 90 Fed. Reg. at 59,470–71.

⁹⁵ 90 Fed. Reg. at 59,471.

That is not only inappropriate, but unprecedented. CMS cites no other instances in which the agency has co-opted physicians’ medical judgment in the name of the Hippocratic Oath—much less done so without accounting for countervailing evidence in support of treatment. And here, the countervailing evidence shows there are serious risks of harm to transgender youth who are *denied* access to care. If gender dysphoria is left untreated, adolescents are likely to experience increased distress, depression, and other mental-health conditions, and increased likelihood of substance abuse, attempts at self-medication, self-harm, and suicidality.⁹⁶ For many transgender adolescents, gender-affirming medical care is medically necessary; physicians may well determine, in their experience and after reviewing the facts of the individual in their care, that withholding such care *violates* their Hippocratic Oath.

B. The Proposed Rule Violates Medicaid’s “Free-Choice-Of-Provider” Provision In Section 1902(a)(23) Of The Social Security Act.

Under the Medicaid Act and CMS’s implementing regulations, Medicaid beneficiaries are entitled to choose any healthcare provider who is “willing” and “qualified to furnish” services covered by their State’s Medicaid program.⁹⁷ As explained above, many States have recognized that gender-affirming medical care is in the best interests of their residents and have chosen to cover such care in their Medicaid plans. The free-choice-of-provider provision protects Medicaid recipients’ ability to choose where to receive these services and prohibits government interference with Medicaid recipients’ choice among qualified medical providers.

Yet the Proposed Rule seeks to do just that. It would disqualify hospitals from participation in Medicare and Medicaid unless they agree to stop offering gender-affirming services to minors. Exclusion from Medicare and Medicaid is an enormous threat to hospitals’ financial viability. In 2023, Medicare and Medicaid paid for roughly 44% of hospital expenditures—nearly \$660 billion.⁹⁸ If the Proposed Rule is finalized, hospitals will likely stop providing gender-affirming medical care to transgender minors rather than risk nearly half of their annual earnings and exclusion from Medicare and Medicaid. As a consequence, transgender adolescents, including those who are Medicaid-eligible, would be denied the ability to obtain necessary medical care from their preferred hospital-based providers.⁹⁹ And if a hospital continued to offer gender-affirming medical care to adolescents, *all* Medicaid beneficiaries would be barred from choosing providers at that hospital simply because they provide gender-affirming medical care. Either way, the Proposed Rule cannot be squared with the free-choice-of-provider guarantee.

⁹⁶ See *infra* n.184-190 and accompanying text.

⁹⁷ 42 C.F.R. § 431.51(b)(1); see also SSA § 1902(a)(23) (requiring State Medicaid plans to ensure that “any individual eligible for medical assistance . . . may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required” and “who undertakes to provide him such services”).

⁹⁸ Kaiser Fam. Found. “Key Facts About Hospitals,” <https://www.kff.org/health-costs/key-facts-about-hospitals/?entry=national-hospital-spending-spending-by-payer> (last visited Feb. 17, 2026).

⁹⁹ Never mind that the most common way for accessing the provision of gender-affirming medical care for an adolescent in a *multidisciplinary* manner, consistent with clinical guidelines, is in a hospital setting where access to multiple disciplines is more easily accomplished. See WPATH SOC8, *supra* n.16, at S56 (“The evolving evidence has shown a clinical benefit for transgender youth who receive their gender-affirming treatments in multidisciplinary gender clinics[.]”).

CMS does not suggest that all Medicare and Medicaid-participating hospitals are unqualified to offer gender-affirming medical care. Nor could it—many hospitals throughout the nation have consistently provided gender-affirming medical care to minors in a safe, competent, ethical manner in accordance with State law and consistent with clinical guidelines. CMS’s attempt to limit the range of qualified Medicaid providers for reasons unrelated to their qualifications violates the free-choice-of-provider provision.

