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February 17, 2026

Via Federal Rulemaking Portal (Reglations.gov)

Secretary Robert F. Kennedy, Jr.

Department of Health and Human Services
Office of Civil Rights
Attention: Condition of Participation NPRM
RIN 0938–AV87, File Code CMS–3481–P
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW, Washington, DC 20201

RE: **Comment on Notice of Proposed Rulemaking to Amend CMS Hospital Condition of Participation to Prohibit Provision of Certain Gender Affirming Care Services for Youth.**

Dear Secretary Kennedy:

On behalf of the Attorneys General of New York, Connecticut, Illinois, Massachusetts, New Mexico, Washington, Arizona, California, Colorado, the District of Columbia, Delaware, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, Oregon, Rhode Island, Vermont, and Wisconsin (the "Undersigned States"), we submit a comment and request for immediate withdrawal of the proposed rule issued by the United States Department of Health and Human Services ("HHS"), Medicaid Program; Proposed Rule Seeking to Amend CMS Hospital Condition of Participation to Prohibit Provision of Certain Gender Affirming Care Services for Young People, December 18, 2025, 90 Fed. Reg. 59463 (Dec. 19, 2025) (to be codified at 42 C.F.R. § 482.46) [hereinafter, "Proposed Rule"], File Code CMS–3481–P. The Notice of Proposed Rulemaking ("NPRM") proposes to prohibit hospitals from providing certain forms of healthcare for transgender youth as a condition of participation in the Medicare and Medicaid programs. As

explained below, this change is an unlawful overreach that is part and parcel of this Administration's efforts to harm transgender people.

The Undersigned States strongly oppose the Proposed Rule and urge HHS to continue to permit Medicaid and Medicare participating hospitals to provide medically necessary healthcare to transgender youth. As Attorneys General, we are deeply concerned that the Proposed Rule is merely a pretextual attempt to further this Administration's ongoing efforts to undermine the essential rights of youth living with gender dysphoria nationwide, including in states with laws that protect their right to receive medically necessary healthcare. With no regard for states' historic role and interests, the Proposed Rule would cast aside the established federal-state partnership over administration of the Medicaid and Medicare Programs that rely on "state lawmakers, not the federal government," as "the primary regulators of professional [medical] conduct."[1]

I. INTRODUCTION

Since the first days of President Trump's second term, the Administration has repeatedly and aggressively targeted transgender individuals and implemented coordinated efforts to end all transgender healthcare[2] for youth. December 18, 2025, marked a significant escalation in the Administration's attacks on transgender healthcare for youth. That day, the U.S. Department of Health and Human Services ("HHS") announced a series of coordinated actions designed to end transgender healthcare for youth: It issued this Proposed Rule, which would prohibit hospitals that participate in Medicare or Medicaid from providing transgender healthcare to youth, alongside two other proposed rules, one of which would end Medicaid and Children's Health Insurance Program ("CHIP") reimbursement for states that provide transgender healthcare ("the Medicaid Reimbursement Proposed Rule") and another which would eliminate a prior rule classifying gender dysphoria as a "disability" covered by Section 504 of the Rehabilitation Act.[3] Additionally, HHS Secretary Robert F. Kennedy, Jr. issued an unprecedented "Declaration" which declares that healthcare for treating gender dysphoria in transgender youth "fails to meet professional recognized standards of health care," and in doing so sweeps aside all contrary "Statewide or national standards of care," including those recommended by national medical organizations ("the Kennedy Declaration").[4] The Kennedy Declaration appears to authorize HHS to exclude *all*

[1] *Oregon v. Ashcroft*, 368 F.3d 1118, 1124 (9th Cir. 2004), *aff'd sub nom. Gonzales v. Oregon*, 546 U.S. 243 (2006) (citations omitted).

[2] In this comment, "medically necessary transgender healthcare" and "transgender healthcare" refer to medical treatment to treat gender dysphoria, also referred to as "gender-affirming care."

[3] *See* Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59441 (proposed Dec. 19, 2025), https://perma.cc/ZK4W-XUFN; Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 90 Fed. Reg. 59478 (proposed Dec. 19, 2025), https://perma.cc/ZND5-TEJN.

[4] Many of the Undersigned States have challenged the Kennedy Declaration as unlawful. *See State of Oregon et al. v. Kennedy et al.*, 6:25-cv-02409 (D. OR.).

providers—not just hospitals—from participation in federally funded healthcare programs if they offer transgender healthcare to adolescents, independent of the promulgation of the Proposed Rule.

The Proposed Rule—aimed at barring hospitals from providing medically necessary transgender healthcare to youth—is a cornerstone of this coordinated attack. The Proposed Rule turns the federal-state healthcare partnership upside down and deprives the States of their congressionally designated ability to run Medicaid programs and regulate the practice of medicine in ways that ensure access to medically necessary healthcare.

As addressed in this letter, the Proposed Rule impermissibly intrudes on the States' rights to regulate medicine within their borders; violates the Spending Clause; is contrary to various statutes; is arbitrary and capricious; is not based on substantial evidence; is discriminatory; and demonstrates HHS's failure to provide required regulatory impact and flexibility analyses. HHS should withdraw the Proposed Rule for all these reasons.[5]

II. BACKGROUND

A. The Administration's Coordinated Attacks on Transgender Healthcare.

On his first day in office, the President issued Executive Order 14168, which directed agencies to prohibit federal funding to promote "gender ideology" and adopt a definition of "sex" that denies the existence of transgender people. Eight days later, the President issued Executive Order 14187, "Protecting Children From Chemical and Surgical Mutilation." In this Order, the President called transgender healthcare a "horrifying tragedy," and "a stain on our Nation's history" that "must end." The Order directed federal agencies to take steps to end access to medically necessary healthcare for transgender individuals under the age of 19, which healthcare the President refers to as "the chemical and surgical mutilation of children."[6] The Administration's goals in these Orders are explicit: to deny the existence of transgender people by declaring it the official policy of the United States that there are only two sexes and that gender is immutable, and to end transgender healthcare for youth nationwide.[7]

Agencies throughout the Administration have taken aggressive action to implement these policy objectives. Through a series of escalating threats, the Administration has pressured providers and States to cease offering and protecting medically necessary transgender healthcare.[8] First, on March 5, 2025, the Centers for Medicare & Medicaid Services ("CMS") issued a Quality & Safety Special Alert Memo ("QSSAM") to "alert[]" hospital providers and other covered entities

[5] Many of the Undersigned States have also submitted a comment letter on the Medicaid Reimbursement Proposed Rule. We incorporate by reference that comment letter and all the arguments and sources cited therein.
[6] Exec. Order No. 14,187, 90 Fed. Reg. 8,771 (Jan. 28, 2025).
[7] Exec. Order No. 14,168, 90 Fed. Reg. 8615 (Jan. 20, 2025).
[8] *See* Proposed Rule at 59470 (describing coordinated actions by CMS targeting transgender healthcare for youth).

of the agency's newfound concerns about what it referred to as "the dangerous chemical and surgical mutilation of children," reminding hospitals of their duty to adhere "to the highest standard of care that is informed by robust evidence and the utmost scientific integrity" and warning that "CMS may begin taking steps in the future" to restrict treatment for gender dysphoria."[9] The next day, the Health Resources & Services Administration ("HRSA") and the Substance Abuse and Mental Health Services Administration ("SAMHSA") sent dear colleague letters reiterating the position taken in the QSSAM.[10] Then on April 11, 2025, CMS sent a State Medicaid Director's letter with the stated purpose of "reminding states of their responsibility to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interest of recipients" and suggesting states take steps to limit medically necessary transgender healthcare for youth within their state Medicaid programs.[11] On April 14, 2025, HHS launched a portal where members of the public could report alleged "chemical and surgical mutilation of children."[12] On April 22, 2025, the Department of Justice ("DOJ") issued a memorandum that directed officials to investigate and prosecute medical providers and pharmaceutical companies that offer medically necessary transgender healthcare. In the memo, U.S. Attorney General Bondi asserted she will use the Department of Justice to "bring [] an end" to medically necessary healthcare for transgender adolescents and young adults. On May 28, 2025, CMS sent a letter to healthcare providers that receive Medicare and Medicaid funding asking for information on their organization's policies on informed consent protocols, billing codes, and revenue generated from treatment for gender dysphoria, among other information.[13]

These actions, separately and in the aggregate, have instilled fear in healthcare providers and patients and caused many hospitals to limit or end their provision of medically necessary transgender healthcare. As the Administration publicly proclaimed, this was its "intended effect—preventing children from being maimed and sterilized by adults perpetuating a radical, false claim that they can somehow change a child's sex."[14] In the wake of these shut downs, the White House boasted: "Hospitals around the country are taking action to downsize or eliminate their so-called 'gender-affirming care' programs" and "Health systems across the nation stopped or downsized their sex change programs for minors following President Trump's [EO]."[15]

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[9] CMS, *Protecting Children from Chemical and Surgical Mutilation* (Mar. 5, 2025), https://perma.cc/Y9TM-YTBM.
[10] HRSA, Dear Colleague letter (Mar. 6, 2025), https://perma.cc/PE3R-XGJF; s*ee also* SAMHSA letter, *PFLAG, et al. v. Trump, et al.,* 8:25-cv-00337-BAH, Doc. 118-1, pg. 3.
[11] CMS, *RE: Puberty blockers, cross-sex hormones, and surgery related to gender dysphoria* (April 11, 2025), https://perma.cc/N6ZM-HXWG.
[12] HHS, *HHS Takes Action to Protect Whistleblowers who Defend Children and Launches First Conscience Investigation* (Apr. 14, 2025), https://perma.cc/A73S-QRLN.
[13] HHS, *Urgent Review of Quality Standards and Gender Transition Procedures* (May 28, 2025), https://perma.cc/KVY6-FZEL.
[14] White House, *President Trump is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025), https://perma.cc/R79H-P25M.
[15] *Id.*; White House, *President Trump is Protecting America's Children* (March 4, 2025), https://perma.cc/HS3J-PJH6.

The Administration then turned to marshalling support for its agenda. In May 2025, HHS issued a report, subsequently revised in November 2025, titled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" (the "HHS Report"),[16] ostensibly to review the existing evidence of the benefits and risks of medically necessary transgender healthcare and ultimately condemning the provision of such care for youth. In July of 2025, DOJ announced that it "sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children" to investigate "healthcare fraud, false statements, and more."[17] The same month, the Administration enlisted the Federal Trade Commission ("FTC") in its efforts, and the Commission issued a request for public comment on "how consumers may have been exposed to false or unsupported claims about 'gender-affirming care' (GAC), especially as it relates to minors, and to gauge the harms consumers may be experiencing[,]" baselessly arguing that such care has been subject to "potential deceptive or unfair practices involved in this type of medical care."[18] This came on the heels of a workshop the FTC held on the same topic.[19]

As discussed above, December 18, 2025, marked a significant escalation of the administration's attack on transgender healthcare, when various HHS officials and components issued unlawful orders and proposed rules, including the Proposed Rule addressed here.

B. Medicare Conditions of Participation and the Proposed Rule.

Under Section 1861(e)(9) of the Social Security Act, CMS may "establish health and safety regulations" that hospitals must meet in order to participate in the Medicare program. Known as "conditions of participation" ("CoPs"), these regulations establish minimum health and safety standards that participating hospitals must meet, including "maintain[ing] clinical records on all patients,"[20] providing 24-hour nursing services,[21] adopting a hospital utilization review plan and discharge planning process,[22] requiring that Medicare patients be treated by a physician or clinical psychologist,[23] and meeting state licensing requirements.[24] Because hospitals that receive Medicaid payments must also meet Medicare CoPs, Medicare CoPs apply to both Medicare—and

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[16] 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.
[17] DOJ, *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children* (July 9, 2025), https://perma.cc/H7FF-Y2HV. As discussed below, every court to have considered the propriety of these subpoenas, at the time of this comment, has held that they are improper, pretextual attempts to end medically necessary transgender healthcare, overly broad, or both. *See infra* Section III.D.1.
[18] *See* FTC, *Request for Public Comment Regarding "Gender-Affirming Care" for Minors* (Jul. 27, 2025), https://share.google/vFRdm0ZZBdIGnlzii.
[19] *See* FTC, *The Dangers of "Gender-Affirming Care" for Minors* (July 9, 2025), https://perma.cc/2B48-V2GT.
[20] 42 U.S.C. § 1395x(e)(2).
[21] 42 U.S.C. § 1395x(e)(5).
[22] 42 U.S.C. § 1395x(e)(6).
[23] 42 U.S.C. § 1395x(e)(4).
[24] 42 U.S.C. § 1395x(e)(7).

Medicaid—participating hospitals. [25] CoP regulations have never been used to outlaw treatment modalities or single out disfavored medical treatments. In fact, the Proposed Rule itself concedes that conditions of participation are typically "specific, process-oriented requirements," such as having emergency and standby power systems.[26]

Yet the Proposed Rule proposes to add as a condition of participation that hospitals may not perform "sex-rejecting procedures" on any "child," whether or not they are covered by Medicaid, Medicare, private insurance, self-pay, or any other source of health insurance. The "sex-rejecting procedures" the Rule proposes to bar are broadly defined as:

> [A]ny pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex either by: (i) Intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits; or (ii) Intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.[27]

Practically speaking, this means hospitals will not be able to participate in the Medicare or Medicaid system if they provide transgender healthcare to patients under the age of 18.

C. Transgender Healthcare Is Medically Necessary Care.

For some transgender people, the incongruence of living in their birth sex can cause clinically significant distress, recognized by the American Psychiatric Association's *Diagnostic & Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* ("DSM-5-TR") as "gender dysphoria."[28] To be diagnosed as gender dysphoria, the incongruence must persist for at least six months and be accompanied by clinically significant distress or impairment in social, occupational, or other important areas of functioning.[29] Gender dysphoria, which even HHS recognizes as a medical condition, is undisputedly serious.[30]

Medical treatments for gender dysphoria are provided based on individualized assessments and require informed parental consent when provided to youth. Medical treatments for gender

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[25] Kate Keith, *Proposed Federal Rules Target Health Care For Transgender Youth (Part 2)*, Health Affairs (Dec. 23, 2025), https://www.healthaffairs.org/content/forefront/proposed-federal-rules-target-heatlh-care-transgender-youth-part-2.
[26] Proposed Rule at 59464.
[27] Proposed Rule at 59477.
[28] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 513–14 (5th ed., text rev. 2022).
[29] *Id.* at 512–13
[30] *See* HHS Report, *supra* note 14, at 10 ("Gender dysphoria is a condition that involves distress regarding one's sexed body and/or associated social expectations. Increasing numbers of children and adolescents in the U.S. and other countries are diagnosed with gender dysphoria. Internationally, there is intense disagreement about how best to help them.").

dysphoria encompass a broad array of medical and psychosocial interventions that vary based on age and other factors, and may include counseling, speech therapy, hormone therapies, puberty-delaying medications, and (in rare cases for youth) surgery.[31] Because the Proposed Rule is aimed at endocrine and surgical treatments, this letter focuses on those forms of medical care for gender dysphoria, and refers to those treatments collectively as "transgender healthcare." Endocrine treatment for gender dysphoria includes hormone therapy and puberty-blocking medications. Hormone therapies used to treat gender dysphoria allow a transgender individual to develop physical traits consistent with their lived sex.[32] These same hormone therapies can also be medically appropriate to prescribe for non-transgender adolescents with delayed puberty or other conditions such as polycystic ovarian syndrome or nonhormonal conditions such as idiopathic hirsutism.[33] Puberty-delaying medications, which include gonadotropin-releasing hormone agonists and are sometimes called "puberty blockers," generally regulate sex hormone production and effectively (and temporarily) "pause" the onset of puberty.[34] They have been studied extensively, are FDA-approved, and are also medically indicated treatments for other conditions, such as precocious puberty in both male and female patients.[35] Surgical treatment can involve a variety of medically necessary procedures, but consistent with guidelines for transgender healthcare, it is rarely used to treat gender dysphoria in adolescents.[36]

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[31] Danyon Anderson et al., *Gender Dysphoria and Its Non-Surgical and Surgical Treatments*, 10 Health Psych. Rsch. 1, 2–5 (2022); *see also,* Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102 J. Clinical Endocrinology & Metabolism 3869 (2017).

[32] Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics 1 (2018), https://perma.cc/DB5G-PG44 (reaffirmed August 2023); *see also* Diane Chen et al., *Psychosocial Functioning in Transgender Youth After 2 Years of Hormones,* 388 NEJM 240 (2023).

[33] *See, e.g.,* Br. of Experts on Gender Affirming Care as Amici Curiae in Support of Pet'r & Resp'ts in Supp. of Pet'r at 12–15, 22, *United States v. Skrmetti*, 605 U.S. 495 (2025) (No. 23-477) (outlining numerous conditions for which hormone therapies are utilized as treatment, noting that "[d]espite potential risks, hormone therapy remains a treatment option for a variety of conditions experienced by cisgender individuals, including gynecomastia, menorrhagia, amenorrhea, primary ovarian insufficiency, hirsutism, short stature, tall stature, delayed puberty, and precocious puberty").

[34] Nita Bhatt, Jesse Cannella & Julie P. Gentile, *Gender-affirming Care for Transgender Patients*, 19 Innovations Clinical Neuroscience 23 (2022).

[35] 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).

[36] Luca Crabtree et al., *A More Nuanced Story: Pediatric Gender-Affirming Healthcare is Associated With Satisfaction and Confidence*, 75 J. of Adolescent Health 772–79 (2024); Madeline B. Deutsch, *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* (2nd ed., 2016). Even the Proposed Rule itself estimates that only 81 transgender healthcare surgeries are performed per year for patients under 18, though it fails to describe how it reached even this low figure, which may be overinclusive. Proposed Rule at 59465.

Transgender healthcare is supported by major medical associations as medically necessary treatment for gender dysphoria[37] and is based on rigorous standards of care.[38] Transgender

[37] Moira Szilagyi, *Why We Stand Up for Transgender Children and Teens*, Am. Acad. of Pediatrics: AAP Voices Blog (Aug. 10, 2022), https://perma.cc/XX23-MWP8; James L. Madara, Am. Med. Ass'n, *AMA to States: Stop Interfering in Health Care of Transgender Children* (Apr. 26, 2021), https://perma.cc/YJ2U-492Q (studies demonstrate gender-affirming care patients report "dramatic reductions in suicide attempts, as well as decreased rates of depression and anxiety"); Press Release, Am. Ass'n Clinical Endocrinology, *AACE Position Statement: Transgender and Gender Diverse Patients and the Endocrine Community* (Mar. 7, 2022), https://perma.cc/ZKW6-GGPQ (hormone therapy and surgery are well-established treatments for interested transgender individuals); Press Release, Am. Coll. Nurse-Midwives, *Health Care for Transgender and Gender Non-Binary People*, at 3 (Mar. 2021), https://perma.cc/FVS7-9E28 ("Available data support the safety of gender-affirming hormone therapy."); Press Release, Am. Coll. Physicians, *Attacks on Gender-Affirming and Transgender Health Care* (Aug. 29, 2025), https://perma.cc/3TZ7-RZVL ("[G]ender-affirming care [is] evidence-based medicine, with study after study showing that gender-affirming care reduces depression and suicide among transgender youth."); Press Release, Am. Nurses Ass'n, *American Nurses Association Opposes Restrictions on Transgender Healthcare and Criminalizing Gender-Affirming Care* (Oct. 26, 2022), https://perma.cc/G9V9-C6DL ("Transgender and gender-diverse individuals report improved health and mental wellbeing after receiving gender-affirming care."); Press Release, Am. Psychiatric Ass'n, *Frontline Physicians Oppose Legislation that Interferes in or Criminalizes Patient Care* (Apr. 2, 2021), https://perma.cc/6JZN-P25D (advocating access to transgender healthcare, including for children and adolescents, as a basic human right); Press Release, Am. Psych. Ass'n, *APA Adopts Groundbreaking Policy Supporting Transgender, Gender Diverse, Nonbinary Individuals* (Feb. 28, 2024), https://perma.cc/89Z6-7AAK (state bans on transgender healthcare "disregard the comprehensive body of medical and psychological research supporting the positive impact of such treatments in alleviating psychological distress and improving overall well-being for [transgender individuals]."); Press release, Endocrine Soc'y*, Endocrine Society Statement in Support of Gender-Affirming Care* (May 8, 2024), https://perma.cc/J4Y2-RUJ2 (The Endocrine Society transgender healthcare practice guidelines are based on "a thorough review of medical evidence, author expertise, rigorous scientific review, and a transparent process."); Ethics Comm., Am. Soc'y for Reprod. Med., *Access to Fertility Services by Transgender and Nonbinary Persons: An Ethics Committee Opinion*, 115 Fertility and Sterility 874, 875 (2021), https://www.fertstert.org/article/S0015-0282(21)00082-0/fulltext ("Most data show that the psychological health of gender dysphoric individuals is improved and comparable to that of non-gender dysphoric individuals after receiving gender-affirming treatment"); Daniel H. Gouger, *AMSA Joins Amicus Brief to Call for VA Support of Surgical Treatment for Transgender Veterans with Gender Dysphoria* (Aug. 13, 2017), https://perma.cc/9S99-KTYL (state-wide bans on transgender healthcare are "unsupported by current medical evidence in the scientific literature"); Am. Heart Ass'n, Comment Letter on Proposed Rule on Nondiscrimination in Health and Health Education Programs and Activities under Section 1557 (Aug. 13, 2019), https://www.regulations.gov/document/HHS-OCR-2019-0007-147945 (describing hormone therapy and surgeries as "medically necessary care" for transgender people); *Medical Association Statements in Support of Health Care for Transgender People and Youth*, GLAAD (June 26, 2024), https://perma.cc/86Y9-HMZ3; Hearing: "Examining the Policies and Priorities of the Department of Health and Human Services," Submission for the Record by Rep. Mark Takano, "Professional Organizations' Position Statements on Care for Transgender People," H. Comm. on Ed. and the Workforce (May 15, 2024), https://perma.cc/Y6HK-HK5Q (listing 30 associations with published statements that support transgender healthcare); Fed'n Pediatric Orgs., *Statement in Support of Transgender Children and Youth, Their Families, and Health Care Providers* (Mar. 28, 2022), https://perma.cc/FLS9-2GKA; *see also* U.S. Professional Ass'n for Transgender Health, *USPATH Position Statement on Legislative and Executive Actions Regarding the Medical Care of Transgender Youth* (Apr. 22, 2022), https://perma.cc/RH7W-PSEV; *see also* Proposed Rule at 59467, nn.62–63.

