WILLIAM TONG
ATTORNEY GENERAL

KWAME RAOUL
ATTORNEY GENERAL

ANDREA JOY CAMPBELL
ATTORNEY GENERAL

LETITIA JAMES
ATTORNEY GENERAL

February 17, 2026

Via Federal Rulemaking Portal (Regulations.gov)

Secretary Robert F. Kennedy, Jr.
Department of Health and Human Services
Office of Civil Rights
Attention: Medicaid & CHIP NPRM, RIN 0938-AV73
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW, Washington, DC 20201

RE: **Comment on Notice of Proposed Rulemaking to Prohibit State Medicaid and CHIP Plans from Using Federal Medicaid Dollars to Fund Transgender Youth Healthcare, Implementing Subpart (N) of 42 C.F.R. § 441.800 and Implementing Subpart (D) of 42 C.F.R. § 457.**

Dear Secretary Kennedy:

The undersigned Attorneys General of Illinois, Connecticut, Massachusetts, New York, Washington, Arizona, California, Colorado, Delaware, District of Columbia, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, Oregon, Rhode Island, Vermont, and Wisconsin write to oppose the United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services' ("CMS") notice of proposed rulemaking ("NPRM"): Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59441 (Dec. 19, 2025) (to be codified at 42 C.F.R. § 441.800 and 42 C.F.R. § 457), hereinafter, "Proposed Rule". We urge CMS to withdraw the Proposed Rule, which would prohibit state Medicaid programs from using federal Medicaid dollars to fund transgender healthcare for individuals under the age of 18. It would also require separate state Children's Health Insurance Programs ("CHIP") to prohibit payment for transgender healthcare for individuals under 19 and to prohibit the use of federal CHIP dollars to fund transgender healthcare for individuals under the age of 19. High-quality, safe healthcare is essential for all residents of our states, including transgender youth, and we oppose this Proposed Rule, which is yet another pretextual attempt to further the Administration's ongoing efforts to undermine the essential rights of youth living with gender dysphoria in states that protect their healthcare.

As state Attorneys General, we oversee laws and regulations that state lawmakers and Medicaid, public health, insurance, and consumer protection agencies have adopted over many years to ensure robust guardrails to protect the health and well-being of all members of our communities. Given our states' traditional and longstanding authority to oversee the regulation of the practice of medicine, and in particular our Congressionally authorized role as Medicaid administrators, we strongly oppose this Proposed Rule, which greatly exceeds CMS's authority. No agency has the power to override federal laws granting state Medicaid and CHIP Programs the authority and discretion to use federal funding to cover transgender youth healthcare. The Proposed Rule must be withdrawn immediately to preserve the balance in the established state-federal partnership over the administration of these programs, because "state lawmakers, not the federal government," are "the primary regulators of professional [medical] conduct."[1]

Introduction

Since the first days of President Trump's second term, the Administration has repeatedly and aggressively targeted transgender individuals, curtailed transgender youth healthcare,[2] instilled fear in healthcare providers and patients, and attempted to usurp state oversight of medical care. December 18, 2025, marked a significant escalation in the Administration's attacks on transgender youth healthcare. That day, multiple components of HHS announced a series of actions that included HHS's release of three NPRMs,[3] including the Proposed Rule, all directed at cutting off transgender youth healthcare.[4] Additionally, the Secretary of HHS, Robert F. Kennedy Jr., issued an unprecedented "Declaration of the Secretary of the Department of Health and Human Services, RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents" ("Kennedy Declaration"),[5] which declares that transgender youth healthcare "fails to meet professional recognized standards of health care," and in doing so purports to sweep aside all contrary "Statewide or national standards of care," including those recommended by national medical organizations.[6]

The Proposed Rule is a central part of this coordinated attack. Together with these other actions, the Proposed Rule strips the states of their inherent healthcare oversight authority and would permit the federal government to unilaterally prohibit certain kinds of healthcare, only when

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

[2] In this comment, "transgender youth healthcare" refers to medical treatment for gender dysphoria, also referred to as "gender-affirming care," for children, adolescents, and individuals under the age of 18 or 19. *See infra* Section I.c.

[3] The two other NPRMs are Proposal to Amend Regulations Implementing Section 504 of the Rehabilitation Act of 1973, to exclude protections related to gender dysphoria, which seeks to eliminate a prior rule that categorizes gender dysphoria as a "disability" covered by Section 504, and Proposed Rule Seeking to Amend CMS Hospital Condition of Participation to Prohibit Provision of Certain Gender Affirming Care Services for Young People.

[4] The undersigned States have also submitted a comment letter on the Medicaid Program; Proposed Rule Seeking to Amend CMS Hospital Condition of Participation to Prohibit Provision of Certain Gender Affirming Care Services for Young People, 90 Fed. Reg. 59463 (Dec. 19, 2025). We incorporate by reference that comment letter and all the arguments and sources cited therein.