Nor could CMS bypass the free-choice-of-provider guarantee simply by calling the proposed Condition of Participation a “qualification.” The Proposed Rule has no connection to the ordinary meaning of the term “qualified,” which refers to a “provider’s competency and professional standing as a medical provider generally.”¹⁰⁰

The free-choice-of-provider provision was intended to protect Medicaid enrollees’ ability to choose where they receive care and to ensure broad access to medical care. CMS instead proposes to limit transgender adolescents to non-hospital providers for obtaining medically necessary gender-affirming medical care. By targeting hospitals who lawfully offer gender-affirming services, the Proposed Rule violates the Medicaid Act and undermines the free-choice-of-provider guarantee.

C. The Proposed Rule Violates Section 1554 Of The Affordable Care Act.

The Proposed Rule also violates the Noninterference Mandate of Section 1554 of the Affordable Care Act (ACA),¹⁰¹ which provides that “the Secretary of Health and Human Services shall not promulgate any regulation that,” *inter alia*, “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;” “impedes timely access to health care services;” “interferes with communications regarding a full range of treatment options between the patient and the provider;” or “limits the availability of health care treatment for the full duration of a patient’s medical needs.”¹⁰²

In direct contravention of this provision, the explicit goal of the Proposed Rule is to impede the ability of minors and their families to obtain particular forms of medical care. The rule was developed to comply with Section 5(a) of Executive Order No. 14187, which directs HHS to “end” the provision of gender-affirming medical care to minors. Indeed, CMS predicts one of the purported “benefits” of the rule is that “half of the 8,570 (or 4,285) children who are receiving [gender-affirming medical care] in hospitals would stop receiving these procedures” due to “factors such as difficulty in identifying in-network providers that have available space and longer commute times.”¹⁰³ By CMS’s own admission, then, the very purpose of the regulation is to do precisely what Section 1554 prohibits: create “unreasonable barriers,” “interfere[] with,” or otherwise “limit[]” the availability of health care.

¹⁰⁰ *Planned Parenthood Ariz., Inc. v. Betlach*, 727 F.3d 960, 969 (9th Cir. 2013). Whether a provider is “qualified” is a matter primarily left to State regulation, not CMS. See *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 364 (2025). CMS cannot override State decisions about whether healthcare providers are qualified to render services through conditions wholly unrelated to the providers’ fitness to treat patients.

¹⁰¹ 42 U.S.C. § 18114.

¹⁰² See *Mayor of Baltimore v. Azar*, 973 F.3d 258, 288 (4th Cir. 2020).

¹⁰³ 90 Fed. Reg. at 59,475.

* * *

The Proposed Rule purports to exercise direct control over the “manner in which medical services are provided” in violation of SSA §§ 1801 and 1902(a)(23), as well as ACA § 1554. CMS cannot disregard congressionally mandated limitations on its authority merely by declaring—contrary to the plain text of the law, congressional intent, and common sense—that they do not apply.

III. The Proposed Rule Discriminates On The Basis of Sex In Violation of Section 1557 Of The Affordable Care Act.

Section 1557 of the 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.”¹⁰⁴ Title IX, in turn, prohibits discrimination based on sex.¹⁰⁵ Courts generally “construe Title IX’s protections consistently with those of Title VII,”¹⁰⁶ 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.¹⁰⁷ Accordingly, Section 1557 prohibits covered health programs from treating transgender patients differently from cisgender patients because of their sex or transgender status.

The Proposed Rule discriminates on the basis of sex by barring Medicare-participating hospitals from providing medical care to transgender adolescents *because they are transgender*, in direct violation of the ACA’s anti-discrimination command. It would define the terms “female” and “male” as “immutable biological classifications” characterized by reproductive system and would prohibit Medicare and Medicaid-participating hospitals from performing “any pharmaceutical intervention that attempts to align” an adolescent’s “physical appearance or body” with a gender “that differs from the individual’s sex.”¹⁰⁸ But the Proposed Rule *permits* those hospitals to provide the exact same treatments to align the adolescent’s appearance or body with a gender that *matches* their biological sex. “If one must know the [biological] sex of a person to know whether or how a provision applies to the person, the provision draws a line based on sex.”¹⁰⁹ CMS cannot bar hospitals from providing medical care on such a prohibited basis.