Note that The American Society of Plastic Surgeons (ASPS) has recently issued a position statement offering guidance to providers to "delay" provision of gender-affirming surgical treatment to individuals under 19. *See* Am. Soc'y Plastic Surgeons, *Position Statement on Gender Surgery for Children and Adolescents* (Feb. 3, 2026), https://perma.cc/V78H-CMP8. Nothing contained in that position statement contradicts the arguments in this letter. The statements contained in the ASPS statement are consistent with current practice. Surgical interventions for

healthcare improves health outcomes and quality of life for transgender people.[39] And while heightened safeguards are in place for youth, there is a strong medical consensus that transgender healthcare has significant benefits for transgender youth and, for some, can be life-saving.[40] The distress of living with gender dysphoria can result in "symptoms of depression and anxiety, substance use disorders, a negative sense of well-being and poor self-esteem, and an increased risk of self-harm and suicidality."[41] For instance, one study of nonbinary and transgender teenagers and young adults between the ages of 13 and 20 found that taking puberty blockers or hormone therapy was associated with 60% lower odds of depression and 73% lower odds of suicidality within the first year of treatment.[42] A longitudinal study of transgender adolescents who received puberty blockers, hormone therapy, and surgery concluded that the care substantially alleviated their gender dysphoria and improved their social and professional functioning, quality of life, and life satisfaction such that the adolescents' well-being was comparable to their cisgender peers.[43] CMS itself has previously acknowledged the critical nature of this care, recognizing "that expanded, gender-affirming coverage vastly improves health care outcomes for the LGBTQ+ community,

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youth are already exceedingly rare, and are based on independent clinical judgments and in-depth, individualized assessments, supported by consensus of a multidisciplinary care team, regarding the risks and benefits, maturity, and medical necessity, alongside robust precautionary measures and heightened requirements for informed consent. Moreover, the position statement specifies that "when interpreting and applying these guiding principles to their individual practice, physicians should also use their personal and professional judgment. These guiding principles should not be considered as a rule and are not meant to serve as the standard of medical care." The statement thus continues to allow for individual clinicians to make such assessments in their practice as to when surgical intervention may be appropriate. We also agree with ASPS that more evidence is valuable here and will help better agree on the best way to provide surgical interventions for transgender youth. This is why HHS and other federal agencies should not cut funds for research into transgender healthcare and instead should fund such research.

[38] Eli Coleman et al., *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* (Sept. 15, 2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.

[39] Tonia Poteat, Andrew M. Davis, & Alex Gonzalez, *Standards of Care for Transgender and Gender Diverse People*, 329 JAMA 1872 (2022); Meredithe McNamara et al., *An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria* (2024); Brett Dolotina & Jack L. Turban, *A Multipronged, Evidence-Based Approach to Improving Mental Health Among Transgender and Gender-Diverse Youth*, 5 JAMA Network Open 1 (2022); Natalie M. Wittlin, Laura E. Kuper & Kristina R. Olson, *Mental Health of Transgender and Gender Diverse Youth*, 19 Ann. Rev. Clinical Psych. 207 (2023).

[40] *See* Stephanie L. Budge et al., *Gender Affirming Care Is Evidence Based for Transgender and Gender-Diverse Youth*, 75 J. Adolesc. Health 851 (2024); Brayden N. Kameg & Donna G. Nativio, *Gender Dysphoria in Youth: An Overview for Primary Care Providers*, 30 J. Am. Ass'n Nurse Prac. 493 (2018); Madeline B. Deutsch, *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* (2nd ed., 2016); *see also* Natalie M. Wittlin, Laura E. Kuper & Kristina R. Olson, *Mental Health of Transgender and Gender Diverse Youth*, 19 Ann. Rev. Clinical Psych. 207 (2023).

[41] Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders 513–14 (5th ed., text rev. 2022); Garima Garg et al., *Gender Dysphoria*, StatPearls (July 11, 2023), https://perma.cc/R7UE-E7YG.

[42] Diana M Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care* (Feb. 25, 2022), https://perma.cc/HU8Q-TL5A.

[43] Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696, 702 (2014), https://doi.org/10.1542/peds.2013-2958.

reduces high rates of depression, anxiety, and suicide attempts as well as decreases substance use, improves HIV medication adherence, and reduces rates of harmful self-prescribed hormone use."[44]

Patients who receive transgender healthcare generally report very high levels of satisfaction with the care and its positive impacts on their mental and physical health.[45] As one father described the impact for his child: "[b]efore she came out as trans, we were having incredible behavioral issues, and she was just not herself and depressed. . . . Coming out really started her journey to flourishing as a person. We've seen her flower and mature and be happy."[46] Anecdotal testimony from patients and parents in active legal challenges to the Administration's attempts to end or limit transgender healthcare bolster these studies, showing firsthand the impacts transgender healthcare can have. Parents explain that their children often endure extended and debilitating periods of depression, self-hatred, hopelessness, anxiety, self-harm, and suicidality before families seek transgender healthcare.[47] After receiving transgender healthcare, some transgender youth "blossomed into well-adjusted, bright, and future-oriented young people after receiving gender-affirming care because they finally felt their lives were worth living."[48] For example, one provider explained that a patient initially presented with "selective mutism, severe depression, and avoidant-restrictive food intake disorder."[49] But with access to transgender healthcare, she eventually overcame these symptoms, graduated from high school and intended to move out of state to start a new career.[50]

D. Implementation of the Proposed Rule Would Be Catastrophic for Patients, Hospitals, and State Provider Networks

This Rule will either deny young transgender individuals access to necessary medical care or require hospitals to forgo all Medicaid and Medicare funding—for most, an untenable choice.[51]

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[44] CMS, *Biden-Harris Administration Greenlights Coverage of LGBTQ+ Care as an Essential Health Benefit in Colorado* (Oct 12, 2021), https://perma.cc/A5DT-KNCJ.

[45] Chantal M. Wiepjes et al., *The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in prevalence, treatment, and regrets,* 15 J. Sex. Med. 582 (2018) (observing that 0.6% of transgender women and 0.3% of transgender men experienced regret); Kristina R. Olson, G. F. Raber, & Natalie M. Gallagher, *Levels of Satisfaction and Regret with Gender-Affirming Medical Care in Adolescence,* 178 JAMA Pediatr. 1354 (2024), https://perma.cc/2BC8-Z8RZ.

[46] Anya Kamentz, *'It Shouldn't Be Happening Here': Parents of trans children in NYC are outraged as hospitals quietly shift their approach to gender-affirming care,* New York Magazine (Feb. 4, 2025), https://perma.cc/9Y5J-HRRH.

[47] *Washington, et al. v. Department of Justice, et al.,* 2:25-cv-00244-LK, ECF No. 60 ¶¶ 5, 7, 11; ECF No. 67, ¶¶ 7, 9–11; ECF No. 113, ¶ 8; ECF No. 34, ¶¶ 7–9; ECF No. 33, ¶ 5; 2 40, ¶ 6; ECF No. 52, ¶ 5; ECF No. 48, ¶ 6; ECF No. 49, ¶ 20; ECF No. 21, ¶¶ 8, 9; ECF No. 54, ¶ 5; ECF No. 63 ¶ 6; ECF No. 71, ¶¶ 6, 9; ECF No. 70, ¶ 7; ECF No. 68, ¶ 6; ECF No. 69, ¶¶ 4–6; ECF No. 25¶¶ 4–5; ECF No. 77, ECF No. 51, ¶¶ 6–7, 11; ECF No. 100, ¶¶ 6–8; ECF No. 58, ¶¶ 14, 19, 40; ECF No. 66, ¶¶ 10, 13,18.

[48] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶ 9.

[49] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶¶ 10–12.

[50] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶¶ 10–12.

[51] Lindsey Dawson et al., *Trans People in the U.S.: Identities, Demographics, and Wellbeing*, KKF (Sep. 28, 2023), https://perma.cc/T48S-TXY3.

This choice impacts not only medical care for transgender and gender-diverse youth, but also medical care for everybody, since virtually all hospitals depend on Medicaid and Medicare funding. Regardless of which choice they make, the impacts to patients, hospitals, the medical community, and the States themselves will be devastating.

1. Hospital exclusion from Medicare and Medicaid would impact medical care for all.

The Proposed Rule forces hospitals into a position where they must choose to either deny life-saving medical care to a marginalized population of patients or risk losing billions of dollars in funding—thereby risking the capacity to provide care to their entire patient population and vastly increasing barriers to healthcare.

Most hospitals could not continue to operate financially without participating in Medicare and Medicaid. The vast majority of health systems participate in Medicare and Medicaid. In 2023, of approximately 6,129 hospitals nationwide, more than 96% participate in Medicare Part A.[52] Most, if not all, of those hospitals are also enrolled as participants in Medicaid plans. Medicare and Medicaid account for a combined 44% of all hospital spending.[53] In terms of patients, Medicare and Medicaid patients together account for about two-thirds of all hospital discharges.[54] For many hospitals, particularly those serving rural and underserved communities, even a reduction of Medicaid funding alone would force them to scale back services, reduce staff, or even close altogether.[55]

Even if some well-resourced hospitals could afford to forego Medicare and Medicaid participation and continue providing transgender healthcare—which is extremely unlikely—all Medicare and Medicaid patients served by those hospitals would have to seek their healthcare elsewhere or pay out of pocket, an impossibility for many, if not most participants—over 62 million enrolled in Medicare, and 80 million enrolled in Medicaid.[56] Investing in healthcare for individuals and ensuring medically necessary services are covered has a well-documented measurable impact on health outcomes. The absence of healthcare options affects not only individual health but also the broader public health landscape. With fewer providers available, people are more likely to experience delays in receiving care, which leads to both poorer health

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[52] *See* KFF, *Number of Medicare Certified Hospitals 2023* (n.d.), https://perma.cc/N577-7TBS.
[53] *See* Zachary Levinson et al., KFF, *Key Facts about Hospitals, National Hospital Spending by Payer* (Feb 18, 2025), https://perma.cc/2FM4-Z9WV.
[54] *See* Zachary Levinson et al., KFF, *Key Facts about Hospitals, Discharges by Payer* (Feb 18, 2025), https://perma.cc/5RLY-U3VW.
[55] *See* Modern Medicaid Alliance, *When Medicaid Cuts Force Hospitals to Close, Patients Pay the Price* (May 8, 2025), https://perma.cc/4FM8-8YFG.
[56] *See* CMS*, Medicare and Medicaid by the Numbers* (July 2025), https://perma.cc/BS6M-QP5X.

outcomes and increased medical costs.[57] The increased costs are often directly borne by the States, many of whom defray these costs through uncompensated care funds.[58]

The false "choice" the Proposed Rule offers to hospitals is really no choice at all. A total loss of Medicare and Medicaid funding would be catastrophic, eliminating hospitals' ability to provide care at all. Given the relatively small percentage of youth Medicare and Medicaid patients and the proportionally lower costs of providing transgender medical care, the revenue from providing such care is miniscule in proportion to all Medicare and Medicaid funding.[59] In New York, for example, the number of youth under age 18 who received medications to support transgender healthcare has ranged from 394 in Medicaid and 117 in Child Health Plus (fiscal year 2023) to 456 in Medicaid and 163 in Child Health Plus (fiscal year 2024). These patients represent approximately 0.02% (or two-hundredths of one percent) of all youth in New York's Medicaid and Child Health Plus programs. Consequently, it is likely virtually all hospitals currently providing transgender healthcare will have to terminate care for transgender youth instead, forcing those individuals to pay the price of this Proposed Rule.

2. Termination of services will deny transgender youth necessary medical care and devastate State health systems.

The costs of denying healthcare to transgender youth are significant and borne by transgender individuals themselves, the hospitals and medical staff that provide care, and the States as health providers and health plan administrators.

Delaying or abruptly discontinuing transgender healthcare can cause grave physical and mental health consequences, as discussed at length in Section III.D.2.c. Further, abrupt termination of transgender healthcare may make transgender youth reluctant to engage with healthcare providers for other types of medical care, including mental health care, primary care services, and emergency care, and result in more significant, and costly, healthcare issues down the road.[60]

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[57] U.S. Government Accountability Office, *Why Health Care Is Harder to Access in Rural America* (May 16, 2023), https://perma.cc/4NQJ-JGV9.

[58] Emmaline Kessee et al., *Uncompensated Care is Highest for Rural Hospitals, Particularly in Non-Expansion States.* 81 Med. Care Rsch. Rev. 164 (2024).

[59] Kellan Baker & Arjee Restar, *Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population*. 50 J. Law Med. Ethics 456 (2022), https://perma.cc/S5BD-WVB6.

[60] Landon D. Hughes et al., *"These Laws Will Be Devastating": Provider Perspectives on Legislation Banning Gender-Affirming Care for Transgender Adolescents*, 69 J. Adolescent Health 976 (2021) ("[P]roviders described how denial of evidence-based, gender-affirming care for [transgender and gender-diverse youth] will necessitate more serious and costly interventions including avoidable surgeries later in life"); *see also Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21 ¶ 30(d), ECF No. 87-2 ¶ 4 ("Stopping gender affirming care for youth would be similar to stopping access to insulin for diabetic children in terms of the negative health impacts and in how much evidence we have that it is helpful to avoid expensive and deadly complications."), ECF No. 87-12 ¶ 37 ("For example, patients who are unable to access pubertal suppression at the appropriate and safest times may ultimately request or require expensive surgery, such as masculinizing top surgery for a transgender boy who developed breast tissue during puberty."), ECF No. 87-25 ¶ 33, ECF No. 87-1 ¶ 46, ECF No. 87-13 ¶ 41(d).

Where transgender healthcare for youth has already been cut off in some states, providers have noted their new patients demonstrate "symptoms of patient abandonment" and a reluctance to engage with new providers.[61]

Doctors in the Undersigned States and elsewhere have expressed concerns about being able to fulfill their legal and ethical obligations if they were unable to provide medically necessary care to treat their patients' gender dysphoria, or are forced to abruptly discontinue ongoing treatment against their medical judgment.[62] The AMA has opined, for instance, that failure to offer medically necessary care can violate providers' professional ethical duty to offer safe and effective medical care that promotes a patient's well-being.[63]

Where hospitals abruptly terminate transgender healthcare for youth, other providers that continue to offer it—if any still exist—will become overwhelmed. In at least one state where care was already terminated by local hospitals, the limited providers that still offered care saw a 400% increase in patients.[64]

In many cases, if hospitals refuse to provide transgender healthcare, that termination may violate state anti-discrimination laws discussed above, forcing another terrible choice on medical providers. Indeed, patients and their families have filed administrative complaints or lawsuits in Pennsylvania, Connecticut, and Colorado alleging hospitals have violated those states' antidiscrimination laws by terminating their transgender healthcare programs for youth.[65]

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[61] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶ 30, (provider testified to the many harms federal intimidation tactics and resulting terminations of care have wrought on patients, including severe symptoms of patient abandonment).

[62] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-22 ¶ 30 ("Ceasing to provide transgender healthcare would violate my ethical obligations as a doctor, causing me moral injury. Stopping hormone therapy has serious physical repercussions and would violate my obligation to serve my patients and to do no harm."); ECF No. 87-1 ¶ 51 ("...denying adolescents medically necessary gender-affirming care would violate our ethical obligations as healthcare providers to provide competent medical care with respect for human dignity and rights and to avoid or minimize harm to our patients. Forcing providers to choose between, on one hand, violating our ethical obligations, and on the other, facing criminal or civil investigation or prosecution causes us profound moral injuries."); ECF No. 87-13 ¶ 38 ("The forced discontinuation and withholding of clinically impactful healthcare services to transgender patients has caused (and continues to cause) me severe moral injury. I have been placed in an impossible position: to place the legal and financial needs of my institution above the legitimate medical needs of my patients. This is an unprecedented situation in my clinical career that directly undermines the ethical and moral tenets of the doctor-patient relationship and directly damages the longitudinal relationships I maintain with legal adult patients."); ECF No. 87-3 ¶ 40; ECF No. 87-24 ¶ 38; ECF No. 87-21 ¶ 36; ECF No. 87-2 ¶ 30; ECF No. 87-12 ¶ 45; *see also* ECF No. 87-5 ¶¶ 39–40; ECF No. 87-18 ¶¶ 33–34.

[63] AMA, *Opinion 1.1.6 Quality. Code of Medical Ethics*, https://perma.cc/9J38-93KT.

[64] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶ 28.

[65] *See* Women's Law Project, *Complaint Filed Against UPMC Children's Hospital for Unlawfully Denying Gender-Affirming Care to Patients Under 19* (Sept. 23, 2025), https://perma.cc/PQ4R-5WBY; Katy Golvala, *CT families file complaint against hospitals over 'severe disruptions' to trans care*, CT Mirror (Dec. 17, 2025), https://perma.cc/2JFE-BF48; John Ingold, *"My child's life is expendable": Fight for gender-affirming care and risk of federal defunding plays out in a Denver courtroom*, The Colorado Sun (Feb. 6, 2026), https://perma.cc/LYJ7-ZULM.

Beyond these immediate impacts, States will see increased costs and strains on their health systems. Investing in coverage for individuals and ensuring medically necessary services are covered has a well-documented measurable impact on health outcomes.[66] Transgender adolescents who are denied medically necessary transgender healthcare are likely to require additional, more costly physical and mental healthcare, now and down the road.[67] The estimated cost of *not* covering an individual's transgender healthcare has been found to be $23,619 for a 10-year period, reflecting the medical costs of negative health outcomes including depression, substance use, and suicide.[68] Access to pubertal suppression and hormone therapy for transgender youth is inversely related to these negative health outcomes that manifest as additional costs to payors.[69] Further, early treatment may reduce the need for higher risk and costly interventions later in life such as gender affirming surgery, which many of the Undersigned States must cover for adults.[70] As administrators of healthcare plans, States will bear the cost of the additional treatments required to treat gender dysphoria in adults when transgender healthcare is unavailable to transgender youth. Additionally, the Proposed Rule would harm State providers' ability to carry out important functions of medical education and research in the area of transgender healthcare.

These devastating costs—from direct impact to patients and providers to long-term costs to States—will undoubtedly be the direct results of the Proposed Rule.

III. ARGUMENTS

A. The Proposed Rule Impermissibly Regulates the Practice of Medicine.

1. The Proposed Rule exercises supervision or control over the practice of medicine in violation of 42 U.S.C. § 1395 (Section 1801), and without other statutory authority.

By conditioning participation in federal healthcare programs on the cessation of a medical treatment that is protected under numerous state laws and provided to an individual based on a clinician's professional judgment, the Proposed Rule seeks to improperly exercise direct

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[66] *See, e.g.,* Samuel Mann et al., *Access to Gender-Affirming Care and Transgender Mental Health: Evidence from Medicaid Coverage*, SSRN (August 7, 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4164673.
[67] *Supra* note 60.
[68] William V. Padula, Shiona Heru & Jonathan D. Campbell, *Societal implications of health insurance coverage for medically necessary services in the U.S. transgender population: a cost-effectiveness analysis*, 31 J. Gen. Int'l Medicine 394 (2016).
[69] Annelou L. C. de Vries et al., *Young adult psychological outcome after puberty suppression and gender reassignment,* 134 Pediatrics 696 (2014); *Outlawing Trans Youth: State Legislatures and the Battle over Gender-Affirming Healthcare for Minors,* 134 Harv. L. Rev. 2163 (2021) (explaining how puberty blockers and hormone replacement therapies allow transgender youth to avoid intense psychological distresses, including anxiety, depression, and suicidal behavior).
[70] Gilbert Gonzales & Kyle A. Gavulic, *The Equality Act is needed to advance health equity for lesbian, gay, bisexual, and transgender populations*, 110 Am. J. Public Health 801 (2020).

supervision over the practice of medicine for all patients at all hospitals (regardless of whether the patient uses Medicaid or Medicare), in violation of the Medicare statute and without any statutory authority.

In accordance with fundamental principles of federalism, 42 U.S.C. § 1395 (Section 1801 of the Social Security Act, codified as the opening provision of Title 18, the Medicare Act; hereinafter "Section 1801") prohibits federal officers from exercising "any supervision or control over the practice of medicine or the manner in which medical services are provided . . . ." This prohibition "was included in the law to offset the criticism made by opponents of the proposal that [f]ederal legislation would give [f]ederal officials the opportunity and the right to interfere in the diagnosis and treatment of the individual."[71] Federal courts have routinely upheld the plain meaning of the statute, emphasizing that interference in diagnosis and treatment is the absolute red line of whether a Medicare regulation is permissible under Section 1801.[72] Indeed, CMS itself has consistently recognized this restriction on its ability to regulate.[73]

The Proposed Rule's attempt to regulate the provision of a class of "pharmaceutical [and] surgical interventions" in order to treat a specific medical condition clearly interferes with the regulation of medicine by injecting CMS—and its policy priorities—directly into the provider-patient relationship.[74] This deprives providers and the medical community writ large of the ability to make medical decisions based on their professional clinical judgments, and in consultation with patients and their families. This federal overreach is a patent violation of Section 1801.

CMS also lacks any statutory authority to enact such regulations. The Proposed Rule locates its authority in 42 U.S.C. § 1395x(e)(9), the provision of the SSA that authorizes CMS to set CoPs. This provision sets forth a long list of specific conditions HHS is authorized to impose (such as maintain[ing] clinical records on all patients, *id.* §1395x(e)(2), and having "a licensed

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[71] Wilbur J. Cohen, *Reflections on the Enactment of Medicare and Medicaid*, Health Care Fin. Rev. 8 (Dec. 1985).
[72] *See Texas v. Becerra*, 89 F.4th 529, 542–43 (5th Cir. 2024), *cert. denied*, 145 S. Ct. 139 (2024); *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989) (holding that regulation did not violate § 1395 because it did not "actually direct or prohibit any kind of treatment or diagnosis"); *Coll. of Am. Pathologists v. Heckler*, 734 F.2d 859, 868 (D.C. Cir. 1984) (holding that requirement that hospital seek reimbursement from Medicare for reasonable cost services did not interfere in doctor-patient relationship, and therefore did not violate § 1395); *see also Mass. Med. Soc. v. Dukakis*, 637 F. Supp. 684, 688 (D. Mass. 1986) (holding that Medicare Act does not preempt state regulation of physician billing practices as to Medicare recipients in part because prohibition on federal interference "[c]learly . . . includes more than treatment choice"), *aff'd*, 815 F.2d 790 (1st Cir. 1987).
[73] *See* Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68,688, at 68,772 (Oct. 4, 2016) (recognizing that "restricting the ability of health care practitioners to prescribe medication for uses other than those that have received FDA approval could violate the prohibition against interference with the practice of medicine"); Medicare Program; Transitional Coverage for Emerging Technologies, 89 Fed. Reg. 65,724, at 65,728 (Aug. 12, 2024) (noting that limitations on payment for items and services does not violate § 1395 where "[p]hysicians can still prescribe or order other services that will not be paid by Medicare, and the beneficiary may agree to pay for items or services that Medicare does not cover"); *see also* Medicare and Medicaid Programs; Omnibus Nursing Home Requirements, 57 Fed. Reg. 4,516, at 4,519 (Feb. 5, 1992) (explaining that prohibition on "chemical restraints" would not violate § 1395 because would only apply where drugs prescribed for "discipline or convenience and not to treat medical symptoms").
[74] *Cf. Heckler*, 734 F.2d at 868 (requirements imposed on hospital billing practice did not intrude on doctor-patient relationship).

practical nurse or registered professional nurse on duty at all times,"[75]) and then grants a generic catch-all authority to impose "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."