[5] *See* Declaration from Robert F. Kennedy Jr., Sec'y of U.S. Dep't of Health & Human Servs., Re: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents (Dec. 18, 2025) [hereinafter *Kennedy Declaration*].

[6] Several of the undersigned States have challenged the Kennedy Declaration as unlawful. *See Oregon v. Kennedy*, 6:25-cv-02409 (D. OR. Dec. 23, 2025).

provided to transgender youth, in a significant departure from longstanding Medicaid policy and in contravention of federal law. CMS acts without Congressional authority or a reasoned basis and ignores evidence-based medicine to support its predetermined outcome to halt transgender youth healthcare. Indeed, the Proposed Rule heavily relies on a report of an advisory committee established by HHS that is not only unscientific and discredited but also fails to comply with the requirements of the Federal Advisory Committee Act. Even though the Proposed Rule would cause significant burdens for states and the operation of their Medicaid programs, CMS fails to provide an adequate Regulatory Impact Analysis, leaving the undersigned States unsure of the costs the Proposed Rule would impose if finalized and why other, less harmful, cost-effective alternatives were not proposed. To our states the warning is clear: HHS seeks to usurp states' authority to regulate transgender youth healthcare, and in doing so sets an unlawful precedent to regulate any other clinically recommended healthcare nationwide.

I. Background

a. States Retain Significant Discretion to Administer Medicaid and CHIP As Part of a Longstanding State-Federal Partnership.

Medicaid is authorized under Title XIX of the Social Security Act ("SSA") via 42 U.S.C. § 1396a ("the Medicaid Act"), and CHIP was created pursuant to Section 2103 of the SSA. Both federally authorized programs are administered by the states but federally funded. And both programs provide essential health insurance for individuals whose household incomes fall below eligibility thresholds that vary by state. Nationwide, Medicaid serves nearly 80 million low-income individuals and families.[7] CHIP serves another seven million people or 2% of the total population.[8] An estimated 37% of people under 18 in the United States are covered by Medicaid or CHIP, though the percentage varies across states.[9]

Since its inception, the Medicaid program has operated as a state-federal partnership that gives broad control to states to implement the program's goals.[10] Once a state chooses to participate in Medicaid it must comply with federal statutory and regulatory requirements, and State Plans must include certain broad categories of medical services by statutory mandate. However, Congress lets states decide whether to include in their State Plans any services that do not fall within these broad categories.[11] Further, states retain "substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage" to ensure standards for coverage adequately meet the needs of the Medicaid population of the state.[12] Consistent with this substantial discretion afforded to them by law, each state designs its Medicaid and CHIP programs in a way that reflects the needs of its residents, resulting in a wide variance across the country.[13] This broad flexibility ensures states can apply different approaches to deliver high-quality, patient-centered, and affordable healthcare through state Medicaid and CHIP programs.[14]

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[7] *Medicaid Enrollment and Unwinding Tracker*, KFF (Jan. 29, 2026), https://perma.cc/ALT5-G9TT.

[8] *September 2025 Medicaid & CHIP Enrollment Data Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://perma.cc/NH3N-LA8Y.

[9] *Id.*

[10] *Alexander v. Choate*, 469 U.S. 287, 303 (1985).

[11] *See* 42 U.S.C. § 1396a(a)(10); 42 C.F.R. § 431.10.

[12] *Alexander*, 469 U.S. at 303.

[13] *See, e.g., Oregon v. Kennedy*, 6:25-cv-02409-MTK, ECF Nos. 33-59 (D. OR. Dec. 23, 2025).

[14] Jonathan Kucskar, *Laboratories of Democracy: Why State Health Care Experimentation Offers the Best Chance to Enact Effective Federal Health Care Reform*, 11 J. HEALTH CARE L. & POL'Y 377 (2008).

Like Medicaid, CHIP benefits also differ in every state, but each State Plan must cover all care in defined broad categories.[15] States may also choose to cover optional services, such as prescription drugs, vision, and hearing services.[16] The SSA authorizes states to cover a range of additional services in CHIP plans at the option of the state.[17]

The Medicaid Act requires states to ensure standards for coverage within each category of service are sufficient in amount, duration, and scope to ensure adequate Medicaid services are available statewide. In addition, each state has the authority to decide what care is "medically necessary." Neither HHS nor CMS has statutory authority to determine the scope of covered services or whether services are medically necessary—that determination is and has always been left to the states. Connecticut, for example, defines "medically necessary" in the statute that provides for the administration of its Medicaid program.[18] Other states similarly have always defined "medically necessary" by their own standards—not CMS's.[19] This Proposed Rule eliminates the states' longstanding discretion to define medically necessary care, shifting that determination to the federal government.