CMS makes no attempt to reconcile the Proposed Rule with Section 1557—the agency does not even cite the federal law. To the extent CMS suggests the Proposed Rule does not discriminate on the basis of sex because many transgender adolescents may simply switch to non-hospital providers of gender-affirming medical care,¹¹⁰ this is irrelevant.¹¹¹ Whether some adolescents can

¹⁰⁴ 42 U.S.C. § 18116(a).

¹⁰⁵ 20 U.S.C. § 1681(a).

¹⁰⁶ *Doe v. Snyder*, 28 F.4th 103, 114 (9th Cir. 2022).

¹⁰⁷ 590 U.S. 644, 669 (2020).

¹⁰⁸ 90 Fed. Reg. at 59,477.

¹⁰⁹ *Dekker v. Weida*, 679 F. Supp. 3d 1271, 1289 (N.D. Fla. 2023).

¹¹⁰ 90 Fed. Reg. 59,474–75.

¹¹¹ CMS’s suggestion is also disingenuous. As CMS acknowledges, 90 Fed. Reg. at 59,474–75, there is, at a minimum, a high cost of changing providers, and many transgender adolescents will be unable to continue receiving the gender-

find alternative providers of care has no bearing on whether the Proposed Rule violates federal antidiscrimination principles. The Proposed Rule remains inconsistent with Section 1557 by denying transgender adolescents meaningful access to treatment they seek because they are transgender, while ensuring that those same services remain available to those who are not transgender. This is textbook discrimination based on sex.

By its terms, the Proposed Rule would penalize hospitals for offering so-called “sex-rejecting” procedures, treatment that would “align an individual’s physical appearance or body” with a gender “that differs from the individual’s sex” assigned at birth, but permit the same treatment for any other purpose, including to “align” the individual’s physical appearance with characteristics of their birth-assigned sex.¹¹² This disparate treatment thus “entrenches the belief that transgender individuals must preserve the genitalia and other physical attributes of their natal sex over not just personal 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.”¹¹³

CMS does not rely on the Supreme Court’s decision in *Skrmetti* to evade Section 1557’s antidiscrimination command. Nor could it for at least three reasons. First, *Skrmetti* was decided on constitutional grounds; the case is silent as to statutory sex discrimination claims.¹¹⁴ Second, even if *Skrmetti*’s constitutional holdings were relevant, the Court acknowledged that “invidious discrimination” against transgender individuals *may* violate the Equal Protection Clause.¹¹⁵ 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.

* * *

In sum, the Proposed Rule is contrary to law because it discriminates based on sex and transgender status, in violation of ACA § 1557. 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.

IV. The Proposed Rule Violates The Constitution’s Equal Protection Guarantee.

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

affirming medical care they need at non-hospital providers because of the limited in-network options and longer commute times.

¹¹² 90 Fed. Reg. at 59,477.

¹¹³ *Boyden v. Conlin*, 341 F. Supp. 3d 979, 997 (W.D. Wis. 2018).

¹¹⁴ 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.”).

¹¹⁵ *United States v. Skrmetti*, 605 U.S. 495, 518 (2025).

contains an equal protection component prohibiting the United States from invidiously discriminating between individuals or groups.”¹¹⁶ Gender identity is a protected characteristic under the equal protection guarantee and is subject to heightened scrutiny.¹¹⁷ To pass muster, the Proposed Rule must be “substantially related to a sufficiently important government interest.”¹¹⁸ Desire “to harm a politically unpopular group” can never satisfy this standard.¹¹⁹

On its face, the Proposed Rule prohibits hospitals from providing medical care and services on the basis of a patient’s sex. The Proposed Rule does not focus on any particular medical treatment but on the particular motive for seeking or providing 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.¹²⁰ Because the Proposed Rule would bar hospitals from providing treatment only to a class of transgender patients, 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.”¹²¹ Not only is the Proposed Rule an “unusual deviation” into an area traditionally regulated by the States, 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.”¹²² 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.”¹²³ “The Administration has been explicit about its disapproval of the transgender community and its aim to end [gender-affirming medical care].”¹²⁴ And as “part of a coordinated and rapid rollback of rights and protections previously afforded to transgender Americans,”¹²⁵ 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.

¹¹⁶ *Washington v. Davis*, 462 U.S. 229, 239 (1976).