As noted in Section II.B, the vast majority of CoPs impose noncontroversial, basic standards on participating hospitals, such as requiring that hospitals "have an organized medical staff" and that that medical staff be composed of "doctors of medicine or osteopathy,"[76] or that hospitals must ensure their staff are appropriately licensed,[77] or establishing requirements for emergency preparedness plans and organ procurement, transportation, and storage.[78]

The Proposed Rule, which overrides individual practitioners' clinical judgment regarding the provision of certain treatments to patients with a specific diagnosis, is fundamentally different in kind. No condition of participation has ever purported to categorically ban a particular medical treatment, much less a suite of services that is legal under numerous state laws, provided in a clinician's professional judgment, and designed to treat a medically recognized health condition. And nothing in this catchall provision grants CMS the sweeping authority to regulate the practice of medicine it claims in the Proposed Rule. As Congress explained, the statute granted catchall administrative authority under subsection (e)(9) "because it would be inappropriate and unnecessary to include in the legislation all the precautions against *fire hazards, contagion, etc.*, which should be required of institutions to make them safe."[79]

Moreover, CMS's authority to issue CoPs is constrained by the prohibition of Section 1801. A CoP may not regulate the practice of medicine. The Proposed Rule would be both unprecedented and unlawful.

It is important to note that the Proposed Rule would apply not just when the federal government is paying for the care under Medicare or Medicaid, but to any patient treated by the covered facility—even one who is paying privately. This fact underscores that CMS is not just simply setting the terms by which it will pay; it is regulating the practice of medicine generally.

Although the plain text of the statute, standing alone, is sufficient to show that CMS lacks authority for the Proposed Rule, canons of interpretation underscore that CMS's catchall authority under 42 U.S.C. § 1395x(e)(9) does not include the power to restrict medical treatment. First, the *ejusdem generis* canon, which provides that "a general or collective term at the end of a list of specific items is typically controlled and defined by reference to the specific classes that precede it,"[80] confirms that conditions of participation under the catchall provision must resemble the statutorily enumerated conditions of participation that precede it. Here, professional clinical judgments about whether a certain treatment is appropriate for a certain patient is "so unlike the

[75] 42 U.S.C. § 1395x(e)(5).
[76] *See* 42 C.F.R. § 482.22.
[77] 42 C.F.R. § 482.11.
[78] *See* 42 C.F.R. § 482.15.
[79] H.R. Rep. 89-213 at 26 (1965) (emphasis added); *accord* S. Rep. 89-404, at 28–29 (1965) (emphasis added).
[80] *Fischer v. United States*, 603 U.S. 480, 487 (2024) (citation modified).

examples" that Congress provided (licensure, discharge planning, 24-hour nursing) that it would be "implausible to assume" that CMS's authority extended to the direct pronouncement of clinical standards, "even if literally covered by the [health and safety] language."[81]

Second, the constitutional avoidance canon confirms that CMS's reading is wrong. Interpreting the catchall provision to vest CMS with authority to override clinical judgments and restrict treatments to certain patients would, among other things, (i) violate the Tenth Amendment, by conflicting with States' traditional authority to regulate the practice of medicine, see *supra* Sections III.A.2, and (ii) create serious nondelegation problems. The nondelegation doctrine requires Congress to "lay down by legislative act an intelligible principle" to which the agency must adhere.[82] But if the phrase "such other requirements . . . as he finds necessary" is interpreted as being so broad as to permit CMS to dictate, as a matter of policy, substantive medical standards, the statute contains no intelligible principle guiding the agency's exercise of discretion.[83]

In some "extraordinary cases" an agency asserts an authority so broad and ahistorical and of such "economic and political significance" that courts must more closely examine the agency's actions.[84] This is such a case. Quite clearly, public healthcare infrastructure that covers 182 million Americans[85] is a question of critical economic significance. Moreover, the question of whether and when youth should be able to access transgender healthcare is a matter of "earnest and profound debate."[86] With this Proposed Rule and its related regulatory actions, CMS attempts to settle that debate and adopt a breathtaking and unprecedented new authority to regulate the practice of medicine. Regardless of the importance of the issue, even as to public health, "an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress."[87]

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[81] *See Fischer v. United States*, 603 U.S. 480, 488 (2024).
[82] *Panama Ref. Co. v. Ryan*, 293 U.S. 388, 429–30 (1935) (citation omitted).
[83] For similar reasons, the Proposed Rule further violates Section 1801's additional prohibition on federal officials "supervising or controlling" the way that institutions operate their facilities. While other conditions of participation have set minimum safety requirements for hospitals, hospitals retain flexibility in how those process-oriented requirements are met.
[84] *West Virginia v. Env't Prot. Agency*, 597 U.S. 697, 721 (2022); *see also Biden v. Nebraska*, 600 U.S. 477, 516 (2023) (Barrett, J., concurring) ("An interpreter should 'typically greet' an agency's claim to 'extravagant statutory power' with at least some 'measure of skepticism.'") (quoting *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 324 (2014)).
[85] CMS, *Medicare and Medicaid by the Numbers* (July 2025), https://perma.cc/BS6M-QP5X.
[86] *See Gonzales v. Oregon*, 546 U.S. 243, 267 (2006); *see also United States v. Skrmetti*, 605 U.S. 495, 525 (2025) ("This case carries with it the weight of fierce scientific and policy debates about the safety, efficacy, and propriety of medical treatments in an evolving field. The voices in these debates raise sincere concerns; the implications for all are profound.").
[87] *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) (recognizing that though tobacco use among children and adolescents posed significant public health threat, FDA could not regulate tobacco industry where Congress had not granted statutory authority to do so and had in fact "squarely rejected" multiple efforts to grant agency authority over tobacco industry).

Read in its context,[88] the Proposed Rule clearly steps beyond the bounds of CMS's statutory authority to impose minimum health and safety requirements on hospitals. This is so perhaps most importantly because if CMS can regulate in the manner it asserts in this Proposed Rule, its power to intrude into the regulation of medicine would know no bounds. Such a result is entirely incompatible with our Constitutional framework.

2. The Proposed Rule regulates the practice of medicine in violation of the separation of powers and the Tenth Amendment.

Apart from the statutory restrictions discussed above, the Proposed Rule also usurps state authority to regulate the practice of medicine, without clear Congressional authorization, in violation of the Tenth Amendment and the separation of powers. Traditionally, it is the province of the states to define and regulate the practice of medicine, which includes delineating the scope of medical care.[89]

The Tenth Amendment reserves for the States all rights and powers "not delegated to the United States" federal government.[90] Commonly referred to as "traditional state police powers," the rights and powers of the States include the "power to protect the health and safety of their citizens."[91] Since at least 1889, the authority to regulate the practice of medicine has been recognized as among these powers.[92]

The Undersigned States exercise their traditional authority to regulate the practice of medicine in myriad ways. States determine medical licensure requirements; oversee professional discipline; impose requirements on healthcare providers and insurers; and more. In some of the Undersigned States, these antidiscrimination laws explicitly protect transgender individuals from discrimination in the provision of healthcare and in public accommodations such as hospitals. Some States likewise prohibit insurance carriers from discriminating against insured individuals based on gender identity and expression.[93] Consistent with their authority to regulate medicine and define what constitutes medically necessary healthcare within their borders, some States cover

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[88] *Biden v. Nebraska*, 600 U.S. 477, 508 (2023) (Barrett, J., concurring).
[89] Patricia Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 San Diego L. Rev. 427, 434–35 (2015); *Watson v. Maryland*, 218 U.S. 173, 176 (1910) ("It is too well settled to require discussion at this day that the police power of the States extends to the regulation of certain trades and callings, particularly those which closely concern the public health. There is perhaps no profession more properly open to such regulation than that which embraces the practitioners of medicine."); *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) (noting that health care is "a subject of traditional state regulation").
[90] U.S. Const. amend. X.
[91] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *see also Slaughterhouse Cases*, 83 U.S. 36, 62 (1873) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons…within the State").
[92] *Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (states have discretion to set medical licensing requirements as they have done since "time immemorial"); *Lambert v. Yellowley*, 272 U.S. 581, 596 (1926) ("[T]here is no right to practice **medicine** which is not subordinate to the police power of the States ....").
[93] *See, e.g.,* Conn. Gen. Stat. § 46a-64; Conn. Insurance Dept. Bulletin IC-34; 151, 15-1A-22; Cal. Code Regs. tit. 10, §2561.2.r.

transgender healthcare under their State Medicaid Plan,[94] and some require that all insurers cover medically necessary transgender healthcare.[95]

To this day, the Supreme Court continues to recognize and defer to states in setting the bounds of medical practice. The Proposed Rule flouts Tenth Amendment jurisprudence, as it single-handedly seeks to prohibit healthcare that an abundance of states affirmatively permit and protect.

Congress may authorize the federal government to regulate some medical practice, but it must do so explicitly and within constitutional limits. Courts accordingly will not read legislation to arrogate states' traditional sovereign authority if it does not manifest clear congressional intent to regulate medicine or if it undermines principles of federalism.[96] Most recently in *Skrmetti*, the Supreme Court deferred to states to determine acceptable forms of healthcare for their residents. Particularly in areas where the Court decides there is "medical and scientific uncertainty," it "afford[s] States 'wide discretion.'"[97] That CMS attempts to regulate medicine in the absence of clear congressional intent *and* in contravention of the structure and limitations of federalism renders the Proposed Rule unlawful and improper.

3. The Proposed Rule fails to comply with Executive Order 13132 ("Federalism")

The Proposed Rule also fails to comply with Executive Order 13132. Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999). The Proposed Rule acknowledges that the rule triggers Executive Order 13132 because it "would pre-empt State laws that prohibit [transgender healthcare] for children that include exceptions for reasons beyond those exceptions provided in this Proposed Rule, including for children who are already undergoing these procedures" and "would also pre-empt State laws requiring hospitals to provide [transgender healthcare]." 90 Fed. Reg. at 59477.

Despite acknowledging that the Proposed Rule triggers EO 13132, the Proposed Rule blatantly violates EO 13132's procedural consultation requirements. EO 13132 specifically requires consultation with State and local officials "early in the process of developing the proposed regulation," 64 Fed. Reg. at 43258, and provides that, "[w]here there are significant uncertainties as to whether national action is authorized or appropriate, agencies shall consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means,"

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[94] For example, non-surgical transgender healthcare has been covered under Connecticut's HUSKY State Plan since 2013, and gender affirming surgery has been covered since 2015.

[95] *See, e.g.,* Del. Code Ann. tit. 18, § 2304 (22); *see also* Proposed Rule at 59470 (noting that various states cover or require coverage of transgender healthcare).

[96] *Gonzales v. Oregon*, 546 U.S. 243, 269–70 (2006) ("The [Controlled Substances Act] and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism").

[97] *U.S. v. Skrmetti*, 605 U.S. 495, 524 (2024) (citing *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007)).

64 Fed. Reg. at 43256. EO 13132 makes the consultation doubly important where there is an alleged conflict and preemption will follow. 64 Fed. Reg. at 43257. HHS did not engage in any such consultation here. Instead, it released the proposal to States at the same time that it released the proposal to the public, without any opportunity for States to offer input prior to this stage, as EO 13132 plainly requires. Nor was there any discussion with State or local officials about whether the objectives could be attained by other means.

The Proposed Rule also violates EO 13132's substantive requirements. EO 13132 expressly provides that preemption shall "be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated." 64 Fed. Reg. at 43257. As discussed (*infra* Sections III.B.3, III.D.3), even under HHS's own purported justification for the rule, pulling all federal funding from hospitals that provide these treatments to any patient under age 19, regardless of whether the patient is self-pay or privately insured, is far from the minimum level necessary to achieve the statute's objectives of protecting the health and safety of Medicare and Medicaid beneficiaries in hospitals.

4. The provision of transgender healthcare is the practice of medicine.

CMS attempts to escape the charge that the Proposed Rule improperly regulates the practice of medicine in violation of both statutory and constitutional restrictions simply by declaring that the care it seeks to end is not healthcare. This is wrong. The Proposed Rule contends that it does not regulate medicine because "we believe that providing the [transgender healthcare] for children is not healthcare and hence are not subsumed under the term of 'practice of medicine.'"[98] But CMS points to no authority suggesting that it can unilaterally deem widely accepted standards of care as "not healthcare" altogether. Further, under CMS's suggestion, the relevant statutory guardrails and the separation of powers would be rendered nullities, as CMS simply needs to declare something "not healthcare," for instance vaccines, and it can prohibit their administration.[99] And what is more, whether or not CMS classifies a given treatment as healthcare does not determine whether regulating it constitutes regulation of the practice of medicine. CMS points to no authority that its unilateral determination about whether a given treatment constitutes "healthcare" is determinative or even relevant to whether regulating that treatment constitutes regulating the practice of medicine.

But even assuming CMS had authority to evaluate whether transgender healthcare is "healthcare" (and assuming that were relevant), it plainly is. CMS cursorily reasons that the aims of "healthcare" are solely to "restore bodily health," including the health of one's "organs, organ

[98] Proposed Rule at 59471.

[99] In fact, delineating what is, and what is not, healthcare has long been understood as an essential part of the regulation of medicine. For instance, whether an individual requires a medical license is determined by state regulations that specify whether that individual's actions amount to the practice of medicine. *See* Patricia Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 San Diego L. Rev. 427, 434–35 (2015). Thus, the proclamation that transgender healthcare is not healthcare itself regulates the practice of medicine.

systems, and processes natural to human development like puberty."[100] One's body is "healthy" if its component parts "operat[e] according to their biological functions"; the Proposed Rule states that since "[o]rgans or organ systems do not become unhealthy simply because the individual may experience psychological distress relating to his or her sexed body," gender dysphoria does not warrant healthcare treatment.[101] Rather, the Proposed Rule explains, gender dysphoria treatment "involves the intentional destruction of healthy biological functions."[102]

The Proposed Rule fundamentally misunderstands healthcare and mental and physical treatments. First, "healthcare" is, obviously, significantly more complex than restoring unhealthy organs. Healthcare entails a variety of chronic, preventive, and rehabilitative care for one's physical and mental well-being, and well-being is understood on a systemic level for the individual as a whole, not organ by organ.[103] Second, mental healthcare is healthcare,[104] not least because the brain is an organ. The Proposed Rule suggests that transgender healthcare is not healthcare because treatment of transgender individuals is predominantly geared towards alleviating mental distress: "removing a patient's breasts as a treatment for breast cancer is fundamentally different from performing the same procedure solely to alleviate mental distress arising from gender dysphoria."[105] It is unclear why CMS asserts the treatment of a mental condition is "fundamentally different" from treatment of any other physical condition. In any event, mental health treatment can involve pharmaceutical and physical interventions, such as electroconvulsive therapy, which requires anesthesia and takes place in a hospital setting, to vagus nerve stimulation, which involves the surgical implantation of a device in a patient's chest.[106] Medicare and Medicaid, the "single largest payer for mental health services in the United States," cover mental health treatment even when such treatment impacts a patient's body.[107]

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[100] Proposed Rule at 59471.
[101] *Id.*
[102] *Id.*
[103] Committee to Design A Strategy for Quality Review & Assurance, Institute of Medicine, *Health, Health Care, and Quality of Care*, 1 Medicare: A Strategy for Quality Assurance (1990), https://perma.cc/ND8U-XED2.
[104] The White House, *The MAHA Report: Make Our Children Healthy Again Assessment* at 14, (2025), https://perma.cc/Z8Y9-E3C2.
[105] Proposed Rule at 59471.
[106] *Mental Illness*, Mayo Clinic, https://perma.cc/4A2M-M2CD (last visited Jan. 27, 2026); *What is Electroconvulsive Therapy?*, Am. Psychiatric Ass'n, https://perma.cc/R7JB-XF2R (last visited Jan. 27, 2026); Robert H. Howland, *Vagus Nerve Stimulation*, 1 Current Behav. Neuroscience Rep. 64 (2014); *see also* Christi R.P. Sullivan et al., *Deep brain stimulation for psychiatric disorders: From focal brain targets to cognitive networks*, 225 NeuroImage 1 (2021) (describing use of deep brain stimulation, an invasive procedure involving the stimulation of certain brain tissue, for depression and obsessive compulsive disorder); Matthew C. Henn et al., *A systematic review of focused ultrasound for psychiatric disorders: current applications, opportunities, and challenges*, 57 J. Neurosurgery E8 (2024) (explaining the use of MRI-guided focused ultrasound as treatment for psychiatric disorders); *Magnetic Seizure Therapy as Effective as Electroconvulsive Therapy for Treating Depression*, Natl. Inst. Mental Health (Dec. 18, 2023), https://perma.cc/Y4EY-GHQG.
[107] *Behavioral Health Services*, Medicaid.gov, https://perma.cc/5VR5-KGRB (last visited Jan. 27, 2026).

Third, mental health is inextricable from physical health, and mental health disorders can cause physical health issues (and vice versa).[108] Gender dysphoria, and related clinical distress, may have deleterious impacts on the body: individuals with untreated gender dysphoria often suffer from eating disorders, suicidal ideation and self-harm, substance use disorders, and other conditions with adverse physical effects.[109]

Fourth, patients routinely undergo physical medical interventions on body parts or organs that are not "unhealthy" within the Proposed Rule's meaning. For instance, many patients seek and receive preventative mastectomies when they have a high risk of breast cancer,[110] breast reductions when they have chronic back pain,[111] or gynecomastia when it causes psychological distress or breast tenderness.[112] Among the many medical procedures and treatments on "healthy" body parts "operating according to their biological functions" also are circumcisions, vasectomies, tubal ligation, elective cesarean sections, several forms of birth control (intrauterine devices, oral contraceptives, etc.), preventative removal of the appendix or tonsils, and some orthodontia. But according to the Proposed Rule's bizarre logic, these treatments are not "healthcare" because they do not "restore bodily health"; rather, they "involve[] the intentional destruction of [currently] healthy biological functions."[113]

Further illustrating the absurdity of its baseless assertion that transgender healthcare is not healthcare, CMS undermines its own argument by grounding the Proposed Rule in documents, court decisions, and statutes that refer to this care as healthcare.[114] For instance, in the Proposed Rule CMS repeatedly cites HHS's "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" ("HHS Report"),[115] which discusses transgender healthcare as healthcare. The HHS Report calls transgender healthcare "pediatric medical transition" and "treatment for gender dysphoria"; refers to related treatments as "medical interventions"; analyzes the care under "widely accepted principles of medical ethics"; recognizes that professional medical associations around the world have adopted clinical guidelines for the care; and evaluates the "medical harms" and "medical benefits" of transgender healthcare treatments.[116] The Proposed Rule also takes note of the Supreme Court's decision in *Skrmetti*, which described transgender healthcare as "medical treatment."[117] In discussing *Skrmetti*, the Proposed Rule itself even refers

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[108] Georgia F. Spurrier et al., *Physical symptoms as psychiatric manifestations in medical spaces: A qualitative study*, 13 Frontiers in Psychiatry 1, 4–9 (2022).
[109] National Academies, *Sex and Gender Identification and Implications for Disability Evaluation* (Nov. 18, 2024), https://perma.cc/7C5D-K2YN.
[110] *Prophylactic (Preventative) Mastectomy*, Cleveland Clinic, https://perma.cc/2MJX-WKN4 (last visited Jan. 27, 2026).
[111] Rajiv Chandawarkar, *Can breast reduction surgery relieve back pain?*, Ohio State Univ. Wexner Med. Ctr. (July 17, 2018), https://perma.cc/6X56-SC7W.
[112] *Gynecomastia*, Cleveland Clinic, https://perma.cc/59EM-LFLA (last visited Jan. 27, 2026).
[113] Proposed Rule at 59471.
[114] These sources furthermore do not question transgender healthcare's designation as healthcare.
[115] HHS, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* (Nov. 19, 2025), https://opa.hhs.gov/gender-dysphoria-report.
[116] *Id.* at 9, 14, 29, 53, 97, 227, 228.
[117] *U.S. v. Skrmetti*, 605 U.S. 495 (2024).

to transgender healthcare as "medical procedures."[118] The Proposed Rule also surveys state laws that protect and restrict transgender healthcare, the vast majority of which treat the care as healthcare.

Additionally, CMS's own language in the Proposed Rule and elsewhere demonstrates that CMS itself considers transgender healthcare to be healthcare. The Proposed Rule states that it is "animated by significant child safety concerns when [transgender healthcare is] used for certain *medical uses*—that is to align a child's physical appearance or body with an asserted identity," thereby recognizing that transgender healthcare interventions are medical treatments.[119] Furthermore, on the same day CMS released this Proposed Rule, it released another to prohibit Medicaid reimbursement for transgender healthcare that explicitly refers to such care as a "healthcare service" which may cause youth deprived of it to suffer and seek other forms of care.[120]

B. The Proposed Rule Violates the Spending Clause.

The Proposed Rule would also run afoul of the Spending Clause. The Undersigned States operate many public hospitals that participate in Medicare or Medicaid and provide transgender healthcare. Although the federal government may use its Spending Clause authority to induce States or other actors to adopt certain policies that Congress could not require using its enumerated article I powers alone, there are well recognized limits to this authority. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 576 (2012) ("*NFIB*"). Here, CMS has exceeded its authority by promulgating a condition on federal hospital funding that is coercive, contains surprise retroactive conditions, is unrelated to the government's federal interest in protecting the health and safety of Medicare and Medicaid beneficiaries in hospitals, and forces recipients—including state-run hospitals—to carry out a discriminatory federal policy motivated by animus. Additionally, it bears emphasizing that the Proposed Rule is exceedingly coercive, as it would exclude hospitals from Medicaid and Medicare entirely if they provide medically necessary transgender healthcare even to patients wholly outside of those programs.