The undersigned States have exercised their longstanding, Congressionally recognized discretion to consider transgender youth healthcare medically necessary and have covered this care in their State Plans in different ways. States like Connecticut, Illinois, Washington, and California have covered comprehensive transgender healthcare for youth and adults for more than a decade.[20] Other states have more recently passed laws protecting this healthcare.[21] For years such states have administered their State Plans' coverage of transgender youth healthcare with approval and without interference from CMS.

b. State-Regulated Medical Care.

The statutory delegation of authority described above is consistent with the states' longstanding general authority, under their police powers, to enact laws and policies aimed at protecting the health and welfare of their residents.[22] And because the states have an interest in ensuring their residents receive safe, effective healthcare, many have implemented legal guardrails on the provision of healthcare. Indeed, all states have had boards that oversee the licensing of

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[15] 42 U.S.C. § 1397cc(c).

[16] For patients under the age of twenty-one states must include coverage for services that constitute medically necessary healthcare under Early and Periodic Screening, Diagnostic and Treatment. 42 U.S.C. § 1396d(a)(4)(B), (r). Regardless of whether the state elected to provide those services generally under its State Plan, such services are required by EPSDT. ESPDT mandates broader coverage for beneficiaries under twenty-one, but—in line with their discretion to determine the appropriate amount, duration, and scope of services—states have long-standing flexibility in covering such care, including determining when a service is medically necessary.

[17] 42 U.S.C. § 1397jj(a)(24).

[18] Conn. Gen. Stat. § 17b-259b.

[19] *See, e.g.*, 215 Ill. Comp. Stat. 200/15 and 215 Ill. Comp. Stat. 134/10 (defining medically necessary). *See also* Nat'l Academy for State Health Policy, *State Definitions of Medical Necessity under the Medicaid EPSDT Benefit*, (Apr. 23, 2021), https://perma.cc/PV7M-XT2Q.

[20] *See, e.g.*, *Oregon, v. Kennedy*, 6:25-cv-02409-MTK, ECF No. 41, ¶¶ 12-13 (D. OR. Dec. 23, 2025); *see also* 89 Ill. Admin. Code 140.413(a)(16) (allowing for coverage of transgender surgeries, services and procedures); 90 Ill. Admin. Code 140.440(h) (allowing for coverage of hormonal therapy); Cal. Code Regs., tit. 10, § 2561.2.

[21] *See, e.g.*, Md. Code Ann., §§ 15-103(a)(2)(XXII), 15-151.

[22] *See Hillsbrough Cnty., Fla. v. Automated Med. Labs., Inc*., 471 U.S. 707, 719 (1985) ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern."); *Slaughter-House Cases*, 83 U.S. 36, 62 (1872) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons…within the State").

medical professionals since the nineteenth century.[23] Fundamental requirements for obtaining a medical license across states include extensive education and residency requirements in addition to passing a licensing examination.[24] State boards also regulate by disciplining licensees who act illegally or unethically and by enacting laws and regulations that circumscribe how licensed practitioners conduct medical practice.[25]

As part of their oversight, individual states have passed laws and regulations that ensure patients are appropriately informed of risks and require their voluntary informed consent for all medical care. This is especially true for youth,[26] whose parents or legal guardians retain the authority to provide informed consent with limited exceptions.[27] Informed consent is also a specific component of the standard of care for treatment of gender dysphoria in youth, described below.

Within the Medicaid program itself, states play a central role in regulating and overseeing the practice of medicine and have established robust safeguards (consistent with the requirements of Medicaid) to ensure high-quality care that aligns with clinical practice standards. States must screen providers to ensure that prospective providers meet enrollment criteria for Medicaid. States also conduct background checks, require Medicaid-participating providers to report certain data to the state, and conduct site visits to monitor and assess providers who are deemed to be of "moderate" or "high" risk.[28] Medicaid not only allows states to choose which providers may deliver covered care, the state-federal Medicaid framework explicitly relies on states doing so. For example, the Medicaid "free-choice-of-provider provision unambiguously requires that states participating in the Medicaid program allow covered patients to choose among the . . . practitioners they could use were they paying out of their own pockets."[29] Under this provision, state law governs whether a provider is "qualified" or not.

c. Transgender Youth Healthcare Is Evidence-Based Medical 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."[30] To be diagnosed with gender dysphoria, the incongruence must persist for at least six months and be accompanied by clinically significant distress or impairment in social,

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[23] David Johnson & Humayun J. Chaudhry, *The History of the Federation of State Medical Boards*, 98 J. MED. REG. 20 23–24 (2012).