¹¹⁷ See *Flack v. Wisconsin Dep’t of Health Servs.*, 328 F. Supp. 3d 931, 952–953 (W.D. Wis. 2018).

¹¹⁸ *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 441 (1985).

¹¹⁹ *United States v. Windsor*, 570 U.S. 744, 770 (2013).

¹²⁰ *Skrmetti*, 605 U.S. at 519 n.3.

¹²¹ *Id.* at 497.

¹²² *Windsor*, 570 U.S. at 770.

¹²³ *Talbott v. United States*, 775 F. Supp. 3d 283, 331 (D.D.C. 2025).

¹²⁴ *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239.

¹²⁵ *Orr*, 778 F. Supp. 3d at 417–18.

CMS, for its part, has not (and cannot) offer an “exceedingly persuasive justification” for the Proposed Rule to establish the necessary close “means-end fit.”¹²⁶ CMS’s asserted interest in “the health and safety of children,”¹²⁷ cannot justify what CMS acknowledges would cause thousands of transgender adolescents to lose access to the medical care they rely on.

First, the Proposed Rule *undermines* CMS’s asserted interest in “child safety.” 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.

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.¹²⁸ 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.”¹²⁹

Second, the 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. The Proposed Rule admits as much by permitting hospitals to offer the same medical interventions to cisgender youth. CMS’s assertions about child safety concerns 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 ban hospitals from providing 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.

V. The Proposed Rule Is Arbitrary, Capricious, And Contrary to the Weight of Scientific Evidence.

CMS’s decision to bar hospitals from offering gender-affirming medical care to minors is also arbitrary and capricious under the Administrative Procedure Act.¹³⁰ Agency actions are arbitrary and capricious when they reverse previous policies without sufficient explanation, rely on flawed

¹²⁶ *Sessions v. Morales-Santana*, 582 U.S. 47, 58, 68 (2017).

¹²⁷ 90 Fed. Reg. at 59,470.

¹²⁸ See *infra* n.184-190 and accompanying text.

¹²⁹ Dopp, *infra* n.165, at 35.

¹³⁰ See 5 U.S.C. § 706(2).

evidence, disregard important evidence, and fail to account for serious reliance interests.¹³¹ All 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.”¹³² 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.”¹³³ And the agency went on to note that “individuals who are experiencing gender dysphoria . . . have a clinically significant decrease in distress if they have access to medically necessary care.”¹³⁴ CMS now seeks to reverse course entirely and prohibit hospitals from providing transgender youth 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.

Nor has CMS explained its new claim that gender-affirming medical care is not health care within the meaning of the Medicare Act. Until now, CMS has treated gender-affirming services like any other health care service under the Medicare Act. Under Section 1862(a)(1), Medicare coverage is available only for items or services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” CMS previously recognized that gender-affirming medical care satisfies this standard in appropriate circumstances and authorized local Medicare Administrative Contractors (MACs) to make coverage determinations for gender reassignment surgery “on a case-by-case basis.”¹³⁵ Yet CMS makes no mention of its previous policy, much less a reasoned explanation for reversing it. That is arbitrary and capricious to a tee.¹³⁶

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

¹³¹ See, e.g., *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–222 (2016).

¹³² *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).

¹³³ 89 Fed. Reg. at 37,575.

¹³⁴ *Id.*

¹³⁵ CMS, Medicare National Coverage Determinations Manual § 140.9 (2023), https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part2.pdf. Using this authority, MACs have issued local coverage determinations (LCDs) that establish coverage criteria for gender-affirming medical care. See, e.g., Palmetto GBA (MAC jurisdictions J and M, Alabama, Georgia, Tennessee, South Carolina, Virginia, West Virginia, North Carolina), Treatment of Males with Low Testosterone (LCD L39086), <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39086&ver=10&bc=0>.

¹³⁶ See *Encino Motorcars*, 579 U.S. at 221–222 (requiring an agency to “display awareness that it is changing position,” show “good reasons for the new policy,” and take into account “serious reliance interests”).