1. The Proposed Rule is highly coercive.

The federal government may use its spending power "to create incentives for States to act in accordance with federal policies." *NFIB*, 567 U.S. at 577. But because the Spending Clause authority rests on the voluntary acceptance by States or other regulated parties, the Spending Clause is violated when the federal government uses "financial inducements to exert a 'power akin to undue influence.'" *NFIB*, 567 U.S. at 577 (quoting *Steward Machine Co. v. Davis*, 301 U.S. 548, 590 (1937)). When "pressure turns into compulsion," the use of the spending power becomes

[118] Proposed Rule at 59470.
[119] *Id.* (emphasis added).
[120] Medicaid Reimbursement Proposed Rule at 59449.

indistinguishable from commandeering, i.e., requiring the States to regulate their own citizens in the federal government's preferred manner. *NFIB*, 567 U.S. at 577.

The test for whether the federal government has crossed the line from influence into coercion is whether the States or other parties retain the option to "defend their prerogatives by adopting 'the simple expedient of not yielding' to federal blandishments when they do not want to embrace the federal policies as their own." *NFIB*, 567 U.S. at 579 (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 482 (1923)). If the States do not retain this option, the financial inducement may become "so coercive as to pass the point at which pressure turns into compulsion." *NFIB*, 567 U.S. at 580 (quotation marks omitted); *see also Health & Hosp. Corp. of Marion Cnty. v. Talevski*, 599 U.S. 166, 222 n.10 (Thomas, J., dissenting) (recognizing that "the Federal Government's overwhelming fiscal resources enable it to create 'gun to the head' situations in which there is no practical possibility of opting out").

Here, as in *NFIB*, the federal government has offered a financial condition that is "so coercive" as to constitute unconstitutional compulsion: namely, stop providing certain medical treatments to a small group of vulnerable patients (and only to that small group of vulnerable patients) or lose *all* Medicare and Medicaid funding.[121]

The Proposed Rule offers no "genuine choice" about whether to accept this condition.[122] As discussed above, and as CMS well knows, hospitals that currently accept Medicare and Medicaid funding, including state-operated hospitals, cannot realistically choose to stop accepting such funds.[123]

Indeed, the situation here is very similar to the situation in *NFIB*, in which the federal sought to leverage a state's need to continue participating in the existing Medicaid program into a means of forcing them to participate in the expansion of Medicaid. The federal government alleged it provided the states with a choice to accept Medicaid expansion funding (and take up the mantle of expanded program administration) or lose their Medicaid funding altogether. The Supreme Court explained that this artificial "choice" was far from a "relatively mild encouragement" permitted by the Spending Clause—it was "economic dragooning that leaves the States with no real option but to acquiesce." *NFIB*, 567 U.S. at 581–82 (quotation marks omitted). Here, likewise, acquiescence is the only realistic option. In this situation, the federal government is leveraging all hospitals' need to participate in Medicaid and Medicare as a means of forcing them to deny medically necessary treatment to transgender youth.

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[121] Although the conditions of participation statute is found in the Medicare program, which States do not administer, the Proposed Rule recognizes that the Medicare conditions of participation are incorporated into the Medicaid program, which States do administer: "Under regulations at §§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii), hospitals that provide inpatient and outpatient services, respectively, to Medicaid enrollees are required to meet the Medicare CoPs to also participate in Medicaid." Proposed Rule at 59464.

[122] *Cf. NFIB*, 567 U.S. at 588.

[123] See *supra* Section II.D.1.

Like the coercive condition in *NFIB*, moreover, the Proposed Rule's threat to withdraw *all* Medicare and Medicaid funding from hospitals, based on select services provided to a small number of patients, is so unrelated to the government's perceived policy interests in funding emergency and other hospital services for poor and elderly individuals that it "serves no purpose other than to force unwilling States"—and their hospitals—"to discontinue this care." *NFIB*, 567 U.S. at 580. The Proposed Rule expressly allows hospitals to continue providing the very same medical treatments to other youth patient populations (such as cisgender youth)—confirming that the treatments do not inherently pose any health and safety risks, much less health or safety risks that would justify withdrawing a hospital's entire complement of Medicare and Medicaid funding.

Further, even if it were operationally and existentially feasible for an individual hospital to stop accepting Medicare and Medicaid (it is not), other features of the Medicaid programs would prevent hospitals or States from exercising any meaningful choice with respect to the new condition announced in the Proposed Rule. For example, federal law requires States, as Medicaid administrators, to ensure that Medicaid beneficiaries have access to an adequate network of providers, including hospitals. *See* 42 U.S.C. § 1396a(a)(30)(A) (fee-for-service); 42 C.F.R. § 438.68 (managed care organizations). And state departments of health must also ensure that private health plans meet network adequacy standards, which would be impossible to do without the hospitals. Thus, network adequacy requirements additionally constrain whether State-run hospitals remain free to accede voluntarily to these conditions of participation follow up with the hospital by requesting information or conducting an onsite review. 42 C.F.R. § 482.74(b). Coupled with a catastrophic loss of funding, these other program features underscore that States and hospitals lack any meaningful choice about whether to comply with the new funding condition in the Proposed Rule.

2. The Proposed Rule contains surprise retroactive conditions.

The Proposed Rule also contains surprise retroactive conditions that would be imposed well after States have agreed to participate in Medicaid, in violation of the Spending Clause, and that also apply retroactively upon publication, as the Proposed Rule contains no effective date. For Spending Clause legislation to be valid, Congress must give clear and unambiguous notice to States and other regulated parties of the legislation's terms, and the federal government may not "'surpris[e] participating States with post-acceptance or 'retroactive' conditions.'" *See NFIB*, 567 U.S. at 584 (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 25 (1981)).

The Executive Branch is likewise forbidden from imposing surprise retroactive conditions when carrying out Spending Clause legislation.[124] As the Supreme Court has observed, it "strains credulity" to think that a State would have had notice of and agreed to unambiguous funding

[124] *See Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172–73 (executive agencies cannot push limits of congressional authority); *New York v. United States Dep't of Health & Hum. Servs.*, 414 F. Supp. 3d 475, 566 n.70 (S.D.N.Y. 2019) ("An agency which Congress has tasked with implementing a statute that imposes spending conditions is also subject to the Clause's restrictions.").

conditions, when the administering agency announces those conditions for the first time well into a long-settled program. *Pennhurst*, 451 U.S. at 25.

Here, the new conditions announced in the Proposed Rule constitute surprise, retroactive conditions of Medicaid and Medicare that none of the administering States or their hospitals agreed to at the programs' outset, or even during the latest rounds of funding.[125] The Social Security Act gives no notice—much less clear or unambiguous notice—that acceding to the President's or federal government's policy preferences for medical treatment is a condition of participation. In fact, in passing Medicare, Congress promised States the opposite: the federal government would not interfere in the practice of medicine or hospital administration.[126] See *supra* at Section III.A.1.

Nor have any decisions of the Supreme Court (or other courts) ever—much less "consistently"—put hospitals on notice that the Social Security Act gives CMS authority to superintend the practice of medicine. *Cf. Jackson v. Birmingham Bd. of Educ.,* 544 U.S. 167, 183 (2005). In fact, courts have routinely reached the opposite position. See *supra* at Section III.A.1. And, as if that were not enough, CMS itself has consistently taken the *opposite* position, repeatedly cautioning States that their federal funding may be compromised *if they discriminate based on diagnosis*—the very thing that the Proposed Rule does. See *infra* Sections III.C.1, 3. Put simply, requiring hospitals "to adopt novel interpretations of the law, favored by Defendants but not yet imposed by Congress or the courts, would have been unforeseeable as a condition to accepting federal assistance for the [hospital's] existing programs." *See Am. Ass'n of Univ. Professors v. Trump*, No. 25-CV-07864-RFL, 2025 WL 3187762, at *24 (N.D. Cal. Nov. 14, 2025).

3. The Proposed Rule violates other requirements of the Spending Clause.

The Proposed Rule also runs afoul of the Spending Clause requirements that the spending condition be related to the "federal interest in [the] particular national project[] or program[]" and that the spending condition not "induce the States to engage in activities that would themselves be unconstitutional." *South Dakota v. Dole*, 483 U.S. 203, 207, 210 (1987).

Here, the spending condition is unrelated to the government's interest in protecting the health and safety of Medicare and Medicaid beneficiaries in hospitals. First, the Proposed Rule allows the same or similar treatments, including purely elective procedures, to be provided to other patient populations, including other patient populations under the age of 18. This inconsistency

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[125] *Cf. New York*, 414 F. Supp. 3d at 568 (HHS conscience rule impermissibly exposed States to "heightened risk, in the middle of a funding period, that funds previously allocated will be withheld or terminated").

[126] Congress has reaffirmed this state primacy over time, including in 42 U.S.C. § 18122(1), which prohibits federal actions under the ACA, Medicare, or Medicaid from being construed "to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim" or to preempt any related state or common law claims. This statute defines federal actions broadly to include "the development, recognition, or implementation of any guideline or other standard under any Federal health care provision" under the ACA, Medicare, or Medicaid. 42 U.S.C. § 18122(1). This is yet another example where Congress underscored that states, not the federal government, are responsible for the regulation of medicine and setting standards of care.

confirms that there is nothing inherently unsafe, hazardous, or unprofessional about providing these medical treatments as part of a hospital's services, nor is there any genuine, good-faith concern that harms will "spill over" to other patient populations (which, under the rule, may legally receive these treatments).

Second, the Proposed Rule applies regardless of whether the hospital provides these treatments to Medicare or Medicaid beneficiaries. In other words, even if CMS's pretextual concerns about "health and safety" were limited to the health and safety of transgender youth covered by Medicare and Medicaid,[127] that concern would provide no justification for the Proposed Rule's broad sweep, which bans hospitals from providing these treatments to anyone, including self-pay or privately insured patients.

In addition to being unrelated to the government's interest in all federal funding for hospitals, the condition of participation induces the States to engage in activities that are unconstitutional. The Proposed Rule, which follows directly from the President's policy preferences announced in an Executive Order,[128] is based on discriminatory animus, and it conscripts state-run hospitals (as well as state surveyors that are typically responsible for evaluating a hospital's compliance with the conditions of participation) into carrying out its discriminatory purpose. See *infra* at Section III.D.1.

Further, the Spending Clause requires that any condition on federal funding be "unambiguous[]," which allows the States to "exercise their choice knowingly, cognizant of the consequences of their participation."[129] But the Proposed Rule's language is impermissibly ambiguous in defining which medical treatments are and are not "sex-rejecting." But the Proposed Rule's definition of sex does not align with any medical understanding of sex of which the States are aware.[130]

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[127] As noted, *supra* at Section II.D.1, in New York, for example, the number of youth under age 18 who received medications to support transgender healthcare represent approximately 0.02% (or two-hundredths of one percent) of all youth in New York's Medicaid and Child Health Plus programs.
[128] Proposed Rule at 59464 (specifying that the Proposed Rule is promulgated pursuant to the Executive Order).
[129] *Pennhurst State School & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).
[130] *See, e.g.*, *Washington v. U.S. Dep't of Health and Human Servs.*, 6:25-cv-01748-AA (Sep. 26, 2025 D. Ore), Doc. 8 ¶¶ 25, 34–37 (expert declaration of Dr. Kate Millington, explaining why sex is not binary and how people with differences of sex development demonstrate that reality).

C. The Proposed Rule Is Otherwise Contrary to Law.

1. The Proposed Rule is contrary to the Medicaid Drug Rebate Program's requirement that States cover FDA-approved medications for their medically accepted uses.

The Proposed Rule is wholly inconsistent with Medicaid's requirement that states cover FDA-approved drugs for medically accepted uses; it would exclude hospitals for prescribing covered outpatient drugs which the state is required by law to make available.[131]

Under Section 1927 of the Social Security Act, any state that participates in the Medicaid pharmacy benefit (which all states do) must offer "covered outpatient drugs" as part of the Medicaid Drug Rebate Program (MDRP). 42 U.S.C. § 1396r-8(k)(2).[132] While a state has some discretion to implement utilization management strategies, such as prior authorization, of a covered outpatient drug, a state may not refuse coverage of a drug if prescribed for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i). A "medically accepted indication" is defined by statute as either the medical use listed on the FDA-approved label or a use listed in one of three pharmaceutical compendia. 42 U.S.C. § 1396r-8(k)(6); 42 U.S.C. § 1396r-8(g)(1)(B)(i) (listing the three compendia). Indeed, CMS has noted that states may not exclude coverage of FDA-approved drugs,[133] and courts have reached the same outcome when evaluating whether exclusion of a covered outpatient drug violates Section 1927.[134] Thus, by law, covered outpatient drugs must be made available through and covered by state Medicaid plans for all medically accepted indications.

The compendia explicitly indicate puberty blockers and hormone therapies as medically accepted treatments for gender dysphoria in adolescents, thus making them covered outpatient drugs. The American Hospital Formulary Service Drug Information states, "GnRH agonists such as leuprolide [] have been used for pubertal hormone suppression in transgender persons undergoing gender-affirming hormone therapy."[135]

The Proposed Rule does an end run around the MDRP, leading to absurd results. If the Proposed Rule is effectuated, a hospital that participates in Medicaid would likely be excluded for prescribing drugs that are covered by Medicaid for uses that are protected, indeed required, by

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[131] This further refutes CMS's assertion that the relevant treatments are not "healthcare."
[132] "Covered outpatient drugs" include biological products dispensed upon prescription, 42 U.S.C. § 1396r-8(k)(2)(B), such as puberty blockers and hormones.
[133] *See* Letter from Tim Hill, Acting Director CMS, to Daniel Tsai, Assistant Secretary MassHealth (June 27, 2018), ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf.
[134] *See, e.g., Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1341 (S.D. Fla. 2006).
[135] American Formulary Service Drug Information, Section 68.18.08, *Leuprolide Acetate, Leuprolide Mesylate, "Other Uses"* (*citing* WC Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, J. Clin. Endocrin. Metab., 2017:3869-3903).

Medicaid law. It could not have been Congress's intention that a Medicaid-participating hospital be prohibited from prescribing a drug that Medicaid is required to cover.

Further contrary to the MDRP, the Proposed Rule attempts to rewrite Section 1927(d)(2) by creating a new extra-statutory exclusion where one does not exist.[136] Under Section 1927(d)(2), Congress identified a narrow list of "drugs or classes of drugs, or their medical uses" that can be excluded.[137] Congress included a very limited number of potentially excludable indications in this list. For instance, the statute does not exclude specific weight-loss drugs.[138] Rather, Congress allows drugs to be excluded "*when used for* anorexia, weight loss, or weight gain."[139] Similar restrictions apply for drugs "*when used to* promote fertility;" "*when used for* the symptomatic relief of cough and colds;" and "*when used for* the treatment of sexual or erectile dysfunction" under most circumstances.[140] The Proposed Rule's new exclusion would apply to drugs when used for the treatment of gender dysphoria in transgender youth. Such an exclusion simply does not exist in the statute, and HHS has no authority to create one.

2. The Proposed Rule violates CMS's statutory obligation to consult with state agencies.

The States are gravely concerned that CMS has entered into this notice-and-comment process with an unalterably closed mind and seeks to reach a predetermined outcome. By employing this predetermined notice-and-comment process, CMS fails to satisfy the obligation to consult with state agencies when making determinations on conditions of participation. Under 42 U.S.C. § 1395z, the Secretary "shall" consult with state agencies and national listing or accrediting bodies "relating to determination of conditions of participation by providers of services, under subsections (e)(9) . . . of section 1395x of this title."[141] But CMS did not do so here.

In order to issue a rule before consulting with state agencies, the Secretary must show "good cause" and must engage in deferred consultation after issuing an interim rule.[142] In *Biden v. Missouri*, the Supreme Court held that the Secretary established good cause for forgoing notice-and-comment rulemaking under 5 U.S.C. § 553(b)(3)(B) and was similarly permitted to delay state agency consultation in issuing an interim final rule requiring hospital staff to be vaccinated against the COVID-19 virus because the rule would significantly reduce COVID-19 infections, hospitalizations, and deaths.[143] In demonstrating good cause, the Secretary effectively complied

[136] *Cf.* 42 U.S.C. § 1396r-8(d)(2) (list of drugs subject to exclusion).
[137] 42 U.S.C. § 1396r-8(d)(2).
[138] 42 U.S.C. § 1396r-8(d)(2).
[139] 42 U.S.C. § 1396r-8(d)(2)(A) (emphasis added).
[140] 42 U.S.C. §§ 1396r-8(d)(2)(B), (D), (H).
[141] 42 U.S.C. § 1395z.
[142] *See* 5 U.S.C. § 553(b)(B); *Biden v. Missouri*, 595 U.S. 87, 96–97 (2022)
[143] *Biden v. Missouri*, 595 U.S. 87, 96–97 (2022)

with the APA's requirement to "incorporate[] the finding and a brief statement of reasons therefor in the rules issued."[144]

The Proposed Rule fails to even mention the statutory consultation requirement, rendering it unlawful. Moreover, the Secretary cannot demonstrate good cause to delay consultation, even if that was his intention, because none exists. Unlike the scenario in *Biden v. Missouri*, the Secretary here is not facing a public health emergency caused by a global pandemic as the winter flu season approaches.[145] Instead, the Secretary is seeking to end the decades-long availability of healthcare to transgender youth in order to implement the Administration's policy priorities.

If the Secretary were to actually consult with states—which have long regulated the practice of medicine—and not just carry out a predetermined notice-and-comment process, he would have to grapple with the fact that many states, with approval from the federal government, have long provided transgender care, which is indeed healthcare, to youth through Medicaid (indeed, as discussed *infra* at Section III.C.4, Medicaid, through requirements like the Early and Periodic Screening, Diagnostic, and Treatment Services ("EPSDT") program, requires states to cover such healthcare). The Secretary would also have to grapple with the fact that the MDRP requires coverage of various puberty blockers and other hormones for the treatment of gender dysphoria in youth. The Secretary would also have to grapple with the fact that the medical community overwhelmingly supports the availability of medically necessary healthcare for transgender youth,[146] which is contrary to the Secretary's attempt to wholesale end such care. Relatedly, the Secretary would have to grapple with the fact that State providers would be hampered in their ability to carry out important functions of medical education and research in the area of transgender healthcare under the Proposed Rule. But rather than consult with state agencies and reckon with reality, the Secretary attempts to unilaterally ban transgender youth's access to medically necessary healthcare at participating hospitals. This violates both 5 U.S.C. § 553(b)(B) and 42 U.S.C. § 1395z.

Additionally, this lack of requisite state consultation highlights the degree to which the Proposed Rule seeks to unilaterally amend approved state Medicaid and CHIP plans. Pursuant to 42 U.S.C. § 1396b, "the Secretary. . . shall pay to each State which has a plan approved" amounts specified by statute.[147] Pursuant to 42 U.S.C.§ 1396a, the Secretary has approved state Medicaid and CHIP plans for each Plaintiff State under which each state provides health services to eligible individuals.[148] "The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program."[149] The Proposed Rule would unilaterally amend state plans by effectively barring transgender healthcare to youth by threatening to drastically reduce the number of eligible

[144] *See* 5 U.S.C. § 553(b) (B) (good-cause statutory requirement).
[145] *Biden v. Missouri*, 595 U.S. 87, 96 (2022).
[146] *Supra* note 37.
[147] 42 U.S.C. § 1396b(a).
[148] *See* 42 U.S.C. § 1396(a).
[149] 42 C.F.R. § 430.10.

providers by deeming them presumptively excluded from participation, and by curtailing the states' traditional authority under the Medicaid Act to determine services covered.

Finally, this lack of consultation also highlights how the Proposed Rule's prohibition of medical providers who provide medically necessary transgender healthcare from participating in the Medicaid program violates the requirement that Medicaid beneficiaries have a free choice of provider. The Medicaid statutes give states the authority to set qualifications for providers who may participate in their State Plan.[150] By effectively ending all hospital-based transgender healthcare for youth, the Proposed Rule takes away the States' ability to set qualifications of medical providers.

3. The Proposed Rule is contrary to Medicaid comparability and flexibility provisions by limiting the availability of services.

The Proposed Rule's categorical ban on transgender healthcare for youth at participating hospitals will prevent state Medicaid agencies from being able to offer hospital-provided healthcare based on a diagnosis of gender dysphoria. Accordingly, it directly conflicts with Medicaid regulations that (1) prohibit state Medicaid agencies from arbitrarily denying or reducing access to care because of an individual's diagnosis, type of illness, or condition (also known as the "comparability requirement"), and (2) allow state Medicaid agencies flexibility in administering their Medicaid programs.[151]

Specifically, state Medicaid agencies are subject to the comparability requirement, which prohibits state Medicaid programs from arbitrarily denying or reducing "the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition."[152] To comply with this comparability requirement, state Medicaid programs must generally cover prescribed medically necessary treatments without arbitrary distinctions based on indication.[153] In other words, the comparability provision prohibits states from discriminating among Medicaid beneficiaries based on diagnosis or age.[154]

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[150] 42 U.S.C. § 1396a(a)(23); 42 C.F.R. § 431.51.

[151] *See* 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. §§ 440.240. 440.230(c) (comparability), 440.230 (flexibility); The comparability requirement at 42 C.F.R. § 442.240 "prohibits discrimination among individuals with the same medical needs stemming from different medical conditions." *Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1018 (W.D. Wis. 2019) (alteration and citations omitted). This requirement "ensures equitable treatment" of Medicaid beneficiaries. *Garrido v. Dudek*, 731 F.3d 1152, 1154 (11th Cir. 2013).

[152] 42 C.F.R. § 440.230(c).

[153] *Davis v. Shah*, 821 F.3d 231, 255–56 (2d Cir. 2016).

[154] *Skrmetti* does not require a different result. While the Supreme Court held in *Skrmetti* that a law restricting certain surgical and chemical interventions for youth diagnosed with gender dysphoria does not discriminate on the basis of sex, the Court did not address whether such a restriction would violate the comparability requirement by discriminating on the basis of diagnosis. *United States v. Skrmetti*, 605 U.S. 495 (2025).