[24] *See e.g.,* Conn. Gen. Stat. § 20-13c; 225 Ill. Comp. Stat. 60/3; Wash. Admin. Code Title 246.

[25] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 S.D. L. REV. 427, 450-52 (2015) https://perma.cc/GCB5-URVV.

[26] *See, e.g.,* Conn. Gen. Stat. § 1-1d; 755 Ill. Comp. Stat. 5/11-1.

[27] *See, e.g*., 410 Ill. Comp. Stat. 210/2 ("Any parent . . . may consent to the performance upon his or her child of a health care service by a physician licensed to practice medicine in all its branches, a chiropractic physician, a licensed optometrist, a licensed advanced practice registered nurse, or a licensed physician assistant or a dental procedure by a licensed dentist.").

[28] 42 C.F.R. 455 sub E.

[29] *Planned Parenthood Arizona Inc. v. Betlach*, 727 F.3d 960, 971 (9th Cir. 2013).

[30] AM. PSYCHIATRIC ASS'N, *Diagnostic and Statistical Manual of Mental Disorders* 513-14 (5th ed., text rev. 2022) [hereinafter *DSM-5-TR*].

occupational, or other important areas of functioning.[31] Gender dysphoria is undisputedly a serious medical condition, which even HHS recognizes.[32]

Medical treatments for gender dysphoria are provided based on individualized assessments and require informed parental consent when provided to youth. Treatment encompasses 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.[33] This letter focuses on the above forms of medical care for gender dysphoria, and refers to those treatments collectively as "transgender youth 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 gender identity.[34] These same hormone therapies can also be medically appropriate treatments for non-transgender youth with delayed puberty or for other conditions such as endometriosis, hypogonadism, polycystic ovarian syndrome, or nonhormonal conditions such as idiopathic hirsutism.[35] 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.[36] 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.[37]

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[31] *Id.* at 512-13.

[32] *See* Ctrs. for Medicare & Medicaid Servs., *Urgent Review of Quality Standards and Gender Transition Procedures*, 10 (May 28, 2025), https://perma.cc/KVY6-FZEL [hereinafter *HHS Letter*]; U.S. DEP'T OF HEALTH & HUMAN SERVS., *Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices,* (Nov. 2025) [hereinafter *HHS Report*] ("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.").

[33] Danyon Anderson et al., *Gender Dysphoria and Its Non-Surgical and Surgical Treatments*, 10 HEALTH PSYCH. RSCH. 1 (2022); *see also,* Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102 J. CLIN. ENDOCRINOL. & METAB. 3869 (2017).

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

[35] *See, e.g.,* Brief of Experts on Gender Affirming Care as Amici Curiae in Support of Petitioner and Respondents in Support of Petitioner at 33-34, *United States v. Skrmetti*, No. 23-477 (U.S. Sept. 3, 2024) (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"). *See also, infra* Section II.b.

[36] Nita Bhatt, Jesse Cannella & Julie P. Gentile, *Gender-affirming Care for Transgender Patients*, 19 INNOVATIONS CLIN. NEUROSCI. 23 (2022).

[37] 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).

Transgender youth healthcare is supported by major medical associations as necessary treatment for gender dysphoria[38] and is based on rigorous standards of care.[39] Transgender healthcare improves health outcomes and quality of life for all transgender people.[40] And while heightened safeguards are in place for youth, there is a strong medical consensus that transgender youth healthcare has significant benefits and, for some, can be life-saving.[41] 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."[42] One study of nonbinary and transgender teenagers and young adults between the ages of thirteen and twenty 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.[43] A longitudinal study of transgender youth who received puberty blockers, hormone

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[38] *Medical Association Statements in Support of Health Care for Transgender People and Youth*, GLAAD (June 26, 2024), https://perma.cc/86Y9-HMZ3; Moira Szilagyi, *Why We Stand Up for Transgender Children and Teens*, AM. ACAD. PEDIATRICS (Aug. 10, 2022), https://perma.cc/JK6C-69J2; Examining the Policies and Priorities of the Department of Health and Human Services: Hearing Before the H. Comm. On Educ. & the Workforce, 118th Cong. 51 (2024) (listing 30 associations with published statements that support gender-affirming care); *APA Adopts Groundbreaking Policy Supporting Transgender, Gender Diverse, Nonbinary Individuals*, AM. PSYCH. ASS'N (Feb. 28, 2024), https://perma.cc/SL9K-ZTJZ; *Endocrine Society Statement in Support of Gender-Affirming Care*, ENDOCRINE SOC'Y (May 8, 2024), https://perma.cc/J4Y2-RUJ2; *Statement in Support of Transgender Children and Youth, Their Families, and Health Care Providers*, FED'N OF PEDIATRIC ORGS. (Mar. 28, 2022), https://perma.cc/KS9J-FQS8; *see also USPATH Position Statement on Legislative and Executive Actions Regarding the Medical Care of Transgender Youth*, U.S. PRO. ASS'N FOR TRANSGENDER HEALTH (Apr. 22, 2022), https://perma.cc/RH7W-PSEV. 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 Position Statement on Gender Surgery for Children and Adolescents*, AM. SOC'Y PLASTIC SURGEONS (Feb. 3, 2026), https://perma.cc/7CMN-WPU7. 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 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. Should HHS agree with ASPS that more evidence is needed on surgical interventions for transgender youth, the agency should not categorically prohibit reimbursement for this care but instead fund research and support the rare and individualized manner in which the care is provided.