Best Practices.”¹³⁷ The HHS Review does not provide a well-founded justification for barring Medicare and Medicaid-participating hospitals from offering 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.¹³⁸

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.”¹³⁹ 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.¹⁴⁰ FACA authorizes federal agencies to utilize “advisory committees” to furnish “expert advice, ideas, and diverse opinions,” though “new 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.¹⁴¹ 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.”¹⁴² 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.”¹⁴³

¹³⁷ 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>.

¹³⁸ 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”).

¹³⁹ Denial-of-Care Order, §§ 1, 2(c).

¹⁴⁰ 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).

¹⁴¹ 5 U.S.C. § 1002(a).

¹⁴² *Id.* § 1004(b)(2), (c)).

¹⁴³ 41 C.F.R. § 102-3.60(b)(1), (2).

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.”¹⁴⁴ 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.¹⁴⁵ 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.¹⁴⁶ Alex Byrne is a philosopher, not a doctor, but has authored a “polemic” book characterizing “transgender healthcare” as an “inflammatory social and political issue[.]”¹⁴⁷ After it was revealed that Byrne helped draft the HHS Review,¹⁴⁸ 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 youth.¹⁴⁹ 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.¹⁵⁰ 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-

¹⁴⁴ CMS, *Medicare Evidence Development & Coverage Advisory Committee*, <https://www.cms.gov/medicare/regulations-guidance/advisory-committees/evidence-development-coverage> (last visited Feb. 17, 2026).

¹⁴⁵ See 5 U.S.C. §§ 1008–09.

¹⁴⁶ Society for Evidence Based Gender Medicine, *What Does SEGM Do?*, https://segm.org/about_us (last visited Feb. 17, 2026).

¹⁴⁷ Alex Byrne, *Trouble with Gender* vii (Polity Press; 2024), <http://www.alexbyrne.org/trouble-with-gender.html>.

¹⁴⁸ 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/>

¹⁴⁹ Dear Professor Alex Byrne (June 26, 2025), <https://dearprofessorbyrne.wordpress.com/>.

¹⁵⁰ See Moti Gorin, Colorado State Univ., <https://www.libarts.colostate.edu/people/mgorin/> (last accessed 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).

affirming medical care in litigation—¹⁵¹ though all three have made statements opposing gender-affirming care.¹⁵²

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.¹⁵³

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.

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.¹⁵⁴ 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.¹⁵⁵ And even the Review’s cherry-picked studies are open to significant critique.

¹⁵¹ 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).

¹⁵² Curlin has expressed opposition to gender-affirming medical care for adults as contradicting the purposes of medicine. Kaliebe opposes gender affirmation for transgender youth. 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. Fla. 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.

¹⁵³ 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://belgipaediatrics.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. Geneesk.* (2023), <https://www.ntvg.nl/artikelen/onzekeerheden-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).

¹⁵⁴ 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).

¹⁵⁵ HHS Review at 11.

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.¹⁵⁶ 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 Cass Review itself 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.¹⁵⁷

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.”¹⁵⁸ 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 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.”¹⁵⁹

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.”¹⁶⁰ 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).”¹⁶¹

¹⁵⁶ Cal Horton, *The Cass Review: Cis-Supremacy in the UKs’ Approach to Healthcare for Trans Children*, Int’l J. Transgender Health 1 (2024).

¹⁵⁷ See, e.g., Meredith McNamara et al., *An Evidence-Based Critique of “The Cass Review” on Gender-Affirming medical/medical 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.158; 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).

¹⁵⁸ 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>.

¹⁵⁹ *Id.*

¹⁶⁰ 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).

¹⁶¹ *Id.* at 5.

The HHS Review also failed to adequately consider more recent clinical practice guidelines from France and Germany endorsing gender-affirming medical care for adolescents,¹⁶² 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.¹⁶³ 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).”¹⁶⁴ 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.”¹⁶⁵ The authors went on to 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.”¹⁶⁶ Finally, the Utah Review found there is “virtually no regret associated with receiving treatments,” even among those who stop taking them.¹⁶⁷

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. *Dekker*, 679 F. Supp. 3d at

¹⁶² 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).

¹⁶³ 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).

¹⁶⁴ *Id.*

¹⁶⁵ 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).

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 91.