But the Proposed Rule will require state Medicaid agencies to provide benefits and services to some beneficiaries in a hospital setting, but not to others, on the basis of their diagnosis or age. Indeed, the Proposed Rule permits the banned procedures for all purposes *other* than to treat gender dysphoria, and it permits the banned procedures for patients over the age of 18, but not under, regardless of the individual characteristics of the patients. It even permits these services for the supposed treatment of complications that arose from earlier transgender healthcare.[155] The Proposed Rule would thus require state Medicaid agencies to discriminate against individuals with gender dysphoria by allowing necessary hospital services to some beneficiaries but not others on the basis of diagnosis and age.[156]

States have also long enjoyed the discretion and flexibility to cover medical treatment of gender dysphoria in hospitals. Under 42 C.F.R. § 440.230, States are authorized to set state-specific standards regarding the amount, duration, and scope of Medicaid-covered services; criteria for determining medical necessity; and adopt procedures to control the utilization of Medicaid-covered services.[157] States have "substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage," subject to minimum federal coverage and FFP limits.[158] Where States have imposed limits on the scope of services, these limits have not been categorical. Instead, any state limits have applied based on a beneficiary's specific circumstances.[159] The requirements of the Early and Periodic Screening, Diagnostic, and Treatment Services ("EPSDT") program, as described below in Section III.C.4, further demonstrate the flexibility given to state Medicaid agencies, as CMS has historically deferred to state determinations of medical necessity in the EPSDT context.[160] This flexibility is particularly important here where CMS does not contend that medical treatments for gender dysphoria are not medically necessary in any case. Indeed, under the Proposed Rule, medical treatment for gender dysphoria in a hospital setting would be available for 18-year-olds under the Medicaid program but categorically medically unnecessary for all 17-year-olds. This strains credulity and demonstrates why it is important that States continue to exercise flexibility to determine whether treatment for gender dysphoria is medically necessary in individual cases.

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[155] Proposed Rule at 59471.
[156] *Davis*, 821 F.3d at 256; *see also Flack v. Wisconsin Dept. of Health Servs*., 395 F. Supp. 3d 1001, 1019 (W.D. Wis. 2019) (holding that categorical exclusion for medically necessary transgender healthcare in a state Medicaid plan violated the comparability provision); *Kadel v. Folwell*, 100 F.4th 122, 163 (4th Cir. 2024) cert. granted, decision vacated, and remanded by *Folwell v. Kadel*, 145 S. Ct. 2838 (2025) (same).
[157] 42 C.F.R. § 440.230.
[158] *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 665 (2003) (citing *Alexander v. Choate*, 469 U.S. 287, 303 (1985)).
[159] Katie Keith, *Proposed Federal Proposed Rules Target Health Care for Transgender Youth (Part 1)*, Health Affairs (Dec. 22, 2025), https://www.healthaffairs.org/content/forefront/proposed-federal-rules-target-health-care-transgender-youth-part-1.
[160] *Infra* Section III.C.4.

The Proposed Rule's inconsistences with these longstanding Medicaid regulations make clear that the "authority desired by [CMS] is inconsistent with the design of the statute in . . . fundamental respects."[161]

4. The Proposed Rule violates Section 1905(r) by frustrating the states' ability to comply with EPSDT requirements.

The Proposed Rule also creates a tension with Section 1905(r) (42 U.S.C. § 1396d(a)(4)(B), (r)), which requires that state Medicaid plans cover Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) for youth. "The goal of EPSDT is to assure that individual children get the health care they need when they need it–the right care to the right child in the right setting."[162] In the Medicaid Reimbursement Proposed Rule, CMS properly acknowledges that "EPSDT requires the provision of screening vision, dental, and hearing services, and such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects and physical and mental illness and conditions discovered by the screening services, whether or not such services are covered under the State plan."[163] In other words, the state must provide qualifying youth access to all medically necessary healthcare services. The Medicaid Reimbursement Proposed Rule also recognizes that "States may only include tentative limits on services and must take into account the individual needs of the child."[164] If a service could be available for adults under a Medicaid state plan, then that service must be available to those under 21 when medically necessary.[165] And, as CMS has also made clear, "[a]ny qualified provider operating within the scope of his or her practice, as defined by state law, can provide a screening service" that triggers EPSDT and requires the state Medicaid program to cover the medically necessary healthcare services.[166]

CMS fails to examine the interaction between the Proposed Rule and states' obligations under EPSDT. The Proposed Rule may make it difficult or impossible for patients to obtain medically necessary transgender healthcare, even though federal law requires that states provide that care under EPSDT. CMS makes no effort to untangle this problem. Further, CMS does not adequately explain its departure from its long-standing practice of deferring to state determinations

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[161] *Gonzales v. Oregon*, 546 U.S. 243, 265 (2006).
[162] CMS, EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents at 1 (June 2014).
[163] 90 Fed. Reg. 59449.
[164] CMS, EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents at 23 (June 2014).
[165] *See*, *e.g.*, *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 590 (5th Cir. 2004) ("[E]very Circuit which has examined the scope of the EPSDT program has recognized that states must cover every type of health care or service necessary for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)."); *see also* SHO #24-005 re: Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements at 21 (Sept. 26, 2024) ("[I]f an optional section 1905(a) service is not covered for adults, that section 1905(a) service must still be made available to EPSDT-eligible children when it is medically necessary.").
[166] CMS, EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents at 6 (June 2014).

of medical necessity in the EPSDT context.[167] The Undersigned States are aware of no prior instance in which CMS has categorically denied EPSDT coverage by a particular provider or in a particular setting, qualified to provide it under state law, for a service used to treat a medical condition that a state has determined is medically necessary. The Proposed Rule's categorical removal of the States' discretion to cover medical treatment of gender dysphoria for youth in hospitals, even where it has been determined to be medically necessary for a particular patient, is at odds with EPSDT requirements under federal law and CMS's own past practice.

5. The Proposed Rule runs counter to ACA Section 1554.

Section 1554 of the Affordable Care Act ("ACA") further demonstrates that the Proposed Rule exceeds CMS's authority. This provision prohibits the Secretary of HHS from promulgating "any" regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;" "impedes timely access to healthcare services;" or "limits the availability of healthcare treatment for the full duration of a patient's medical needs."[168] For purposes of Section 1554, "medical care" is defined to include "amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body" and "amounts paid for insurance covering medical care."[169]

Despite CMS's assertion to the contrary, treatment for gender dysphoria in youth falls squarely within the statute's definition of "medical care,"[170] and the Proposed Rule creates unreasonable barriers and impedes timely access to such treatment in a hospital setting. HHS acknowledges as much, estimating that about half of the 8,500 transgender youth who receive treatment for gender dysphoria in hospitals would simply go without treatment for gender dysphoria if the rule were to be finalized.[171] Further, these are not "reasonable" barriers nor is this healthcare "inappropriate" per the terms of the statute. For reasons discussed above, medically necessary transgender healthcare for youth is widely accepted as evidence-based, safe, and effective.[172] The Proposed Rule's categorical ban on such safe and effective healthcare at participating hospitals is clearly not reasonable.

This is not a novel interpretation of Section 1554. In *Mayor of Baltimore v. Azar*, the Fourth Circuit held that an HHS rule violated Section 1554 by prohibiting abortion referrals and "placing

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[167] *See* CMS, EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents at 24 (June 2014) (describing how individual determinations of medical necessity are made and advising that "the state is responsible for making a decision" which is subject to fair hearing procedures).
[168] 42 U.S.C. § 18114.
[169] *See* 42 U.S.C. § 18111 (incorporating the definitions, including "medical care," as defined in 42 U.S.C. § 300gg-91 unless specified otherwise). "Medical care" is defined in 42 U.S.C. § 300gg-91(a)(2).
[170] *See* 42 U.S.C. § 18111 (incorporating the definitions, including "medical care," as defined in 42 U.S.C. § 300gg-91 unless specified otherwise). "Medical care" is defined in 42 U.S.C. § 300gg-91(a)(2).
[171] Proposed Rule at 59475.
[172] *Supra* at Section II.C.

limits on [a provider's] ability to act."[173] Likewise, this Proposed Rule will prevent hospitals and their providers from offering this care to any transgender patient under the age of 18, regardless of the source of coverage. The Proposed Rule also violates Section 1554 by impeding timely access to healthcare services through forcing States, managed care entities, and providers to abruptly cease offering certain healthcare services and develop and adapt new systems, which risks disruption to coverage and care for existing patients—likely permanently.

D. The Proposed Rule Is Arbitrary and Capricious.

1. The Proposed Rule reflects a predetermined outcome and is premised on pretextual justifications.

This Administration has made its intention plain: it seeks to end transgender healthcare for youth nationwide. As described in Section II.A, eight days after taking office, the President issued Executive Order 14187, "Protecting Children From Chemical and Surgical Mutilation" ("the EO"), and announced that transgender healthcare for youth "must end."[174] The EO directed federal agencies to restrict youth from accessing puberty blockers, hormones, and surgeries if (and only if) the treatments are used to treat gender dysphoria.[175] It specifically directed HHS to "take all appropriate actions to end the chemical and surgical mutilation of children" including "Medicare or Medicaid conditions of participation or conditions for coverage[.]"[176] The EO caused healthcare providers across the country to halt provision of transgender healthcare, the White House has boasted was its "intended effect—preventing children from being maimed and sterilized by adults perpetuating a radical, false claim that they can somehow change a child's sex."[177] As described in Section II.A, CMS and other agencies have promptly and aggressively followed the President's instructions.

As several courts have now noted in the context of litigation over subpoenas issued by DOJ, the administration's actions in this sphere smack of bad faith. As one of those courts observed:

> The Administration has been explicit about its disapproval of the transgender community and its aim to end [transgender healthcare]. The subpoena reflects those goals, comprising overbroad requests for documents and information seemingly unrelated to investigating fraud or unlawful off-label promotion. It is abundantly clear that the true purpose of issuing the subpoena is to interfere with the Commonwealth of Massachusetts' right to protect [transgender healthcare] within

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[173] 973 F.3d 258, 288 (4th Cir. 2020).

[174] Executive Order No. 14,187, *Protecting Children From Chemical and Surgical Mutilation*, 90 Fed. Reg. 9,771 § 1 (Jan. 28, 2025).

[175] *Id.*

[176] *Id.*

[177] The White House, *President Trump is Delivering on His Commitment to Protect our Kids* (Feb. 03, 2025), https://perma.cc/VHV5-2HMT.

> its borders, to harass and intimidate [Boston Children's Hospital] to stop providing such care, and to dissuade patients from seeking such care. For the above reasons, I find that the Government has failed to show proper purpose and, even if it had, that BCH has demonstrated that the subpoena was issued for an improper purpose, motivated only by bad faith."

In Re: Administrative Subpoena No. 25-1431-019, 800 F. Supp. 3d 229, 239 (D. Mass. 2025).

This Proposed Rule flows directly from the President's direction: the Agency's actions in proposing the rule were preordained by the Executive Orders signed nearly a year before the proposal was issued and by the administration's numerous subsequent actions targeting this form of care.[178] And if this were not sufficiently clear, the Kennedy Declaration—and the fact that it took immediate effect and was issued contemporaneously with the notices of proposed rulemaking—demonstrate that HHS had already made up its mind about banning treatment for gender dysphoria in young people. Working backwards from its conclusion, and relying repeatedly and almost exclusively on its own discredited and unscientific review that elevates a handful of disputed studies, CMS's portrayal of transgender healthcare as unsafe is dishonest, incomplete, and incorrect. The justifications set forth in the Proposed Rule are patently pretextual.

Also, as discussed *infra* at Section III.B.3 the Proposed Rule's vagueness in defining "sex-rejecting" is further evidence of why it is arbitrary and capricious.

2. The Proposed Rule ignores important aspects of this issue.

a) The Proposed Rule ignores copious research that demonstrates that transgender healthcare is evidence-based, safe, and beneficial—including evidence that was presented by the States in an OIRA meeting.

CMS failed to consider copious research that demonstrates that transgender healthcare is evidence-based, safe, and beneficial—including evidence that was presented by States in an OIRA meeting.

In the fall of 2025, after States observed that a notice of rulemaking had been listed on the public website of the Office of Management and Budget ("OMB"), States proactively reached out and requested a meeting with OMB to discuss the proposal (whose text had not been published), under the same mechanism for requesting meetings that is available to any member of the public.

On September 2, 2025, a group of States met with Office of Information and Regulatory Affairs ("OIRA") and OMB to discuss this Proposed Rule and the Proposed Medicaid Reimbursement Rule. During that meeting and in writing immediately afterward, the States

[178] *See* Proposed Rule at 59464; *see also In Re: Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229 (D. Mass. 2025).

provided OIRA and OMB with ample evidence regarding the safety and efficacy of this care.[179] Yet the Proposed Rule does not respond to any of the States' concerns beyond asserting in a conclusory manner that any contrary views are outweighed by uncertainties described in the HHS Report. CMS's failure to engage in any meaningful consideration of studies, research, and accounts that conflict with and undermine its justification for this regulatory action violates basic principles of administrative law.[180] Nor does the HHS Report, as noted above, offer a reasoned rebuttal of the evidence the states have placed before the agency.

First, CMS did not consider plentiful evidence outlining the effectiveness of transgender healthcare in mitigating known symptoms of gender dysphoria. Studies have shown that patients who receive puberty-delaying medications, hormone therapies, and/or surgical procedures to treat gender dysphoria report lower rates of anxiety and depression,[181] and suicidality,[182] and improvements in the patient's quality of life.[183] CMS has long been aware of the studies that evidenced these benefits, and was further aware that dozens of professional medical associations which reviewed and relied on those studies also found the treatments beneficial.[184] Yet CMS

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[179] EO 12866 Meeting 0938-AV87, Brief Response to Questions Posed During September 2, 2025 OIRA Meeting and Exhibits 1–68, Reginfo.gov, https://perma.cc/VV37-F4K8. This meeting does not come close to satisfying CMS's obligation to consult with states, as there was not yet any proposed rule to review. Additionally, as discussed, the proposed rule ignores all the research and other input the States provided OIRA and OMB, further demonstrating the predetermined nature of this entire process.

[180] See *supra* Section II.C.

[181] Brett Dolotina & Jack L. Turban, *A Multipronged, Evidence-Based Approach to Improving Mental Health Among Transgender and Gender-Diverse Youth*, 5 JAMA Network Open e220926 (2022) ("accessing PB/GAH was associated with 60% lower odds of moderate to severe depression and 73% lower odds of suicidality"); Diana M. Tordoff et al., *Mental health outcomes in transgender and nonbinary youth receiving gender-affirming care*, 5 JAMA Network Open e220978 (2022); Jaclyn M. White Hughto & Sari L. Reisner, *A Systematic Review of the Effects of Hormone Therapy on Psychological Functioning and Quality of Life in Transgender Individuals*, 1 Transgender Health 21, 29 (2016) (two studies reported statistically significant reduction in depression and anxiety after initiating hormone therapy); Marco Colizzi et al., *Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: results from a longitudinal study*, 39 Psychoneuroendocrinology 65 (2014); Gunter Heylens et al., *Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder,* 11 J. Sex Med. 119 (2014).

[182] Danyon Anderson et al., *Gender Dysphoria and Its Non-Surgical and Surgical Treatments*, 10 Health Psych. Rsch. 1, 5 (2022); Brett Dolotina & Jack L. Turban, *A Multipronged, Evidence-Based Approach to Improving Mental Health Among Transgender and Gender-Diverse Youth*, 5 JAMA Network Open 1 e220926 (2022) (. . . [T]hose who access gender-affirming medical care during adolescence had lower odds of suicidality and other adverse mental health outcomes when compared with those who are unable to access such care."); Jack L. Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, 18(6) J. Plos One e0287283 (2023), https://perma.cc/4VEK-7M8N (gender-affirming hormones during adolescence and adulthood have been shown to lead to "decreases in internalizing psychopathology, improved general wellbeing, and decreased suicidality.").

[183] Danyon Anderson et al., *Gender Dysphoria and Its Non-Surgical and Surgical Treatments*, 10 Health Psych. Rsch. 1, 5 (2022), https://doi.org/10.52965/001c.38358) ("Treatment decreases suicidality among individuals with gender dysphoria and leads to improved quality of life."); Nita Bhatt, Jesse Cannella, & Julie P. Gentile, *Gender-affirming Care for Transgender Patients*, 19 Innovations Clinical Neuroscience 23, 31 (2022) (transgender healthcare has consistently been shown to improve quality of life).

[184] *See supra* note 37.

simply refused to consider evidence that ran contrary to their predetermined outcome, let alone cogently explain why such evidence does not support a different course.

Second, CMS had and ignored evidence that possible side effects of transgender healthcare services can be safely monitored and mitigated. One study found that transgender women had factors that may contribute to an increased risk of osteoporosis, as an example. But "transgender women who received hormones were found to have lower, higher, and no change in bone density after initiating hormones."[185] Providers are encouraged to measure this risk on a patient-by-patient basis, inform the patient of the possible risk, and encourage interventions known to help develop bone mineral density.[186] Most published studies of bone mineral density in transgender men, on the other hand, have shown either no change or an increase in bone mineral density when the patient is treated with testosterone.[187]

Third, available research reports that patients' rates of regret for having received transgender healthcare are very low. One study reported that 0.6% of transgender women and 0.3% of transgender men experienced regret.[188] Another study reported that regret was documented in 1.1% of adult gender-diverse patients.[189] Studies of adolescents and youth who receive transgender healthcare as youth report similar findings. One study of over 200 adolescents and youth who received medical treatment for gender dysphoria found that five years after the start of treatment using puberty-blockers, 4% of the youth reported having some regret, and even fewer reported stopping treatment.[190] Again, CMS simply failed to consider this research.

b) The Proposed Rule fails to account for other existing and proposed HHS regulations.

As described above, HHS announced the Proposed Rule simultaneously with "a series of proposed regulatory actions" intended to "carry out President Trump's Executive Order directing HHS to end the practice of sex-rejecting procedures on children."[191] Despite their coordinated

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[185] Madeline B. Deutsch, *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* (2nd ed., 2016) at 78.
[186] *See* 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, S153 (2022) (providers are encouraged to discuss bone health with patients and advise on interventions).
[187] Madeline B. Deutsch, *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* (2nd ed., 2016) at 78.
[188] *See* Chantal M. Wiepjes et al., *The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in prevalence, treatment, and regrets,* 15(4) J. Sex Med. 582 (2018).
[189] *See* R Hall et al., *Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review,* 7(6) BJPsych Open. e:184 (Oct. 1, 2021).
[190] *See* Olson, K.R., Raber, G.F., & Gallagher, N.M., *Levels of Satisfaction and Regret with Gender-Affirming Medical Care in Adolescence*, 178(12) JAMA Pediatrics 1354 (2024); *see also* Gupta, P., Cunha, L.M., Diego, D., & Tangpricha, V., *Continuation of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Individuals: A Systemic Review*, 30(12) Endocr. Pract. 1206 (2024); van der Loos, M.A.T.C., Hannema, S.E., Klink, D.T., et al., *Continuation of Gender-Affirming Hormones in Transgender People Starting Puberty Suppression in Adolescence: A Cohort Student in the Netherlands*, 6(12) *Lancet Child Adolesc. Health* 869 (2022).
[191] HHS, *HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children* (Dec. 18, 2025), https://perma.cc/XW3R-LG82.

design and synchronized promulgation, the Proposed Rule does not acknowledge the other two HHS actions—the Kennedy Declaration and the proposed Medicaid Reimbursement Rule—nor discuss their impact on or interaction with this Proposed Rule, save a single mention of the Medicaid Reimbursement Rule.

An agency must "display awareness" of the regulatory environment in which it operates and must "provide reasoned explanation for its action." *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009). An agency also has an "obligation to acknowledge and account for" the "regulatory posture the agency creates." *Portland Cement Ass'n v. EPA*, 665 F.3d 177, 187 (D.C. Cir. 2011) (per curiam); *accord Zen Magnets, LLC v. Consumer Prod. Safety Comm'n*, 841 F.3d 1141, 1150 (10th Cir. 2016).

Here, the Proposed Rule does not even mention, much less "account for" or "provide reasoned explanation" of the impact of the Kennedy Declaration—a final agency action with immediate consequences—or the proposed Medicaid Reimbursement Rule on this rule. The Proposed Rule is premised upon CMS's assumption that youth who require medical treatment for gender dysphoria but can no longer obtain it from covered hospitals "are likely to switch to other provider types that are not affected by this proposed requirement."[192] CMS estimates that 50% of youth currently receiving medical care for gender dysphoria from covered hospitals will transfer their care accordingly.[193] However, this assumption is irreconcilable with the purpose and intended effects of the Kennedy Declaration and the proposed Medicaid Reimbursement Rule.

If CMS had properly accounted for the Kennedy Declaration, CMS would have been unable to represent that this care could shift to small, private, non-hospital-based providers because the Kennedy Declaration seeks to effectively bar all providers from providing this care nationwide. Under the Declaration, HHS can purportedly exclude healthcare providers for life from participation in any federally funded medical programs, even if they do not voluntarily enroll as providers in Medicare or Medicaid, simply for providing transgender medical care to patients under 18 years old.[194] Exclusion has numerous collateral consequences for providers, including the inability to join private insurance panels, obtain loans for medical practices, or secure malpractice insurance. Few providers, if any, can risk such consequences. Because exclusion would effectively render a provider unable to practice medicine in the U.S., the "other providers" this Proposed Rule assumes will absorb hospital patients seeking to transfer care will no longer exist. And in fact, HHS has already referred at least four LGBTQ+ community health centers to the Inspector General for investigation under the Kennedy Declaration for their provision of transgender healthcare to youth.[195]

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[192] Proposed Rule at 59474.
[193] *Id.*
[194] Kennedy Declaration.
[195] HHS General Counsel Mike Stuart, X (Feb. 11, 2026, 1:16 PM), https://perma.cc/8SN5-ADJK; *see also* Erin Reid, *Trump Administration Targets Major LGBTQ+ Health Care Centers In Latest Legal Attack*, Erin in the Morning (Feb. 12, 2026), https://perma.cc/TEE8-U24L.

The proposed Medicaid Reimbursement Rule likewise undermines the Proposed Rule's assumption that patients who need transgender medical care will be able to obtain it from other providers. If that Rule takes effect, patients who rely on Medicaid will be stripped of insurance coverage for transgender medical care for youth. Even if a patient located a provider willing to continue their transgender medical care despite the existential threat posed by the Kennedy Declaration, any patient on Medicaid would instead be forced to pay for that care out-of-pocket—an obvious impossibility for many of the low-income patients the Medicaid program serves. The Proposed Rule acknowledges that nearly 45% of children rely on Medicaid or CHIP for their insurance coverage.[196] These patients—primarily low-income youth—will be unable to simply transfer their care to another provider as the Proposed Rule assumes. The Proposed Rule fails to address this.

The Proposed Rule thus offers a totally illusory solution to the problem it creates. It does not reflect reality and fails to demonstrate any awareness of the regulatory environment in which it operates and is in fact creating itself.

Further, CMS fails to acknowledge that several aspects of the HHS actions are inconsistent with each other. The definitions in this Proposed Rule, the Proposed Medicaid Reimbursement Rule, and the Kennedy Declaration do not uniformly define "sex-rejecting procedures" or exceptions to such procedures.[197] CMS must explain how States and all impacted parties should understand the varying definitions of sex, male, and female that are proposed in each of HHS's December 18, 2025, regulatory actions. Without further explanation, it would be nearly impossible for the States to implement the inconsistent definitions across the three agency actions.