[39] *Coleman, supra* note 37.

[40] Tonia Poteat, et al., *Standards of Care for Transgender and Gender Diverse People*, 329 JAMA 1872 (2023); 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).

[41] *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); *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People* (Madeline B. Deutsch ed., 2nd ed., 2016), https://perma.cc/VCN3-7AC7; *see also,* Wittlin, *supra* note 40.

[42] *DSM-5-TR*, *supra* note 30; Garima Garg et al., *Gender Dysphoria* (2023), https://perma.cc/R7UE-E7YG.

[43] Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS 696, 702 (2014)*; see also* Diana M Tordoff, et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care,* 5 JAMA NETW. OPEN 1 (2022).

therapy, and gender-affirming 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 youth's well-being was comparable to their cisgender peers.[44] 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, 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."[45]

Youth who receive transgender healthcare generally report very high levels of satisfaction with the care and its positive impacts on their mental and physical health.[46] 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."[47] Anecdotal testimony from youth and parents in active legal challenges to the Administration's attempts to end or limit transgender youth healthcare bolster these studies, showing firsthand the impacts transgender youth 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 obtain transgender youth healthcare.[48] After receiving care, some medical professionals report witnessing the transgender youth they treated "blossom[] into well-adjusted, bright, and future-oriented young people after receiving gender-affirming care because they finally felt their lives were worth living."[49]

d. The Administration's Coordinated Attacks on Transgender Youth Healthcare.

In January 2025, the President issued Executive Order ("EO") 14187, directing federal agencies to take steps to end access to transgender youth healthcare, which the President refers to as "the chemical and surgical mutilation of children."[50] On his first day in office, the President also issued EO 14168, which directs agencies to prohibit federal funding from being used to

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[44] *Annelou*, *supra* note 43.

[45] CTR. FOR MEDICARE & MEDICAID SERVS., *Biden-Harris Administration Greenlights Coverage of LGBTQ+ Care as an Essential Health Benefit in Colorado* (Oct. 12, 2021), https://perma.cc/SLM4-VKVN.

[46] Wiepjes CM, et al. *The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets*, 15 J SEX MED. 582 2018 (that 0.6% of transgender women and 0.3% of transgender men experienced regret); Olson KR, et al., *Levels of Satisfaction and Regret With Gender-Affirming Medical Care in Adolescence*, 178 JAMA PEDIATR. 1354 (2024).

[47] 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,* N. Y. MAG. (Feb. 4, 2025), https://perma.cc/9Y5J-HRRH.

[48] *Washington v. Dep't of Just*., No. 2:25-cv-00244 (W.D. Wash. Feb. 7, 2025), ECF. No. 60, Decl. of N.M. ¶¶ 5, 7, 11; *id*., ECF No. 67, Decl. of S.B. ¶¶ 7, 9-11; *id*., ECF No. 113, Decl. of A. Johnson ¶ 8; Seaton ¶¶ 7-9; *id*., ECF No. 33, Decl. of E.C. ¶ 5; *id*., ECF No. 40, Decl. of Ullom ¶ 6; *id*., ECF No. 52, Decl. of K.S. ¶ 5; *id*., ECF No. 48, Decl. of K.C.C. ¶ 6; *id*., ECF No. 21, Decl. of L.L. ¶¶ 8, 9; *id*., ECF No. 54, Decl. of M.B. ¶ 5; *id*., ECF No. 63, Decl. of R.D. ¶ 6; *id*., ECF No. 71, Decl. of S.S. ¶¶ 6, 9; *id*., ECF No. 70, Decl. of Parent S.O. ¶ 7; *id*., ECF No. 68, Decl. of S.F. ¶ 6; *id*., ECF No. 69, Decl. of S.N. ¶¶ 4-6; *id*., ECF No. 25, Decl. of V.S. ¶¶ 4-5; *id*., ECF No. 26, Decl. of A.J. ¶ 5; *id*., ECF No. 77, Decl. of Provider B.M. ¶¶ 6, 12; *id*., ECF No. 51, Decl. of K.H. ¶¶ 6-7, 11; *id*., ECF No. 100, Decl. of Kaefer ¶¶ 6-8; *id*., ECF No. 58, Decl. of M.F. ¶¶ 14, 19, 40; *id*., ECF No. 66, Decl. of R.T. ¶¶ 10, 13,18.