1285. By adopting the HHS Review, the Proposed Rule makes identical errors which leads to an arbitrary and capricious result.¹⁶⁸

First, the HHS Review’s claim that gender-affirming medical care is based on “low quality evidence” does not hold up.¹⁶⁹ 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.¹⁷⁰ 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.¹⁷¹ 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.¹⁷²

HHS was wrong to claim that the lack of “randomized controlled trials” involving gender-affirming medical care indicated a “lack of methodologically rigorous studies.”¹⁷³ 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.¹⁷⁴ 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.”¹⁷⁵ This analysis is backwards: The substantial evidence of benefit for the overwhelming majority of

¹⁶⁸ *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”).

¹⁶⁹ See, e.g., HHS Review at 71, 74, 91, 97.

¹⁷⁰ Dkt. No. 6, Expert Declaration of Dr. Armand Antommara, at ¶¶ 6, 20–41, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

¹⁷¹ *Id.* at ¶¶ 37–38.

¹⁷² 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); Tornese, *supra* n.47, at 2.

¹⁷³ See, e.g., HHS Review at 92.

¹⁷⁴ HHS Review, *supra* n.45, at 85.

¹⁷⁵ *Id.* at 13, 101.

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.¹⁷⁶

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.”¹⁷⁷ However, *all* psychiatric conditions are diagnosed based on self-reporting and behavioral observations.¹⁷⁸ So are medical conditions like migraines. But HHS did not single out depression or 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).”¹⁷⁹ 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. 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.¹⁸⁰

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

¹⁷⁶ Expert Declaration of Hilary Mabel, JD, HEC-C, at ¶¶ 30, 33, 46, *Soe v. Louisiana State Bd. of Med. Exam’rs*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

¹⁷⁷ HHS Review, *supra* n.45, at 22.

¹⁷⁸ 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).

¹⁷⁹ HHS Review at 22.

¹⁸⁰ 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 Antommara, 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).

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.¹⁸¹ In medicine, treatment with an improvement rate of 70% is considered a very powerful intervention.¹⁸² 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.¹⁸³ 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.¹⁸⁴ 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.¹⁸⁵ These youths are then at high risk of suicidality, self-harm, depression, and anxiety compared to their peers.¹⁸⁶ Lack of access to gender-affirming care therefore directly contributes to poorer mental health outcomes for transgender people.¹⁸⁷

Fourth, the HHS Review’s 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.¹⁸⁸ “Detransition,” unlike regret, refers to ceasing treatment or undoing “social, medical, and/or administrative changes achieved” through gender transition.¹⁸⁹ 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

¹⁸¹ Turban, et al., *supra* n.24, at e20191725.

¹⁸² 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).

¹⁸³ Turban, et al., *supra* n.24, at e0287283; *see also* Allen, et al., *supra* n.24, at 114883; 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).

¹⁸⁴ *See* Dkt. No. 6, Expert Declaration of Dr. Armand Antommara, at 24, *Loe v. Kansas*, No. DG-2025-cv-000241 (Kan. Dist. Ct. 2025).

¹⁸⁵ *See* Expert Declaration of Dr. Jennifer Creedon, at ¶¶ 76-77, *Soe v. Louisiana State Bd. of Med. Exam’rs*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

¹⁸⁶ *See* Kameg & Nativio, *supra* n.9.

¹⁸⁷ 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).

¹⁸⁸ *See* Mireille Chehade et al., *Patient-Related Decisional Regret: An Evolutionary Concept Analysis*, 33 *J. Clinical Nursing* 4484 (2024).

¹⁸⁹ 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).

discrimination after transitioning (31%), having trouble getting a job (29%), or pressure from a parent (36%), spouse (18%), or other family members (26%).”¹⁹⁰

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).¹⁹¹ 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).¹⁹² To the contrary, studies report “overwhelmingly positive” results from gender-affirming medical care “compared with other medical and nonmedical decisions.”¹⁹³

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,¹⁹⁴ and another 2024 study revealed almost half of patients who had undergone weight loss surgeries expressed some level of regret postoperatively.¹⁹⁵ Despite the high levels of reported regret, minors are routinely encouraged to undergo weight loss surgery.¹⁹⁶

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

¹⁹⁰ 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>.

¹⁹¹ 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).