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[196] Proposed Rule at 59472.

[197] For example, the Kennedy Declaration defines "sex-rejecting procedures" quite broadly as "pharmaceutical or surgical interventions . . . that attempt to align an individual's physical appearance with an asserted identity that differs from the individual's sex." Kennedy Decl. at 9. The Kennedy Declaration does not define "sex." The CoP Proposed Rule goes a step further, defining [transgender healthcare] as interventions that "intentionally disrupt[] or suppress[] the development of biological functions" and "remov[e], minimize[e], or permanently impair[] the function of primary or secondary sex-based traits." 90 Fed. Reg. at 59,477. The Reimbursement Proposed Rule differs still, including interventions that "disrupt[] or suppress[] the *normal* development of *natural* biological functions" and "amputate[e], minimize[]e, or destroy[] primary or secondary sex-based traits." 90 Fed. Reg. at 59,463 (emphasis added). Each definition by itself suffers from ambiguity—that lack of clarity is compounded by the variety of alternative meanings in the accompanying regulatory actions. Should the States read the definitions together? Must providers now apply different definitions for the same term depending on the context?

Additionally, under the CoP Proposed Rule, "child" is defined as anyone under the age of 18, 90 Fed. Reg. at 59,477; whereas under the Medicaid Reimbursement Proposed Rule, "child" is defined as "an individual under the age of 19." 42 C.F.R. § 457.10; 90 Fed. Reg. at 59,463. In both rules, whether the provision applies turns on whether the patient is a "child." 90 Fed. Reg. at 59,477; 90 Fed. Reg. at 59,463. The Kennedy declaration does not define "children or adolescents." Under these competing definitions, a patient might be able to be treated in a hospital without violating the conditions of participation, but that treatment would not be reimbursable by Medicaid, leaving doctors, administrators, and billing staff to parse through the details.

c) The Proposed Rule fails to adequately consider important reliance interests.

The Proposed Rule ignores the overwhelming reliance interests of transgender patients and their families, healthcare institutions (including state-operated facilities), state Medicaid and Medicare programs, and individual healthcare providers.

Harms to transgender youth and their families: Critically, the Proposed Rule disregards the reliance interests of the thousands of young people currently receiving transgender healthcare from covered hospitals. CMS completely ignores that the proposal will severely harm youth who have already been diagnosed and rely on ongoing treatment to manage their gender dysphoria. There are significant risks to abruptly stopping or delaying most medical treatments, including treatment of gender dysphoria. Termination of endocrine treatment can cause both psychological and biological problems.[198] For example, physicians report that patients whose endocrine treatments have been interrupted because of President Trump's coordinated campaign to end transgender medical care have suffered serious consequences, including dysmenorrhea and other menstrual issues; hot flashes; irritability; sexual function changes; permanent physical changes such as voice deepening and muscle mass growth; and the onset or progression of natal puberty that is inconsistent with their gender identity.[199] One provider saw patients experiencing medical problems as a result of having pubertal suppression implants remain in their bodies after the implant expired or ceased functioning when their previous provider refused to remove them due to the President's coordinated efforts to end transgender healthcare.[200] Leaving any medical device or foreign object inside the body presents significant health risks including a more difficult removal and increased growth of scar tissue.[201] Some of these harms—such as the progression of natal puberty—are irreversible.

Abrupt cessation or interruption of transgender healthcare can also trigger acute psychological distress, including anxiety, depression, episodes of self-harm, anhedonia, insomnia, hypervigilance, suicidal ideation, and social dysfunction.[202] It can cause the young person to experience more acute symptoms of gender dysphoria than they experienced before beginning medical treatment.[203] Some patients who have faced termination of care have reported symptoms of psychological distress. One provider reported an adolescent "ended up in the emergency department with acute suicidal ideation after learning that he would no longer be able to get healthcare at his prior practice; he felt abandoned and that nobody cared about him."[204] Another physician tragically lost a patient to suicide in August 2025 after the patient's mental health

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[198] Kristen L Eckstrand, Emrys (Fiona) Fonseca, Kellan Baker, Katie Dalke, *Mental Health and Care Denial in Transgender Youth,* 83(1) JAMA Psychiatry 9 (Jan. 1, 2026), https://perma.cc/YUX9-XQXV.
[199] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF Nos. 87-13, ¶ 41 and 87-12, ¶ 37.
[200] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-12, ¶ 37a.
[201] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-12, ¶ 37a.
[202] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF Nos. 87-21, ¶ 30, 87-13, ¶ 41, and 87-12, ¶ 37.
[203] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-13, ¶ 41 and 87-12, ¶ 37.
[204] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶ 30.

deteriorated significantly as a result of the federal attacks on transgender healthcare.[205] In the U.K., there has been a reported surge in deaths by suicide of transgender youth following the limitation of transgender healthcare.[206]

CMS also fails to address that specific forms of treatment upon which many patients currently rely may become nearly impossible to obtain or continue under the Proposed Rule. Many hospitals work with in-house Pharmacy Benefit Managers ("PBMs"), and with their increased funds, may purchase large amounts of particular medications, or front payment for very costly medications or devices, for which the PBMs then reimburse the hospital pharmacy as the medications are dispensed to patients. For example, a histrelin implant (a common subcutaneous puberty blocker implant that is often preferred by patients for its ease and efficacy as compared to puberty blocker injections) is costly, and many insurance programs cover it only through a buy-and-bill model. This requires the healthcare provider to buy the implant upfront—which can cost nearly $80,000 a piece—and bill insurance *after* inserting it into the patient. In other words, the provider must absorb the significant initial cost. While large hospitals, particularly those with on-site pharmacies, are often able to front the cost for these implants, many of the non-hospital-based practices simply cannot afford the expense of purchasing even one histrelin implant, let alone the large volume they would need in order to treat the hundreds or thousands of patients no longer able to continue this course of care at hospital centers. Accordingly, this form of treatment may become permanently unavailable, even to youth who are already relying on it.

Some youth who are denied access to legitimate transgender healthcare feel so desperate to avoid the grave consequences of the loss of care that they attempt self-treating in ways that can become unsafe.[207] The abrupt cessation of care that would occur under the Proposed Rule exacerbates the health risks facing transgender youth.

CMS estimates that if the Proposed Rule takes effect, 50% of youth currently receiving transgender medical care would immediately lose access to care[208] and be forced to endure the grave medical consequences of abrupt medical detransition. As discussed above in Section III.D.2.b, this figure grossly underestimates the number of patients who will lose access to care. The President's coordinated attack on *all* providers of transgender healthcare—including the Kennedy Declaration, which seeks to effectively ban the care nationwide—means that few providers, if any, will be able to offer transgender healthcare to patients under 18 years of age. Accordingly, the percentage of youth who will be unable to continue treatment, and therefore forced to immediately medically detransition, is likely far higher than 50%. And even those youth who are eventually able to find another provider willing to continue providing transgender healthcare may have to travel long distances or contend with long waiting lists in order to receive

[205] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-12, ¶ 41.
[206] Good Law Project, *New data shows surge in trans kids' suicides following healthcare rollbacks* (Feb. 7, 2026), https://goodlawproject.org/new-data-shows-surge-in-trans-kids-suicides-following-healthcare-rollbacks/.
[207] *See e.g.*, *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF Nos..87-21, ¶ 30 and ECF No. 87-12, ¶ 37(b).
[208] Proposed Rule at 59474.

it. Like those forced to detransition, youth forced to delay ongoing treatments face the same serious medical risks.

Stopping any treatment prematurely creates new unknowns and possible risks to the patient. The young people who began medical treatment for gender dysphoria, their parents and guardians who gave their informed consent, and the hospital doctors that prescribed it did so in reliance on the existing rules. By abruptly rendering continued care difficult or impossible to obtain, the Proposed Rule creates extreme and unanticipated risks for patients currently receiving medical treatment for gender dysphoria.

To account for the serious medical risks posed by abrupt cessation of care, many states that currently restrict transgender healthcare provide a "tapering period" or a "grandfather provision," allowing youth already receiving treatment to gradually be weaned off of it or continue to receive it, respectively. The Proposed Rule recognizes that these approaches exist but declines to adopt any similar exception here.[209]

The Proposed Rule also fails to account for patients' and families' economic reliance interests. Many transgender young people and their families have made major life decisions in reliance on the current rules and their ability to obtain necessary medical care from covered hospitals. For example, some parents moved their families from states that restrict transgender healthcare into states where their child would be able to receive such care, often at covered hospitals.[210] Some transgender youth have decided where they will attend college based upon their ability to obtain transgender healthcare near campus.[211] Many transgender young people spend months or years on waiting lists for care, and those who finally secure an appointment often plan their lives carefully around their expected treatment date. Other patients may have invested in long-term steps to manage potential risk factors, such as weight, in order to become eligible to receive care.[212] These young people and their families have planned their lives and expended significant resources in reliance upon the current rules.

Harms to the States: The Proposed Rule did not acknowledge States' enduring reliance interests in their ability to regulate the practice of medicine, which has long encompassed the ability to regulate transgender healthcare. States possess sovereign interests in maintaining the medical authorities and regulatory bodies that resolve questions about the practice of medicine under state law, as well as a range of laws and regulations states have established to protect patients and providers. These laws include some that regulate the provision of medically necessary transgender healthcare for patients under 18 and that shield providers of such care from threats by entities outside of the States. As explained above, CMS cannot disturb these sovereign interests in an area of states' traditional police powers absent Congressional authority, which it lacks.[213] Yet

[209] Proposed Rule at 59469.
[210] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21 ¶ 5, ECF No. 87-12 ¶ 14, ECF No. 87-1 ¶ 24.
[211] *Washington, et al. v. Department of Justice, et al.,* 2:25-cv-00244-LK, ECF No. 52, ¶ 11.
[212] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-12 ¶ 40(c).
[213] *Supra* at Section III.A.2.

the Proposed Rule would disturb this entire framework without accounting for any of the costs to States.

The Proposed Rule also ignores the States' significant reliance interests in designing their Medicare and Medicaid systems under the current rules. Many of the States' Medicaid programs cover medically necessary transgender healthcare,[214] and several States require by law that all health plans do so.[215] These States have designed their Medicaid programs in reliance upon the current rules. They have made critical decisions such as setting rates, allocating budgets, and entering agreements with managed care plans or providers based upon the current rules, their own state laws and regulations, and their long understanding that the federal government may not regulate the practice of medicine within their states. If the Proposed Rule causes hospitals—which provide the vast majority of transgender medical treatment—to cease offering such care, this will drastically alter the costs and availability of such care, and therefore impact the rates and program design, and impede states' ability to meet their legal obligations under federal and state law.

Harms to participating hospitals: Further, the Proposed Rule fails to account for the reliance interests of hospitals (including state-run facilities) that currently provide transgender healthcare and participate in Medicaid or Medicare. Many of these hospitals have entire centers devoted to transgender healthcare for which they have invested in highly specialized staff and facilities. These hospitals have allocated resources, including money and facility space, in reliance upon the existing rules. Further, some hospitals have already purchased specialized medications, such as puberty blocker implants, that they will be unable to deliver to patients and for which they will therefore be unable to obtain any reimbursement.[216] The Proposed Rule ignores hospitals' reliance interests in staffing their facilities and allocating their resources under the existing rules. The Proposed Rule further fails to discuss its potential impacts on care provided throughout hospital networks, in either the preamble or Regulatory Impact Analysis.

Harms to individual healthcare providers: Finally, the Proposed Rule overlooks the range of economic and professional harms the proposed abrupt ban on transgender healthcare at Medicare-participating hospitals will cause to the reliance interests of the thousands of individual

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[214] Or. Rev. Stat. § 414.769; Me. Rev. Stat. Ann. tit. 22, § 3174-MMM (Supp. 2025); *see also* 2023 Or. Laws 583–609 (enacting House Bill 2002 (2023)).

[215] *See, e.g.*, *State of Oregon et al. v. Kennedy et al.*, 6:25-cv-02409-MTK, ECF No.38, ¶¶ 8–9. Some states also prohibit providers in the state Medicaid program from refusing to provide medically necessary transgender healthcare, categorically excluding transgender healthcare, or discriminating based on gender identity. *See, e.g.,* Wash. Rev. Code § 74.09.675(2); N.Y. Exec. Law § 296 et seq.; Cal. Ins. Code § 10140; Colo. Rev. Stat. § 24-34-601; Colo. Rev. Stat. § 10-16-104(30)(b); Conn. Gen. Stat. § 46a-64; D.C. Code §§ 2-1402.31(a)(1), 31-2231.11(c); 775 Ill. Comp. Stat. 5/1-102(A); 775 Ill. Comp. Stat. 5/1-103(O); 775 Ill. Comp. Stat. 5/1-103(O-1); Me. Rev. Stat. Ann. tit. 22, § 3174-MMM(3); Md. Code Ann., Health § 15-151; Mass. Gen. Laws ch. 272, §§ 92A, 98; Minn. Stat. § 256B.0625; Nev. Rev. Stat. §§ 422.272362, 695G.1718; N.J. Stat. Ann. § 30:4D-9.1; N.M. Stat. Ann. § 24-34-3; 23 R.I. Gen. Laws § 23-17-19.1; Vt. Stat. Ann. tit. 8, § 4071.

[216] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-13, ¶ 42 ("My colleagues and I were forced to cancel previously scheduled treatments, including costly puberty-suspending medications that were already delivered to The AYA Program for administration to adolescent patients[.]").

healthcare providers who will be impacted by the Proposed Rule. Some of the economic and noneconomic harms the States anticipate include lost income, professional and career injuries, and harms that result from impaired patient-provider and patient-hospital relationships.

If the Proposed Rule takes effect, all or many hospitals that participate in Medicaid and Medicare will be forced to terminate their transgender healthcare programs for young people. Transgender healthcare is a specialized area of medicine; many healthcare providers have dedicated their careers to developing this expertise. The providers at hospitals that terminate transgender healthcare may lose employment or be forced to drastically alter their careers in order to remain employed, and would face uncertainty over long-term professional opportunities. Providers who do not continue to provide transgender healthcare will face burdens such as transitioning to a different practice area, developing new skills, and pursuing additional training, board certification, and licensure. Providers currently associated with Medicare-participating hospitals who offer transgender healthcare services to youth and wish to continue doing so will have to adjust their practice scope, location, and affiliations. Additionally, hospitals, including States' hospitals, will lose talent as practitioners who can no longer provide the care they currently offer may leave. And the Proposed Rule would harm State providers' ability to carry out important functions of medical education and research in the area of transgender healthcare. The Proposed Rule ignores these reliance interests and the likely impact of the Proposed Rule on the medical profession.

d) The Proposed Rule failed to adequately consider reasonable alternatives.

In refusing to consider reasonable and obvious alternatives to the Proposed Rule, CMS displays its failure to engage in reasoned decision making.

The Proposed Rule concedes that CMS could have used "different standards" in developing the new Condition of Participation, and even describes various alternative approaches in the preamble to the Proposed Rule.[217] However, CMS does not even attempt to analyze or compare these approaches, nor explain why the agency considered none an acceptable alternative to the Proposed Rule's categorical ban on transgender healthcare for youth in participating hospitals.

The Proposed Rule acknowledges that states across the country approach transgender healthcare differently and describes the various models—some states restrict the care with certain exceptions, and others affirmatively support provision.[218] For example, as discussed above in Section III.D.2.c, many states that restrict transgender healthcare allow exceptions for patients already receiving care to continue receiving it or to wean off their treatment gradually. The

[217] Proposed Rule at 59469–70, 59476.
[218] Proposed Rule at 59469–70.

Proposed Rule neglects to explain its reasoning for rejecting these alternatives, instead only opting to solicit comments on whether CMS should adopt any exceptions.[219]

The Proposed Rule also notes that states that restrict care employ different age cutoffs for different forms of care, variously prohibiting certain types of transgender healthcare (types not specified in the rule) for individuals under the age of 18, some under the age of 19, and some under the age of 21.[220] But the Proposed Rule does not explain its reasoning for rejecting these various alternatives either, and does not request comment on its decision to ban all forms of care for all individuals under the age of 18.

CMS also failed to consider the approaches of states that protect care for youth, which the Proposed Rule mentioned in its preamble, or approaches from countries like Germany, Spain, and France, all of which present less restrictive regulations on treatments for gender dysphoria.[221] Nor did the Proposed Rule consider approaches like that of the Utah Study commissioned by the state legislature and performed by the University of Utah College of Pharmacy's Drug Regimen Review Center, which conducted a review of gender dysphoria treatment and subsequently recommended offering transgender healthcare to youth with comprehensive, interdisciplinary teams and "an enhanced and explicit informed consent and assent process."[222] Indeed, the studies assessed in the HHS Report uniformly disagree with the categorical, no-exceptions approach adopted by CMS in the Proposed Rule.[223] Even the Cass Review, upon which CMS heavily relied in its regulatory actions, does not advocate a wholesale restriction on youth access to transgender healthcare, but rather that the care be delivered in a research environment.[224] The Proposed Rule makes no effort to analyze the many protective or permissive approaches adopted throughout the U.S. and around

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[219] The Proposed Rule mentions that 12 states provide "tapering off periods," and 10 provide "grandfather clauses" allowing patients to continue treatment indefinitely, and then solicits feedback on whether CMS should adopt exceptions. Proposed Rule at 59469–70.

[220] Proposed Rule at 59469.

[221] Spain regulates a progressive model of transgender healthcare that centers informed, patient consent and an emphasis on self-determination for individuals aged 14 and older to make legal and medical decisions for themselves. Studies have found that Spain's healthcare model can improve mental health among the transgender community and fight back against transphobia which has been linked to increased rates of anxiety, depression, and suicide amongst the transgender and gender dysphoric community. *See*, *e.g.*, Maria Presague-Pecina and Pepita Gimenez-Bonafe, *Comparative Study of Trans Healthcare Models in Catalonia*, 10 Heliyon 18 (Sept. 30, 2024), https://www.sciencedirect.com/science/article/pii/S2405844024122050#sec6.
See also Katie Keith, *Proposed Federal Rules Target Health Care For Transgender Youth (Part 1)* (Feb. 15, 2026), https://www.healthaffairs.org/content/forefront/proposed-federal-rules-target-health-care-transgender-youth-part-1.

[222] Joanne LaFleur, *Drug Regimen Review Center, Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* (Aug. 6, 2024), https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=287; *see also* . Dep't Health & Hum. Servs., *Report to the Utah Legislature Health and Human Services Interim Committee: Transgender Medical Treatments and Procedures Amendments (S.B. 16, 2023)* at 14 (May 2025), https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=289.

[223] HHS Report *passim*.

[224] *See* Cass, H., *Independent review of gender identity services for children and young people: Final report*, *Recommendations* (April 2024), https://perma.cc/2C9B-BX4Z.

the world, nor approaches that turn on individualized assessment by qualified medical providers rather than imposing a categorical ban on all forms of care.

CMS had a range of "significant and obvious alternatives" to the categorical ban on transgender healthcare for youth in Medicare-participating hospitals.[225] Rather than analyze these approaches and explain why the agency considered none an acceptable alternative to the Proposed Rule, CMS chooses its own, most extreme model with *no* exceptions permitting continued provision of transgender healthcare to transgender youth, and provides no explanation save the vague justification that it did so "to maximize health and safety for all children."[226] The Proposed Rule failed to explain what it means to "maximize" child health and safety, or why this version of the rule facilitates that maximization despite creating health risks for transgender youth who are forced to abruptly discontinue treatment. Failure to meaningfully consider any regulatory alternatives, including the less restrictive alternatives described in the preamble, is enough to invalidate final agency action resulting from CMS's Proposed Rule.[227]

3. The Proposed Rule lacks a nexus to the Medicare population.

CMS cites to Section 1861(e)(9) of the Social Security Act to justify the new rule it proposes, which authorizes the agency to establish requirements for participation in the Medicare program that are necessary to protect the health and safety of hospital patients.[228] In doing so, CMS asserts that this provision authorizes it to establish conditions of participation for the Medicare program that protect the health and safety of *children*. But Medicare covers minors only in very limited circumstances—namely, if they have end-stage renal disease ("ESRD").[229] Because the program covers minors in such limited circumstances, there is very little precedent for any condition of participation that specifically refers to children or minors. There is one exception: a condition of participation governing hospitals that perform organ transplants in pediatric patients. This requirement has a clear nexus to Medicare because Medicare covers organ transplants for minors with ESRD. Here, however, CMS fails to establish any real nexus between the Medicare program or population and the Proposed Rule.

Additionally, as stated *supra* (at Sections III.B.3, III.D.3), because the Proposed Rule would eliminate transgender healthcare across all hospitals, its impact is much broader than just beneficiaries of Medicaid and Medicare. The Proposed Rule would effectively end transgender

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[225] *See Pennsylvania v. Trump*, 795 F. Supp. 3d. 607, 645 (E.D. Pa. 2025), ("The agencies failed to consider significant and obvious alternatives." (citing *State Farm*, 463 U.S. at 51))
[226] Proposed Rule at 59476.
[227] *See Pennsylvania v. Trump*, 795 F. Supp. 3d. 607, 642 (E.D. Pa. 2025) ("Yet in promulgating the Final Rules, the Agencies failed to consider such an alternative, let alone provide 'a reasoned explanation for' rejecting" (citations omitted)).
[228] Proposed Rule at 59464.
[229] CMS, *Original Medicare (Part A and B) Eligibility and Enrollment* (Feb. 15, 2026), https://perma.cc/SH7T-J64X; CMS, *Children & End-Stage Renal Disease (ESRD)* (Feb. 15, 2026), https://perma.cc/J3VN-8EH7; *see also* Proposed Rule at 59465 (noting Medicare does not pay for "a significant number" of transgender healthcare treatments).

healthcare for any patient needing such care at a hospital, even privately insured or self-paying patients. This broad impact further demonstrates the lack of nexus between the Medicare population and the Proposed Rule.

4. The Proposed Rule uses selective and arbitrary reasoning.

As previously described *supra* (at Section III.A.4), CMS arbitrarily asserts that transgender healthcare is not "healthcare" and thus is something the federal government can regulate.[230] But this argument is completely without merit and its absurdity demonstrates the arbitrary nature of the Proposed Rule.

CMS further fails to acknowledge that its justifications for banning these forms of treatment when provided to treat gender dysphoria would necessarily extend to the provision of these or comparable forms of care for other diagnoses. It further fails to explain why it concluded these forms of care constitute permissible healthcare in one context but not another. The Proposed Rule draws an arbitrary and unsupported line between transgender healthcare and identical or comparable forms of care and fails to explain why those types of care are permissible while transgender healthcare is not.