[49] *Massachusetts v. Trump,* 1:25-cv-12162-AK, (D. Mass. Dec. 19, 2025), ECF No. 87-21, ¶ 9.

[50] Exec. Order No. 14187, 90 Fed. Reg. 8771 (Jan. 28, 2025).

promote "gender ideology." With these EOs, the Administration announced that the official policy of the United States is that there are only two sexes, that gender is equivalent to birth sex and immutable, and that federal agencies should end federal funding for any institution that disagrees (i.e., promotes "Gender Ideology").[51] The Administration's goals are explicit: the EOs deny the very existence of transgender individuals and would refuse them legal, safe, and necessary healthcare.

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 transgender youth healthcare. First, on March 5, 2025, CMS issued a Quality & Safety Special Alert Memo ("QSSAM") to "alert[]" hospital providers and other covered entities 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.[52] 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.[53] 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 transgender youth healthcare within their state Medicaid programs.[54] On April 14, 2025, HHS launched a portal where members of the public could report alleged "chemical and surgical mutilation of children."[55] On April 22, 2025, the Department of Justice ("DOJ") issued an internal memorandum that directed officials to investigate and prosecute medical providers and pharmaceutical companies that offer transgender youth healthcare. In the memo, U.S. Attorney General Bondi asserted she will use the DOJ to "bring [] an end" to transgender youth healthcare.[56] 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.[57] On June 11, 2025, Assistant Attorney General Brett A. Shumate issued a memorandum to all U.S. DOJ Civil Division employees directing the Civil Division to "use all available resources to prioritize investigations of doctors, hospitals,

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[51] Exec. Order No. 14168, 90 Fed. Reg. 8615 (Jan. 20, 2025).

[52] CTR. FOR CLINICAL STANDARDS & QUALITY, *Protecting Children from Chemical and Surgical Mutilation* (Mar. 5, 2025), https://perma.cc/Y9TM-YTBM.

[53] Letter from Thomas J. Engels, Adm'r, Health Res. & Servs. Admin., to Hospital Administrators, Colleagues, & Grant Recipients (Mar. 6, 2025), https://perma.cc/PE3R-XGJF; *see also, PFLAG, Inc. v. Trump*, No. 8:25-cv-00337-BAH, ECF No. 118-5, Ex. C, at 3 (D. Md. Mar. 7, 2025).

[54] Letter from Drew Snyder, Deputy Adm'r & Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Directors, Re: Puberty Blockers, Cross-Sex Hormones, and Surgery Related to Gender Dysphoria (Apr. 11, 2025), https://perma.cc/N6ZM-HXWG.

[55] *HHS Takes Action to Protect Whistleblowers who Defend Children and Launches First Conscience Investigation*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Apr. 14, 2025), https://perma.cc/A73S-QRLN.

[56] Mem. from Pamela Bondi, Att'y Gen., on Protecting American Children from Chemical and Surgical Mutilation (Apr. 22, 2025), https://perma.cc/FFE7-38ML.

[57] Letter from Dr. Mehmet Oz, Adm'r, Centers for Medicare & Medicaid Services, on Urgent Review of Quality Standards and Gender Transition Procedures (May 28, 2025), https://perma.cc/KVY6-FZEL.

pharmaceutical companies, and other appropriate entities" to pursue alleged violations "of the Food, Drug, and Cosmetic Act and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition; and (2) dealers such as online pharmacies suspected of illegally selling such drugs."[58]

These actions, separately and in the aggregate, have instilled fear in healthcare providers and patients and caused some hospitals to limit or end their provision of transgender youth healthcare. As the Administration publicly proclaimed, this was its "intended effect."[59] In the wake of the shutdown of transgender youth healthcare by some providers, the White House boasted: "Hospitals around the country are taking action to downsize or eliminate their so-called 'gender-affirming care' programs" and "[h]ealth systems across the nation stopped or downsized their [transgender youth healthcare programs] following President Trump's [EO]."[60]

The Administration has also attempted to marshal "scientific" 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"),[61] ostensibly to review the existing evidence of the benefits and risks of transgender youth healthcare and ultimately condemning the provision of such care for youth. Also, in the spring and summer of 2025, the Administration began to ramp up its targeted investigatory and enforcement efforts. HHS sent a second letter to an unspecified group of providers, state medical boards, and health risk managers urging them to update treatment protocols to stop transgender youth healthcare.[62] 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" investigating "healthcare fraud, false statements, and more."[63] The same month, on the heels of a workshop on the same

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[58] Mem. from Brett A. Shumate, Asst. Att'y Gen. to All Civil Division Employees on Civil Division Enforcement Priorities (June 11, 2025), https://perma.cc/2EEV-33KM.