¹⁹² See de Vries et al., *supra* n.24; 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.194; 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).

¹⁹³ Bruce et al., *supra* n.194, at E5.

¹⁹⁴ 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).

¹⁹⁵ Phillip J. Dijkhorst et al., *Factors Associated with Decision Regret After Bariatric Surgery*, 14 *Clinical Obesity* e12597 (2024).

¹⁹⁶ See Maurizio De Luca et al., *Scientific Evidence for the Updated Guidelines on Indications For Metabolic and Bariatric Surgery*, 34 *Obesity Surgery* 3963 (2024).

medications.¹⁹⁷ 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.¹⁹⁸

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.¹⁹⁹ Existing research demonstrates that gender-affirming medical treatments for adolescents with gender dysphoria are consistently linked to improved mental health.²⁰⁰ Peer-reviewed and cross-sectional studies demonstrate an association between pubertal suppression and improved mental health outcomes.²⁰¹ Longitudinal studies show similar results.²⁰² The same is true for gender-affirming hormone therapy.²⁰³

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.²⁰⁴ 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.²⁰⁵

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.²⁰⁶ As

¹⁹⁷ Blake S. Cavve et al., *Reidentification With Birth-Registered Sex in a Western Australian Pediatric Gender Clinic Cohort*, 178 JAMA Pediatrics 446 (2024).

¹⁹⁸ van der Loos et al., *supra* n.195, at 869.

¹⁹⁹ *Supra* ____.

²⁰⁰ 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. Exam’rs*, 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. Exam’rs*, No. 751385, Div. 21 (La. 19th Jud. Dist. Ct. 2025).

²⁰¹ See, e.g., de Vries et al., *supra* n.24 Turban et al., *supra* n.24, at e20191725; van der Miesen et al, *supra* n.24; Achille et al., *supra* n.24.

²⁰² 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.____.

²⁰³ 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.24; López de Lara et al., *supra* n.24.

²⁰⁴ WPATH SOC8, *supra* n.16, at S50–51.

²⁰⁵ 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).

²⁰⁶ 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*

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.²⁰⁷

4. Even If The HHS Report’s Methodology And Conclusions Were Sound (They are Not), That Does Not Justify Barring Hospitals from Providing 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 barring Medicare and Medicaid-participating hospitals from offering medically necessary gender-affirming medical care for adolescents. An agency must provide “a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.”²⁰⁸ 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.”²⁰⁹ To the extent CMS relied on the HHS Review, the Review itself therefore suggests further research rather than “broad implementation.”²¹⁰ Moreover, the

LGBTQI+ Youth, SAMHSA Pub. No. PEP22-03-12-001 (2023), <https://archive.org/details/httpsstore.samhsa.gov/sites/default/files/pep22-03-12-001>. 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.165, 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.

²⁰⁷ 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>.

²⁰⁸ *Ohio v. EPA*, 603 U.S. 279, 292 (2024) (quoting *State Farm*, 463 U.S. at 43).

²⁰⁹ HHS Review, *supra* n.45, at 3-4, 85.

²¹⁰ *See also* Gordon Guyatt, et al., *Systematic reviews related to gender-affirming care* (Aug. 14, 2025) (the Guyatt Statement) (available at <https://hei.healthsci.mcmaster.ca/systematic-reviews-related-to-gender-affirming-care/>). The Guyatt Statement is signed by five authors of recent systematic reviews related to gender-affirming care whose research concluded that “only low certain evidence exists ...regarding the benefits of gender-affirming medical care interventions.” *Id.* The authors made clear that their findings should not be used “to forbid clinicians from delivering

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.²¹¹ 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.²¹²

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.²¹³ 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. Nothing in the HHS Review justifies excluding hospitals providing gender-affirming medical care from the entire Medicare and Medicaid program.

* * *

In short, the HHS Review does not provide a well-founded justification for barring Medicare and Medicaid-participating hospitals from offering 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.