For example, CMS reasons that physical interventions, such as hormones, are not medically necessary treatment for gender dysphoria—which it deems to be nothing more than psychological distress.[231] But the agency does not and cannot explain why such physical interventions to treat gender dysphoria are different from other physical interventions used to treat psychological conditions, such as electroconvulsive therapy for treatment-resistant depression, nor does CMS purport to restrict covered hospitals from offering such care to youth.

CMS can provide no justification for the arbitrary lines it draws in the Proposed Rule because no legitimate medical or scientific explanation exists. Instead, the Proposed Rule relies on unsupported assertions about the safety of transgender healthcare to advance the Administration's clear policy priority of ending this form of healthcare full stop.

E. The Proposed Rule Relies on Discredited Studies and Misinterpretations Rather Than Substantial Evidence.

CMS attempts to support the Proposed Rule and its clear politicization of medicine by repeatedly pointing to its own commissioned HHS Report without addressing medical and scientific evidence unfavorable to its position. However, the HHS Report has been discredited as methodologically flawed, including because it was anonymously published initially without peer review and issued at the direction of the President with the specific aim of supporting his goal of

[230] See discussion *supra* Section III.A.4.
[231] Proposed Rule at 59471.

ending transgender healthcare. It has accordingly been widely rejected by medical experts.[232] But even accepting the HHS Report on its terms, it does not actually support CMS's Proposed Rule—it does not conclude that transgender healthcare for youth is unsafe or fails to ameliorate gender dysphoria. The HHS Report's (initially anonymous) authors noted a "lack of robust evidence" regarding the harms of providing transgender healthcare to youth.[233] Indeed, the HHS Report itself refers to evidence of harms as "sparse."[234] These conclusions do not support the Proposed Rule's unprecedented action to ban such healthcare as a condition of participation for hospitals to participate in Medicaid and Medicare. Simply put, HHS's own report does not document clear harm caused by the targeted healthcare that could lend any support to its proposed ban.

In addition to relying on the discredited HHS Report, CMS cites studies and summary accounts of international policies on puberty blockers, hormone therapy, and surgical treatments to try to justify its predetermined goal of ending transgender healthcare for youth, including by asserting that such healthcare is not actually healthcare. This narrow position put forth by CMS ignores the full findings of many of these studies, relies on anecdotal news articles about international policy, and draws arbitrary conclusions about the data considered.

CMS attempts to support its proposal by stating that several other countries have reversed their policies, "following systematic review of evidence," yet repeatedly concedes throughout each section of the Proposed Rule that many of these countries have not banned puberty blockers or

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[232] *See, e.g.*, Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77(3) J. Adolescent Health 342 (Sep. 2025) ("The HHS report provides no evidence for its assertion that puberty-pausing medications and hormone therapy are harmful to TGD youth, and it even states that evidence of harms is 'sparse.' Instead of providing evidence, it lists hypothesized harms of these medications, although they have been safely and effectively used for decades to treat cisgender youth with medical conditions such as precocious puberty. A recent comprehensive review commissioned by the Utah state legislature and completed by experts at the University of Utah assessed data from more than 28,000 youth with gender dysphoria and concluded that puberty-pausing medications and hormone therapy can also be used safely in TGD youth."); Phie Jacobs, *Researchers Slam HHS Report on Gender-Affirming Care for Youth*, Science (May 2, 2025), https://www.science.org/content/article/researchers-slam-hhs-report-gender-affirming-care-youth; Mary Kekatos, *HHS finalizes report on gender-affirming care for youth, medical groups push back*, ABC News (Nov. 20, 2025), https://perma.cc/6T3C-HCKP; Susan Kressly, *AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria*, Am. Acad. of Pediatrics (May 1, 2025), https://publications.aap.org/aapnews/news/32145/AAP-speaks-out-against-HHS-report-on-gender?autologincheck=redirected.

[233] HHS Report at 13. CMS bases this Proposed Rule on its claimed concern there is insufficient evidence on the long term safety and efficacy of transgender youth healthcare, which is belied by HHS's agency wide actions to defund such research, as well as the fact that this Proposed Rule would exclude research-hospital settings, including state research institution hospitals that provide transgender youth healthcare in a research environment, from participation in Medicare and Medicaid. *See* Evan Bush, *Judge Deems Trump's Cuts to National Institutes of Health Illegal,* NBC News (June 16, 2025), https://perma.cc/C8DV-RFJL; Ian Lopez, *Gender Care Pullback Led by Trump's HHS Moves Boldly Into 2026*, Bloomberg Law (Jan. 5, 2026, 4:05 AM), https://news.bloomberglaw.com/health-law-and-business/gender-care-pullback-led-by-trumps-hhs-moves-boldly-into-2026.

[234] *See* HHS Report at 13; *see also* Dowshen et al., *supra*. note 232.

hormone intervention and allow for continued access for adolescents with gender dysphoria.[235] Finland, Sweden, England, Norway, and Denmark simply **did not** recommend banning transgender healthcare for youth outright, and many of these countries continue to allow such care in clinical trials. For example:

- Finland: After a 2020 review, the Board for Selection of Choices for Health Care in Finland issued recommendations, including that "puberty suppression treatment… may be initiated on a case-by case basis after careful consideration and appropriate diagnostic examination."[236] These guidelines also provide that "hormone treatment that alter sex characteristics" be based on thorough case-by-case considerations."[237] Thus, it is not accurate for CMS to say that Finland reversed its policy when it merely clarified policies related to its existing and continuing access to care.
- Sweden: In updating its 2015 treatment guidelines for children and adolescents with gender dysphoria, the National Board of Health and Welfare questions the risks of hormone treatment but ultimately concludes that it should be an available treatment provided for gender dysphoria, following the Dutch Protocol.[238]
- UK: National Health Services (NHS) England commissioned Dr. Hillary Cass to conduct a review of puberty blockers and hormone therapies for adolescents. The review raised questions about the evidence available concerning the risks of puberty blockers but does not call for a ban or lack of access. In fact, unlike the Proposed Rule, even with the risks, Cass concluded puberty blockers should be offered under a research protocol with care continuing for patients already on treatment. This recommendation has been put into effect in the UK, with a new clinical trial beginning.[239] Additionally, hormone therapies remain available for adolescents under the age of 18.[240]

All these countries are working with their hospitals and healthcare systems; they are not forcing hospitals to choose between continuing treatment for some patients and being cut out of the ability to access federal funding for the provision of care for all patients. These countries also

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[235] *See* Proposed Rule, 42 CFR Part 482, at 2b. Finland: "While not banning SPRs the guidelines state, …. Hormonal interventions[puberty blockers, hormone therapy] may be considered before reaching adulthood…"; Sweden: "While not banning access to [transgender healthcare], NBHW suggests restricting treatment … adhering to the original "Dutch Protocol…"; United Kingdon: "While not banning access to puberty blockers, Dr. Cass concluded…. [puberty blockers] should only be offered under a research protocol. .. NIHR have engaged this recommendation…"; Norway and Denmark: "… are exploring or have restrictions, though neither have issued direct bans of [transgender healthcare]…."

[236] *Recommendation by the Board for Selection of Choices for Healthcare in Finland,* Finland Council for Choices in Health Care, https://perma.cc/3D9Y-G3HN (last visited Feb. 6, 2026).

[237] *Id.* The Finnish 2020 guide acknowledges some limitations of puberty blockers, including that puberty blockers did not show in their study of 70 adolescents to improve gender dysphoria on their own as there were not changes to the body image, and cautioned use without first providing psychosocial support, especially in the event of a comorbidity.

[238] The National Board of Health and Welfare (Socialstyrelsen), *Care of children and adolescents with gender dysphoria: Summary of National Guidelines* (Dec. 2022), https://perma.cc/M3EJ-4E2W (last visited Feb. 6. 2026).

[239] Pathways Trial. https://www.kcl.ac.uk/research/pathways-trial (last visited Feb 6, 2026).

[240] *Treatment for Gender Dysphoria,* NHS, https://perma.cc/6TE2-BS8T (last visited Feb 6, 2026).

recognize the impact restrictions will have for patients receiving care and even in the narrowest case, the UK, current patients will be able to continue puberty blockers and current and new patients will continue to receive access to hormone therapy from their doctors and hospitals.[241] Thus, CMS either misreads or misleads in its attempted reliance on information about these countries policies and practices on transgender healthcare.

CMS then cites numerous news articles to assert that Italy, Brazil, New Zealand, and Australia "have considered or restricted various gender dysphoria treatments." Yet CMS does not provide any additional analysis or context for why the purported policies of these countries should outweigh scientific studies that supporting providing transgender healthcare. Additionally, other comprehensive systematic reviews have found "a robust international consensus in the peer-reviewed literature that gender transition, including medical treatments such as hormone therapy and surgeries, improves the overall well-being of transgender individuals."[242] And CMS completely overlooks the fact that treatment for gender dysphoria continues to be more widely available in other countries, as discussed in this letter.

Additionally, no study CMS cites comes close to concluding that transgender healthcare for youth is sufficiently dangerous to effectively ban it by denying hospitals that provide such care with Medicare and Medicaid funding. Lacking any support for its proposal, CMS instead misrepresents the data and attempts to piece together calls for additional research as justification for intervening in the provision of evidence based medical care.

Finally, CMS's conclusions about the need for, and benefits of, the Proposed Rule depend on a series of shaky estimates. As discussed below in Section IV.B, CMS acknowledged as much; the Proposed Rule posed at least ten discrete requests for additional comments on the agency's data sources, estimates, and "assumption[s]"—many of which CMS pulls out of thin air. For instance, "[i]n the absence of data showing the likely share of patients" who would cease receipt of care or transfer care to non-hospital providers, CMS "assumed that 50 percent of affected children would fall into each of the categories," with no accompanying explanation.[243]

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[241] NHS, National CYP Gender Referral Support Service, *Patients and Parents*, https://perma.cc/KS9N-6QCC (last visited Feb 6, 2026) ("NHS patients who are already receiving these medicines for gender dysphoria or incongruence can continue to access them, as can patients receiving the medicines for other uses."); *see also* NHS, *Clinical Commission Policy: Prescribing of Gender Affirming Hormones (masculinising or feminising hormones) as part of the Children and Young People's Gender Service* (Mar. 21, 2024), https://perma.cc/93ZY-EDZB (last visited Feb. 6, 2026).

[242] Cornell University, The Public Policy Research Portal, *What does the scholarly research say about the effect of gender transition on transgender well-being?* (2018), https://perma.cc/UH3U-RRRJ; *see also* Joanne LaFleur, *Drug Regimen Review Center, Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* (Aug. 6, 2024), https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=287; Utah Dep't Health & Hum. Servs., *Report to the Utah Legislature Health and Human Services Interim Committee: Transgender Medical Treatments and Procedures Amendments (S.B. 16, 2023)* at 14 (May 2025), https://le.utah.gov/AgencyRP/downloadFile.jsp?submissionId=289.

[243] Proposed Rule at 59474.

Given CMS's misrepresentation of many of the sources it cites, as well as its reliance on the discredited HHS Report, by no means does HHS have substantial evidence on which to base the Proposed Rule that would drastically end transgender healthcare in virtually all hospitals in this country.

F. The Proposed Rule Is Discriminatory.

1. The Proposed Rule is based on animus against transgender individuals.

The Proposed Rule should also be withdrawn because it is based on animus against transgender individuals rather than furthering any valid scientific or medical purpose. *See City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 448 (1985) (the Equal Protection Clause prohibits government policies that express negative attitudes or fear only toward people viewed as "different"); *see also Nguyen v. Immigration & Naturalization Serv.,* 533 U.S. 53, 68 (2001) (Equal Protection Clause bars decisions built on stereotypes and "irrational or uncritical analysis").

Here, the Proposed Rule patently discriminates on the basis of transgender status. Animus toward transgender individuals is the only basis on which to differentiate the treatment of treatment of transgender youth, whose ongoing access to transgender healthcare at a hospital would be barred under the proposed conditions of participation, from cisgender youth who may require the same treatment, but for a different diagnostic purpose. Such differentiation is unsupported by the science, as noted *supra* at Section II.C, and can only be explained by animus and bad faith. Indeed, the courts that have examined actions taken by the federal government (*see infra* at Sections III.D.1, III.F.1) targeting transgender healthcare to date have found actions seeking to restrict access to such care motivated by animus. *See, e.g., QueerDoc v. United States Dept. of Justice*, 2:25-MC-00042-JNW (W.D. Wash. Oct. 27, 2025) ("DOJ issued the subpoena first and searched for a justification second"; concluding "the record before the Court establishes that DOJ's subpoena to QueerDoc was issued for a purpose other than to investigate potential violations of the FDCA or FCA," and was instead served to "pressure providers to cease offering gender-affirming care"); *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *1 (collecting cases); *see also In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 239 (Trump Administration has been "explicit about its disapproval of the transgender community" and subpoena to Boston Children's Hospital "was issued for an improper purpose, motivated only by bad faith"); *In re Subpoena Duces Tecum No. 25-1431-016*, 2025 WL 3562151, at *13 (quashing subpoena to Seattle Children's Hospital because it "was issued for an improper purpose"); *In re 2025 Subpoena to Children's Nat'l Hosp.*, No. 1:25-cv-03780-JRR, 2026 WL 160792, at *9 (D. Md. Jan. 21, 2026) (quashing subpoena to Children's National Hospital because it "bears no credible connection to an investigation of any statutory violation" and "appears to have no purpose other than to intimidate and harass the Hospital and Movants"); *In re: Dept. of Justice Admin. Subpoena No. 25-1431-030*, 2026 WL 33398, at *7 (report and recommendation recommending that subpoena to Children's Hospital Colorado be quashed; explaining "the government's aim is not actually to investigate FDCA violations, but to use the FDCA as a smokescreen for its true objective of pressuring

pediatric hospitals into ending gender-affirming care through commencing vague, suspicionless 'investigations'").

The same is true here. CMS's proposed rulemaking, using a different lever of the federal government, seeks to end transgender healthcare for youth under the guise of protecting children, based only on bare animus, not science.

2. The Proposed Rule conflicts with Section 1557 of the Affordable Care Act.

Section 1557 of the ACA prohibits health programs and activities that receive Federal financial assistance from discriminating "on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of Title 29 . . ."[244] The majority of courts have thus far interpreted Section 1557 as prohibiting discrimination on the basis of gender identity because policies such as transgender-specific health insurance exclusions impermissibly discriminate on the basis of sex.[245] For this reason, a categorical ban on transgender healthcare for youth at participating hospitals impermissibly violates Section 1557. And *Skrmetti*[246] does not require a different result. There, the Court considered only whether a state ban on medically necessary transgender healthcare for youth violated the Equal Protection Clause of the Fourteenth Amendment, not any statute, including Title IX or Section 1557.[247] Indeed, the Court expressly declined to address whether *Bostock*'s reasoning would apply to other statutes.[248]

However, even if the Proposed Rule does not constitute impermissible sex discrimination, it still runs afoul of Section 1557's prohibitions on age and disability discrimination. As the Court

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[244] 42 U.S.C.A. § 18116(a).

[245] *See, e.g., Doe v. Snyder*, 28 F.4th 103, 113 (9th Cir. 2022) (*Bostock* applies to Section 1557's prohibition against sex discrimination and thus prohibits discrimination based on transgender status); *Fain v. Crouch*, 618 F. Supp. 3d 313, 331 (S.D.W. Va. 2022), *aff'd sub nom. Kadel v. Folwell*, 100 F.4th 122 (4th Cir. 2024), *cert. granted, judgment vacated sub nom. Crouch v. Anderson*, 145 S. Ct. 2835, 222 L. Ed. 2d 1124 (2025), and *cert. granted, judgment vacated*, 145 S. Ct. 2838, 222 L. Ed. 2d 1124 (2025) (state health plan exclusion for transgender healthcare constituted unlawful sex discrimination under Section 1557); *Flack v. Wisconsin Dep't of Health Servs*., 395 F. Supp. 3d 1001, 1015 (W.D. Wis. 2019) (same); *Doe v. Indep. Blue Cross*, 703 F. Supp. 3d 540, 549 (E.D. Pa. 2023) (denial of transgender healthcare procedure constituted intentional discrimination based on sex in violation of Title IX and consequently the ACA); *L.B. v. Premera Blue Cross*, 781 F. Supp. 3d 1128, 1142 (W.D. Wash.), *adhered to,* 795 F. Supp. 3d 1311 (W.D. Wash. 2025) (insurer's policy banning mastectomies for patients with gender dysphoria under 18 constituted unlawful sex discrimination under Section 1557); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (discrimination on the basis of transgender status constituted sex discrimination in violation of Section 1557); *see also Cruz v. Zucker*, 195 F. Supp. 3d 554, 581 (S.D.N.Y. Jul. 5, 2016) (holding that exclusion on gender-affirming surgery and hormone therapy for individuals under eighteen violated Section 1557); *but see* Tennessee v. Kennedy, 2025 WL 2982069 (S.D. Miss. 2025) (vacated the Biden rule interpreting Section 1557 as covering GID).

[246] This includes, by extension, the district court's decision in *Tennessee v. Kennedy*, -F. Supp. 3d--, 1:24CV161-LG-BWR, 2025 WL 2982069, *10 (S.D. Miss. Oct. 22, 2025).

[247] *Skrmetti*¸ 605 U.S. at 500

[248] *See id.* at 519–20.

recognized in *Skrmetti*, a ban on medically necessary transgender healthcare for youth classifies on the basis of both age and medical use.[249] Section 1557 prohibits discrimination based on both. It incorporates the Age Discrimination Act, which bars entities receiving Federal financial assistance from excluding, denying benefits to, or discriminating against people on the basis of age.[250] This provision applies to discrimination against the young as much as the elderly.[251] Section 1557 permits age-based distinctions only under certain circumstances (e.g., when necessary for any statutory objective of a program or activity) and where those circumstances are not present, the distinction must be justified by a legitimate, nondiscriminatory reason.[252] As explained above in Section III.F, the Proposed Rule is not supported by legitimate, nondiscriminatory reasons.

Section 1557 also incorporates the Rehabilitation Act, which prohibits programs and activities receiving Federal financial assistance from discriminating solely on the basis of disability. Gender dysphoria is a protected class under the Rehabilitation Act, which incorporates the American with Disabilities Act's ("ADA") definition of "disability."[253] This is yet another reason the Proposed Rule's exclusion of an entire category of hospital-provided healthcare violates Section 1557.[254]

IV. INADEQUATE REGULATORY IMPACT ANALYSIS

The Proposed Rule is premised upon a woefully deficient Regulatory Impact Analysis (RIA). The RIA completely disregards many substantial costs the Proposed Rule would impose on transgender youth and their families, States, participating hospitals, and individual healthcare providers; relies on unreasoned guesswork to estimate the few costs it does consider; ignores CMS's obligation to consider the costs and benefits or reasonable alternatives; and ultimately fails to conduct the careful analysis of costs and benefits required.

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[249] 605 U.S. at 511.
[250] 42 U.S.C. § 6102.
[251] *Rannels v. Hargrove*, 731 F. Supp. 1214, 1220 (E.D. Pa. 1990) (legislative history supports an "expansive interpretation of the ADA"). And age-based distinctions remain presumptively discriminatory under Section 1557. Dep't of Health & Human Servs., Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522 (May 6, 2024) (recognizing that while some age distinctions in care may be permissible, they must be substantiated by a "legitimate, nondiscriminatory reason" to survive under Section 1557).
[252] Dep't of Health & Human Servs., Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 3604-5 (May 6, 2024) (recognizing that while some age distinctions in care may be permissible, they must be substantiated by a "legitimate, nondiscriminatory reason" to survive under Section 1557).
[253] 29 U.S.C. § 705(20)(B). It is worth noting, however, that HHS has proposed another rule that seeks to exclude "gender dysphoria" from the definition of "disability" under the Rehabilitation Act, which is currently in the comment period. Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 90 Fed. Reg. 59478 (Dec. 19, 2025) (to be codified at 45 C.F.R. pt. 84).
[254] *See Williams v. Kincaid*, 45 F.4th 759, 774 (4th Cir. 2022) (holding that gender dysphoria is a covered disability under the ADA).

A. The RIA Fails to Account for Many Substantial Costs the Proposed Rule Would Create.

1. The RIA's assessment of costs and burdens is grossly inaccurate.

The Proposed Rule's cursory and incomplete assessment of the regulatory impact and burdens of the proposed regulation is wholly unreasoned, unjustified, and unexplained. The assessment is riddled with "assumptions" and "estimates" as to key data. More egregiously, those assumptions and estimates seem to be either pulled from thin air or derived from extraneous sources. Given the impact of Medicare and Medicaid coverage and accessibility on the health and welfare of the American people, and the vast accompanying economic implications, this is not just sloppy governance—it is dangerous.

Take for example the Proposed Rule's "Regulatory Review Cost Estimation."[255] The Proposed Rule first assumes that "all hospitals will review this rule," then that "[i]t is also possible that other individuals and providers will review this proposed rule."[256] Based on these two propositions, the Proposed Rule "thought that doubling the number of Medicare or Medicaid certified hospitals . . . would be a fair estimate of the number of reviewers of this proposed rule."[257] CMS offers no further explanation of this conclusion. This is particularly curious given the agency's experience in rulemaking. By way of comparison, CMS received 26,396 public comments in response to its March 19, 2025, proposed rule addressing changes to the Affordable Care Act[258]; here, the assessment assumes that a mere 9,664 individuals will review the Proposed Rule.[259]

But the guesswork does not end there. For reasons not explained, the Proposed Rule "assume[s] that reviewers review 75% of the rule."[260] It then estimates an average review time based on an average word speed multiplied by the number of words in the Proposed Rule, less 25%. That figure multiplied by the average wage of medical and health service managers comes to a cost per entity of $62.91.[261] The assessment thus presumes that only a single individual per "entity" will conduct review, that review consists of a single read-through of three-quarters of the Proposed Rule, and that that individual's hourly wage will be the equivalent of the average of a specialized profession. Given the complexity and import of the Proposed Rule, such assumptions defy even basic common sense, much less agency expertise. The Proposed Rule also guesses that only 75% of hospitals in will need to update their policies and procedures, and that this would be

[255] Proposed Rule at 59476.
[256] *Id.*
[257] *Id.* at 59476.
[258] Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 Fed. Reg. 12942 (Mar. 19, 2025), https://perma.cc/2AFT-3SHP.
[259] Proposed Rule at 59476.
[260] Proposed Rule at 59463.
[261] *Id.*

accomplished by a single physician over the course of three hours.[262] But these guesses, too, are nonsensical. In reality, most hospitals will likely need to revise their policies and practices, a time-consuming process that will likely be undertaken by a team of providers, administrative staff, and hospital counsel.