[59] *President Trump is Delivering on His Commitment to Protect our Kids*, THE WHITE HOUSE (Feb. 3, 2025), https://perma.cc/3EDU-GHSM.

[60] *Id*.; *President Trump is Protecting America's Children*, THE WHITE HOUSE (Mar. 4, 2025), https://perma.cc/FG3C-TXRV.

[61] *HHS Report*, *supra* note 32.

[62] *HHS Letter*, *supra* note 32.

[63] Press Release, Dep't of Just., Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children (July 9, 2025), https://perma.cc/H7FF-Y2HV. Every court to have considered the propriety of these subpoenas, at the time of this comment, have held that they are improper, pretextual attempts to end transgender youth healthcare, overly broad, or both. *See, e.g.*, *QueerDoc, PLLC v. U.S. Dept. of Justice*, No. 2:25-MC-00042-JNW, 2025 WL 3013568 at *6-7 (W.D. Wash. Oct. 27, 2025), appeal filed, No. 25-7384 ("DOJ issued the subpoena first and searched for a justification second"; concluding "the record before the Court establishes that DOJ's subpoena to [gender-affirming care provider] was issued to "pressure providers to cease offering gender-affirming care"); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2025 WL 3724705, at *1 (W.D. Pa. Dec. 24, 2025) (collecting cases); *see also In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 239 (D. Mass. Sept. 9, 2025) (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 (W.D. Wash. Sept. 3, 2025) (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*, No. 25-mc-00062-SKC-CYC, 2026 WL 33398, at *7 (D. Colo. Jan. 5, 2026) (report and recommendation recommending that subpoena to Children's Hospital Colorado be quashed; explaining "the government's aim is not actually to investigate FDCA

topic,[64] the Federal Trade Commission ("FTC") 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 there have been potential deceptive or unfair practices involved in this type of medical care.[65]

The Administration's attacks on transgender youth healthcare culminated in a series of actions by HHS on December 18 targeting this care. The actions include this Proposed Rule, the Conditions of Participation Proposed Rule,[66] which proposes to prohibit hospitals from providing certain forms of healthcare for transgender youth as a condition of participation in the Medicare and Medicaid programs, and the Kennedy Declaration,[67] which declares that transgender youth healthcare "fails to meet professional recognized standards of health care."[68]

II. The Proposed Rule's Departure from Longstanding Medicaid Policy Is Contrary to Law.

In an unprecedented departure from well-defined state and federal roles, CMS seeks to establish a national prohibition on the provision of transgender youth healthcare for individuals under 18 who depend on Medicaid. CMS's efforts to regulate this aspect of Medicaid run headlong into core federalism principles and respect for state power, including as embodied in the Tenth Amendment and 42 U.S.C. § 1395. The Tenth Amendment reserves for the states all rights and powers "not delegated to the United States," commonly referred to as "traditional state police powers."[69] These powers include "primary responsibility over matters of health and safety, including the regulation of the practice of medicine."[70] Further, under settled law, it is the states, not CMS, that are primarily responsible for administering Medicaid. States enjoy "substantial discretion" in administering their Medicaid programs.[71] Although state Medicaid administrators

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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'").

[64] *See* The Dangers of "Gender-Affirming Care" for Minors, FED. TRADE COMM'N (July 9, 2025), https://perma.cc/2B48-V2GT.

[65] *See* FED. TRADE COMM'N, FTC Requests Public Comment Regarding "Gender-Affirming Care" for Minors (July 28, 2025), https://perma.cc/FBX6-NNAY.

[66] Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59463 (Dec. 19, 2025) (to be codified at 42 C.F.R. pt. 482.46).

[67] *See Oregon v. Kennedy*, 6:25-cv-02409 (D. OR. Dec. 23, 2025).

[68] On the same day, HHS 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).

[69] U.S. Const. amend. X; *see Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.") (internal quotation marks omitted).

[70] *Medina v. Planned Parenthood S. Atl*., 606 U.S. 357, 364 (2025) (internal quotation marks omitted); *see also United States v. Skrmetti*, 605 U.S. 495, 524 (2025) ("We afford States wide discretion to pass legislation in areas where there is medical and scientific uncertainty.") (internal quotation marks omitted)); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) ("[W]e begin by noting that the historic police powers of the State include the regulation of matters of health and safety."); *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977); *Linder v. United States*, 268 U.S. 5, 18 (1925); *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002).