C. The Proposed Rule Fails To Consider Serious Reliance Interests And The Downstream Costs Of Barring Hospital From Providing 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 barring Medicare and Medicaid-participating hospitals from providing this care.²¹⁴

Multiple stakeholders rely on Medicare and Medicaid-participating hospitals’ ability to offer 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

gender-affirming care” and called such efforts “unconscionable.” *Id.* The authors further commented that it is “profoundly misguided to cast health care based on low-certainty evidence as bad care or as care driven by ideology, and low-certainty evidence as bad science” because “[m]any of the interventions” health care providers offer “are based on low certainty evidence” and patients “often legitimately and wisely choose such interventions.” *Id.*

²¹¹ Dkt. No. 6, Expert Declaration of Dr. Armand Antommara, 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).

²¹² 42 U.S.C. § 1396d(a)(30).

²¹³ See Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report* 30, 35, 180, 197 (Apr. 2024).

²¹⁴ 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).

staffing and training investments to account for gender-affirming medical care; and States whose funding and investment decisions may have relied on Medicare and Medicaid-participating hospitals providing gender-affirming medical care to 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.²¹⁵

The Proposed Rule recognizes that some transgender patients will be forced to seek alternative providers but does not acknowledge the additional societal and financial costs to this switch. Patients and their families will be forced to abandon trusted healthcare providers to seek treatment elsewhere—assuming they can find accessible treatment at all. Providers 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.”²¹⁶ 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.²¹⁷ The Proposed Rule considers none of these costs.

The Proposed Rule similarly fails to consider the society-wide cost of excluding hospitals from the Medicare and Medicaid programs. For those hospitals that continue to provide gender-affirming medical care for adolescents and are consequently excluded from Medicare and Medicaid, millions (if not tens of millions) of Medicaid and Medicare recipients will lose access to needed health care—from cardiac surgery to cancer treatment to primary care—at those hospitals, will be forced to seek care from providers not of their choosing at other hospitals, or may lose access to this care altogether. CMS has not demonstrated that it has considered the societal costs of terminating huge swaths of care or determined whether those costs are actually outweighed by the Proposed Rule’s benefit.

CONCLUSION

If CMS were to finalize its Proposed Rule prohibiting Medicare and Medicaid-participating hospitals from providing gender-affirming medical care to young people, thousands of transgender adolescents will lose access to critical medical care they depend on to treat their gender dysphoria—regardless of whether they are Medicare or Medicaid recipients. The Proposed Rule is unconstitutional, exceeds CMS’s authority, violates the Medicare and Medicaid Acts and anti-discrimination law, and is arbitrary, capricious, and contrary to scientific and medical evidence. It is also wrong. If CMS proceeds with this action, it will face immediate and multi-pronged challenges in court, and it will lose.

²¹⁵ *Solar Energy Indus. Ass’n v. FERC*, 80 F.4th 956, 981 (9th Cir. 2023).

²¹⁶ *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 56 (D.D.C. 2020).

²¹⁷ *Id.* at 56.

Respectfully submitted,

AMERICAN CIVIL LIBERTIES UNION
FOUNDATION

Joshua Block
Harper Seldin
Alexandra R. Johnson
125 Broad Street, Floor 18
New York, NY 10004
Telephone: (212) 549-2500
Facsimile: (212) 549-2650
jblock@aclu.org
hseldin@aclu.org
a.johnson@aclu.org

Barbara Schwabauer
Dena Robinson
915 15th Street NW
Washington, DC 20005
bschwabauer@aclu.org
DRobinson@aclu.org

LAMBDA LEGAL DEFENSE AND EDUCATION
FUND, INC.

Omar Gonzalez-Pagan
Karen L. Loewy
Jessica Polansky
Luna Floyd
120 Wall Street, 19th Floor
New York, NY 10005
Telephone: (212) 809-8585
Facsimile: (855) 535-2236
ogonzalez-pagan@lambdalegal.org
KLoewy@lambdalegal.org
jpolansky@lambdalegal.org
LFloyd@lambdalegal.org

Nora Huppert
3656 N. Halsted St.
Chicago, IL 60613
Telephone: (312) 663-4413
nhuppert@lambdalegal.org

LAMBDA LEGAL DEFENSE AND EDUCATION
FUND, INC.

Nicholas J. Hite
3500 Oak Lawn Avenue, Suite 500
Dallas, TX 175219
Telephone: (214) 219-8585
nhite@lambdalegal.org

With Enclosures