The Proposed Rule's analysis is replete with similar gaps in logical reasoning and empirical data—gaps that CMS openly recognizes.[263] Indeed, CMS makes no fewer than ten discrete requests for additional comments on data that is essential to the Proposed Rule but that the agency did not have when formulating the Proposed Rule as it exists now.[264] This does not stop the Department from "estimating" in the dark—even as to its foundational assumptions regarding the Proposed Rule's impact.[265] For example, as discussed above in Section III.D.2.b, CMS guesses (apparently at random) that, if the Proposed Rule is implemented, 50% of youth currently receiving transgender healthcare at hospitals will be able to continue receiving the care they need by transferring to other providers. CMS provides zero factual support for this figure and, as discussed above, it is grossly inflated. In reality—and because of CMS's own coordinated regulatory attacks on transgender healthcare—very few youth would be able to continue receiving transgender healthcare if the Proposed Rule is implemented. Further, the Proposed Rule makes clear that CMS has no idea how many non-hospital providers offer transgender healthcare to youth nor what share of youth currently receiving transgender healthcare are receiving it in non-hospital settings.[266] That CMS has proposed a major change to public healthcare infrastructure with little to no evidence and relying upon incoherent reasoning strongly suggests that CMS has adopted a policy first and asked questions later.

2. The RIA inadequately accounts for the Proposed Rule's substantial costs and burdens.

CMS failed to properly determine and analyze the enormous costs and burdens the Proposed Rule will impose on transgender youth and their families; the States; hospitals that

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[262] Proposed Rule at 59473.
[263] *Id.* (acknowledging "[CMS] do[es] not have quantitative financial data on the impact of the proposed rule's provision").
[264] *See, e.g.*, Proposed Rule at 59469 (request for peer-reviewed evidence on the effects of similar restrictions on insurers, providers, and patients in the U.S. and internationally); 59472 (request for comment on the assumption used to estimate affected children in states without current restrictions); 59473 (requests for data on how many U.S. hospitals currently offer transgender healthcare for children; the number of children receiving puberty blockers or hormone therapy outside hospital settings, and the estimated physician time burden associated with providing written notice to patients); 59475 (request for input on improving the methodology used to estimate regulatory compliance costs); 59475–76 (request for comment on additional potential benefits of the proposed rule and data sources to quantify benefits, including estimates of children who may discontinue transgender healthcare); 59469 (request for comments establishing impact on insurers, providers, or patients).
[265] Proposed Rule at 59475 ("estimating" in the absence of data the number of children the rule would "positively effect").
[266] Proposed Rule at 59472–73.

participate in Medicare or Medicaid; and individual healthcare providers. These harms are described in Section III.D.2.c.

The RIA's cursory consideration of the impacts on transgender youth and their families consists of only a general reference to "the avoidance of unnecessary health complications;" a rough estimate of the cost of switching providers for patients able to do so, which it bases on willingness-to-pay estimates that are completely inapplicable here, as they describe patients willingness to transfer between primary care providers, which—compared to transgender healthcare providers—are abundant and accessible; and a brief acknowledgement that some patients "may choose new forms of treatment such as psychotherapy." CMS conducted no further analysis of the overwhelming costs and harms that transgender youth and their families would bear under the Proposed Rule. *See* Section III.D.2.c. Furthermore, CMS did not account for the likely disproportionate impact on low-income children, who are more likely to seek care in hospital settings as opposed to private practices, and less likely to be able to travel long distances or pay out of pocket to obtain care.

The RIA acknowledges no potential costs to the States, aside from its absurdly low estimate of the time required to review the Proposed Rule and implement needed policy changes. It instead identifies only the purported *benefit* of reducing payments from payors to hospitals when these treatments are no longer available. This ignores the many other costs to the States. *See* Section III.D.2.c. Further, the RIA did not attempt to quantify the increase in costs to payors, including the States, from the likely increase in utilization of other services, such as mental health services to treat worsening depression, anxiety, and worsening gender dysphoria.[267] Further, it neglects that payors, including the States, may ultimately bear the costs of covering more expensive treatments for gender dysphoria when patients who are denied care in their youth reach 18.[268]

The RIA also neglected to consider the costs to payors, including State plans, of having to analyze the Proposed Rule and issue new guidance to members who can no longer get transgender healthcare at Medicare-affiliated hospitals. Payors in the vast majority of states, including those with only some restrictions on transgender healthcare, will have to review their policies to confirm that all relevant policy documents have been updated in compliance with new federal requirements. If the two other December 18, 2025, HHS actions are in effect as well, payors—including States—will have to investigate how all three actions impact coverage policies, utilization rates, provider directories, provider manuals, and any other relevant documents to ensure compliance.

The Proposed Rule altogether forgot about managed care providers, many of which need state approval before issuing communications and guidance to members; this state approval

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[267] *See Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-13 ¶ 41(d); *see also* William V. Padula, Shiona Heru & Jonathan D. Campbell, *Societal implications of health insurance coverage for medically necessary services in the U.S. transgender population: a cost-effectiveness analysis*, 31 J. Gen. Int'l Medicine 394 (2016) (estimating costs of denying medically necessary transgender healthcare).

[268] *Supra* notes 67, 68, 70.

process represents yet another unconsidered series of costs. Managed care providers also will have to assist members who need transgender healthcare no longer available in hospitals in finding replacement providers, which sometimes includes paying the cost of travel to such replacements.

Additionally, States will have to recalculate rates outside of their normal rate calculation schedules given this Proposed Rule's impact on utilization rates. The RIA neglectfully left out any model to estimate costs to state actuaries and agencies that must review data on utilization, membership, and other factors to set rates for each plan and each type of plan. Although many states set rates at specific times of the year, the Proposed Rule would take effect immediately, and states will have to engage in a separate rate setting process unless the effective date of the rule coincides with a pre-planned rate setting period.

The RIA's meager assessment of the impact on the healthcare system is limited to the cost to participating hospitals of notifying patients they are no longer providing transgender healthcare; of reviewing 75% of the Rule and revising their policies and procedures; and $53.5 million in losses due to patients transferring their care elsewhere—all of which it woefully underestimates. The RIA also completely ignores the enormous impact the Proposed Rule would have on non-hospital providers of transgender healthcare. Hospitals currently provide the vast majority of transgender healthcare to youth; if they can no longer do so, the smaller non-hospital providers (to the extent that the Kennedy Declaration allows them to continue providing care at all, see *supra* Section III.D.2.b) will be inundated with patients desperately seeking to transfer their care, despite the fact that many do not have the capacity to absorb that volume of patients. See *infra* Section V.A. The RIA fails to account for these impacts, nor does it address the life-altering burdens it will impose on individual healthcare providers who are currently employed by participating hospitals or specialize in transgender healthcare. The RIA's only acknowledgement of the massive disruption this Proposed Rule would wreak on the healthcare ecosystem is a brief mention the Proposed Rule might require "upfront transition activity," such as the establishment of free-standing clinics for transgender healthcare, and impose costs on individual clinicians who must leave hospital jobs to continue to provide transgender healthcare. But CMS made no effort to estimate any of these costs, let alone weigh them against purported benefits.

Ultimately, the RIA is devoid of the data necessary to properly assess the relative costs and benefits of the Proposed Rule. CMS acknowledges this deficiency, openly acknowledging the "various uncertainties" on which its cost estimates rely and "request[ing] comment on how to refine the estimation of regulatory costs"[269] and soliciting "any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients"[270]—in other words, CMS proposed this Rule without first considering any real measure of its relative costs and benefits.

[269] Proposed Rule at 59475.
[270] Proposed Rule at 59469.

B. The RIA Fails to Account for the Impact of Other Proposed and Existing HHS Regulations on the Proposed Rule.

As previously noted, this Proposed Rule was announced on the same day that HHS promulgated the Medicaid Reimbursement Proposed Rule and the Kennedy Declaration—part of its explicit and coordinated attack on transgender healthcare for youth. But the Proposed Rule declines to explain how the three measures would interact despite their obvious implications on each other. *See supra*, Section III.D.2.b.

CMS did not take the interaction between the Kennedy Declaration, this Proposed Rule, and the Medicaid Reimbursement Proposed Rule into account in its evaluation of this Proposed Rule's impact. The RIA provides zero information about the real-world costs and effects of HHS's concurrent regulatory actions. The only mention of either action is a single line in which CMS notes that the amount of money that hospitals stand to lose if this Proposed Rule takes effect and all their transgender healthcare patients transfer to other providers would be lower if the Medicaid Reimbursement Proposed Rule takes effect first because—though this is implied rather than explained—that Rule would already have caused many patients to stop seeking care.

Though the potential interactions between the three regulations raises myriad factual questions, the RIA makes no effort to answer them, nor does it invite comment. For example, CMS does not estimate how many non-hospital providers will continue to provide transgender healthcare for youth given the existential threats presented by the Kennedy Declaration.[271] Nor does CMS estimate or ask what percentage of institutions could or would continue to operate without participating in federally funded healthcare programs, or state what percentage of providers could or would limit their careers to practicing only in settings that receive no federal support. And CMS does not say how many providers are currently subject to any exclusion from federally funded healthcare programs and for what reasons.

Additionally, this Proposed Rule differs from the Medicaid Reimbursement Proposed Rule in its estimation of costs in states that have restricted transgender healthcare. Whereas this Proposed Rule declines to estimate the cost of care for patients living in states with transgender healthcare restrictions, noting that the care in those states is not "significant," the preamble to the Medicaid Reimbursement Proposed Rule asserts that "States that had not banned gender dysphoria treatments for children as of 2023 accounted for 76 percent of spending…" The Medicaid Reimbursement proposed rule thus found 24 percent of transgender healthcare spending to occur in states with restrictions. This is either the result of a definitional tension between the analysis CMS offered in each proposed rule—the two RIAs use different definitions to reach their estimates—or the arguments in the separate proposed rules directly conflict. In either case, such

[271] In fact, CMS does not even know how many non-hospital providers currently offer transgender healthcare or what share of youth patients currently receives their care in such settings. Proposed Rule at 59472-73.

inconsistencies make it impossible for the States to assess the reasonableness of the cost estimates in the two proposed regulatory impact analyses HHS announced on the same day.

C. The RIA Failed to Analyze the Costs and Benefits of CMS's No-Exceptions Ban on Transgender Youth Healthcare Against Reasonable Alternatives.

As described in Section III.E.4.c, CMS acknowledged that it considered no regulatory alternatives to its categorical, no-exceptions ban on transgender youth healthcare in participating hospitals. Among the alternatives the agency failed to consider in its cost benefit analysis are numerous alternative international approaches that afford broader protection for medically necessary transgender healthcare for youth, such as Spain, as discussed in this letter; and the diversity of approaches adopted by states that the preamble described. The RIA makes no effort to compare the relative costs and benefits of these potential alternatives against costs and benefits of the Proposed Rule.

V. FAILURE TO COMPLY WITH THE REGULATORY FLEXIBILITY ACT

A. CMS Failed to Analyze the Impact on Small Entities.

The Proposed Rule acknowledges CMS has a statutory obligation to "analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities." Its meager effort to meet this requirement falls short in three ways.

First, it concludes that the statutory requirement does not apply because it will not have "a significant economic impact" on hospitals. But, as described above, CMS's estimate of the financial burden on participating hospitals is absurdly low. The Proposed Rule will cost hospitals much more than CMS claims—enough to trigger this statutory requirement. Further, CMS artificially deflates the economic impact it predicts on participating hospitals. CMS claims that the change in revenue among impacted small entities resulting from the Proposed Rule is only 0.0008%. But this is based on bad math and poor logic. To calculate this number, CMS divided the gross annual loss in revenue it predicts among hospitals that currently offer transgender healthcare by the gross annual revenue of all hospitals in the U.S. However, the appropriate denominator is not the gross revenue of *all* hospitals in the U.S., because CMS—by its own admission—does not know how many of them provide transgender healthcare.[272] Hospitals that do not currently provide transgender healthcare likely will not be impacted by the Proposed Rule and should therefore be excluded from the calculation. Their inclusion artificially deflates the change in revenue. CMS must calculate the economic impact on the small entities that *are impacted* by the Proposed Rule. In fact, HHS's own guidance on this statutory requirement expressly forbids this kind of manipulation: "A low average impact on all small entities should

[272] Proposed Rule at 59471.

not be used to disguise a significant impact on a subset."[273] The agency is permitted to rely on average impact only where "the economic impact is expected to be similar for all affect small entities, and if those entities have similar costs and revenues."[274] Likewise, hospitals that are *not* small businesses should be excluded from the calculation—but CMS simply assumed that "most" hospitals are small businesses.[275] These faulty calculations cannot support CMS's conclusion that the Proposed Rule will not have a significant economic impact on small entities.

Second, CMS's analysis fails to consider any other measure of economic impact besides change in revenue. A proposed rule may have a significant economic impact on small entities sufficient to trigger this statutory requirement even where the change in revenue does not reach 3 to 5%. HHS guidance instructs that "[a] complete analysis should examine all the factors required to bring the entity into compliance with the regulation[,]" including training, the development of procedures and policies, technology migration paths, insurance, rent, utilities, capital purchases, and inventory.[276] This Proposed Rule is likely to impose significant burdens in many of those categories upon impacted hospitals, but CMS failed to consider any of these measures. Additionally, the Small Business Administration advises that a proposed rule may also have a significant economic impact on small entities "if the cost of the proposed regulation (a) eliminates more than 10 percent of the businesses' profits; (b) exceeds 1 percent of the gross revenues of the entities in a particular sector or (c) exceeds 5 percent of the labor costs of the entities in the sector."[277] The Proposed Rule fails to consider any of these measures.

Finally, the Proposed Rule fails to consider any impact this will have on the non-hospital healthcare practices that will be inundated with patients seeking to transfer care if the Rule takes effect. As discussed above, hospitals currently provide the vast majority of transgender healthcare. When large practices terminate transgender healthcare services, it places enormous strain on other nearby healthcare practices, which see large and immediate spikes in patient demand—often far greater than the practice is equipped to handle. For example, in one state where care was already terminated by large hospitals, the limited providers that still offered care saw a 400% increase in patients.[278] The California Primary Care Association, which represents 2,300 nonprofit community health centers, stated that "hospital reductions or discontinuation of gender-affirming care

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[273] HHS, *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services*, at 7 (May 2003) ("Moreover, if the rule will result in a disproportionate economic impact on a subset of affected small entities (for example, hospital-based as compared with free-standing skilled nursing facilities), a determination must be made as to whether the impact on them will be significant.") (hereinafter "2003 HHS Guidance"), https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf.

[274] *Id.*

[275] Proposed Rule at 59476.

[276] 2003 HHS Guidance at 5.

[277] U.S. Small Business Administration, *A Guide for Government Agencies How to Comply with the Regulatory Flexibility Act* at 19 (Aug. 2017), https://perma.cc/7KJ6-C3TC.

[278] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-21, ¶ 28.

services" have "placed increased pressure" on community health centers and led to "longer wait times, staff shortages, and strain on clinical and administrative resources, making it challenging for [our members] to fully meet the increased demand for care."[279] One hospital-based practice's wait times for new patients went from 2 months to 5 months after other nearby providers shut their doors.[280] Another practice's call center was so "overwhelmed" by the number of patients seeking to transfer from providers who terminated services that it had to set up an entirely new referral and intake system for those patients, and the clinic's wait time increased from three weeks to four months.[281] As one physician noted, "[p]rivate practitioners can only absorb so many patients . . . our pipelines are already bottlenecked because of the sudden closure of [a nearby hospital's] large program."[282]

While these increased burdens challenge healthcare practices of all sizes, they are particularly burdensome for non-hospital providers, which tend to be smaller than hospital-based practices and have far fewer patients, staff, and resources. The Proposed Rule itself predicts that non-hospital providers will absorb 50% of current hospital patients.[283] These entities likely all meet the definition of small entities, and the Proposed Rule's impact on these healthcare practices will be massive. But the Proposed Rule utterly fails to acknowledge these significant burdens, let alone meet its obligation to "analyze options for regulatory relief" of these small entities.[284]

CMS's claim that it need not comply with the Regulatory Flexibility Act's requirements[285] because the Proposed Rule will not have a significant economic impact on a substantial number of small entities rests on warped, inaccurate calculations and a grievously incomplete analysis.

B. CMS Failed to Analyze the Impact on Rural Hospitals, in Violation of 42 U.S.C. § 1302 (Section 1102(b)).

CMS has a duty to "prepare and make available for public comment" an analysis describing "the impact of the proposed rule on small [rural hospitals]" if the proposed rule "may have a significant impact on the operations of a substantial number of small rural hospitals."[286] That duty is mandatory.[287] The Proposed Rule acknowledged this requirement, but failed to conduct this analysis because it estimates that individual hospitals will lose $2,194 annually, which amounts to a "negligible impact" in CMS's view.[288] However, CMS provides no basis for reaching the conclusion that this figure does not constitute a "significant impact" and therefore does not trigger the requirement. Additionally, this figure is almost certainly inaccurate, given the many substantial

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[279] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-23, ¶¶ 13–15.
[280] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-2, ¶ 25.
[281] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-22, ¶ 24
[282] *Massachusetts v. Trump, et al.,* 1:25-cv-12162-AK, ECF No. 87-14, ¶ 71.
[283] Proposed Rule at 59474.
[284] Proposed Rule at 59474, 59476–77.
[285] *Cf.* 5 U.S.C. § 603.
[286] 42 U.S.C. § 1302(b); 5 U.S.C. § 603(a).
[287] *Biden v. Missouri*, 595 U.S. 87, 97 (2022).
[288] Proposed Rule at 59476–77.

costs that CMS failed to account for that would flow from this Proposed Rule. See *supra* Section IV.A.1. Even assuming CMS's estimate approaches accuracy, parsing costs across all hospitals *pro rata* fails to account for the important fact that rural hospitals have more Medicare and Medicaid patients than urban hospitals.[289] Accordingly, small rural hospitals may face disproportionate impacts from the Proposed Rule. Moreover, rural hospitals are more likely to be operating a negative budget, especially small rural hospitals.[290] Thus, even a $2,194 annual loss may be the difference between updating outdated technology, retaining staff, purchasing supplies and equipment, and other essential decisions for hospitals serving those who need it most.

VI. FAILURE TO COMPLY WITH THE FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act ("FACA") governs the establishment and operation of advisory committees within the executive branch, including by providing general procedures for such committees. The Proposed Rule relies heavily on the HHS Report. However, HHS did not comply with the requirements of FACA or its regulations in establishing the HHS Report committee, in the composition of the committee, or in the procedures followed by the committee.

The authors of the HHS Report plainly constituted an "advisory committee" under FACA. Specifically, the HHS Report authors were a "group . . . established or utilized to obtain advice or recommendations for . . . one or more agencies or officers of the Federal Government," the group was "established or utilized by one or more agencies," and the group was not "composed wholly of full-time, or permanent part-time, officers or employees of the Federal Government."[291] HHS clearly states that "HHS commissioned" the study, and names as authors nine individuals, none of whom are full-time or permanent part-time officers or employees of the federal government.[292] Further, the HHS Report was clearly intended to offer recommendations for agencies or officers of the federal government. It states specifically that it is "intended for policymakers" and claims it "summarizes" and "evaluates the existing literature on best practices."[293] Indeed, the Proposed Rule is itself evidence that HHS has relied on the Report's recommendations to promulgate regulations.

As an advisory committee, the HHS Report author group was subject to FACA. But the HHS wholly failed to comply with the FACA requirements.[294] For example, HHS did not consult with the General Services Administration ("GSA") to explain why the group was "essential to the conduct of agency business" and why its "functions cannot be performed by the agency."[295] HHS also did not publish a notice in the Federal Register announcing the author group,[296] submit a Membership Balance Plan to GSA describing HHS's "plan to attain fairly balanced

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[289] Scott Hulver et al., *10 Things to Know About Rural Hospitals*, KFF (Apr. 16, 2025), https://perma.cc/G3KB-7EL9.
[290] *Id.*
[291] 5 U.S.C. § 1001(2).
[292] HHS, Press Release: *HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures* (Nov. 19, 2025), https://perma.cc/3HME-XGM9.
[293] HHS Report at 11.
[294] Some of the relevant FACA regulations were updated in December 2025. However, because the HHS Report was drafted and published prior to December 2025, the prior versions of these regulations apply.
[295] *See* 41 C.F.R. § 102-3.60(b)(1)(2).
[296] 41 C.F.R. § 102-3.65(a).

membership,"[297] or "[c]onduct broad outreach, using a variety of means and methods," to interested parties and stakeholder groups likely to possess [the] points of view" required for fairly balanced membership.[298] Nor did HHS comply with FACA's meetings and records requirements, which require notice of meetings in the Federal Register and the ability of the public "to attend, appear before, or file statements" at meetings,"[299] and that an agency make available "all materials that were made available to or prepared for or by an advisory committee,"[300] including all "records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by" the committee.[301] And FACA also "requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest."[302] The HHS author group made no effort to do so here. As such, all actions taken by the author group, including the authoring of the HHS Report, were unlawful under FACA.

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For all the reasons discussed in this letter, we oppose the Proposed Rule and request the Secretary and CMS to withdraw it. If the Proposed Rule is not withdrawn, we urge the Secretary and CMS to seriously engage with its statutory duty to assess the real impact the provision will have on communities who are already vulnerable and under-resourced. Limiting healthcare to all in order to deny medically necessary healthcare to a politically disfavored minority group does not promote the health and safety of the American people.

Sincerely,

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[297] 89 Fed. Reg. 27673, 27682 (Apr. 18, 2024).
[298] 41 C.F.R. § 102-3.60(b)(2).
[299] 5 U.S.C. §1009(a)(2)–(3).
[300] *Food Chem. News v. HHS*, 980 F.2d 1468, 1469 (D.C. Cir. 1992).
[301] 5 U.S.C. § 1009(b).
[302] *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020).

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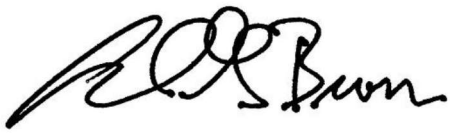

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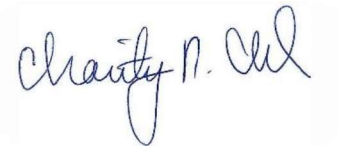

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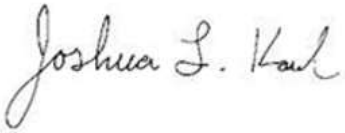

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