[71] *Alexander v. Choate*, 469 U.S. 287, 303 (1985) (discussing how the federal Medicaid Act "gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in 'the best interests of the recipients'") (internal citation omitted).

are subject to certain federal statutory and regulatory requirements, including that Medicaid coverage must include or exclude certain categories of medical services as determined by Congress,[72] each state has the authority to decide what additional coverage to include in its State Plan.[73] And while CMS approves the State Plan,[74] it has limited authority to reject the State Plan or any amendments to it.[75] Indeed, CMS is prohibited from "exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided" under 42 U.S.C. § 1395,[76] and CMS itself has recognized this restriction on its ability to regulate.[77] Therefore, the agency has consistently deferred to states' determinations, as set out in a State Plan, to establish medically necessary safeguards for determining eligibility for care and services.[78]

The Proposed Rule contravenes this fundamental and crucial state-federal division of responsibility for the administration of Medicaid in several ways. First, CMS lacks the authority to promulgate this Rule, and the only authority it relies on in support of the Rule are the very statutory provisions and regulations intended to thoughtfully balance the state-federal partnership and effectuate state flexibility in administering the Medicaid program. Nothing about the well-settled interpretation of the laws and regulations that form the backbone of the Medicaid program affords CMS the power it aims to grab through this Proposed Rule. Second, the Proposed Rule violates and is contrary to additional regulations and statutes, including the Medicaid Drug Rebate Program, CHIP, and Sections 1554 and 1557 of the Affordable Care Act. Third, the Proposed Rule usurps state authority to regulate the practice of medicine, and imposes retroactive conditions, which the states neither considered nor consented to, in violation of the Tenth Amendment and the Spending Clause.

a. SSA Provisions Related to State Medicaid Programs Regulate States' Processes and Have Never Been Used to Justify a Categorical Prohibition on the Use of Federal Funds for Certain Healthcare Procedures or Diagnoses.

The Social Security Act affords states flexibility to set state-specific standards regarding the amount, duration, and scope of Medicaid-covered services; to set criteria for determining

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[72] *E.g.*, 42 U.S.C. 1396d(a) (listing the mandatory services State Medicaid programs must cover); 42 U.S.C. §1396d(a)(32)(B) (prohibiting the use of federal Medicaid funds to certain Medicaid-eligible individuals who are patients in institutions for mental diseases).

[73] 42 C.F.R. 431.10; 42 U.S.C. § 1396a(a)(10).

[74] *See*, *e.g.*, 42 U.S.C. § 1396a(b) (requiring the Secretary to approve any State Plan that meets the requirements of the Medicaid Act); 42 C.F.R. § 430.15 (setting out approval and disapproval authority).

[75] 42 C.F.R. §§ 430.16, 430.18 (HHS must give the state notice and provide an opportunity to request an administrative hearing to contest the decision).

[76] *See American Medical Association v. Weinberger*, 395 F. Supp. 515 (N.D. Ill. 1975), *aff'd sub nom*. *AMA v. Mathews*, 522 F.2d 921 (7th Cir. 1975). While 42 U.S.C. § 1395 is part of Title XVIII of the Social Security Act, which governs Medicare, not Medicaid, HHS has long interpreted it to apply in principle to Medicaid as well. *See, e.g.*, *Evelyn v. Kings County Hosp. Center*, 819 F. Supp. 183 (E.D.N.Y. 1993) ("Such deference to the states is consistent with Congress's express directive that Medicaid and Medicare not become vehicles for federal 'supervision or control over the practice of medicine or the manner in which medical services are provided.'").

[77] *See* Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688, at 68772 (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").

[78] *Cf. W. Virginia v. Env't Prot. Agency*, 597 U.S. 697, 729 (2022) ("'When [an] agency has no comparative expertise' in making certain policy judgments, we have said, 'Congress presumably would not" task it with doing so.'").

medical necessity; and to adopt procedures to control the utilization of Medicaid-covered services. The Act balances this flexibility against a requirement that states adopt specific procedural safeguards to ensure that their Medicaid programs yield efficient, quality healthcare that is in the best interest of beneficiaries. Within this framework, federal regulations also expressly prohibit state Medicaid agencies from arbitrarily denying or reducing access to care because of an individual's diagnosis, type of illness, or condition.[79]

CMS now invokes these provisions and regulations to justify the Proposed Rule and explain how it is consistent with existing federal law. But the cited federal authorities do neither. Instead, they specifically regulate *state* processes to ensure states adopt a minimum floor of safeguards to guarantee high-quality care that is in the best interest of their beneficiaries. CMS's proposed rule, which is unsupported by any statutory or regulatory authority to make sweeping coverage determinations, is nothing more than a politically motivated effort to exclude an entire category of medical care based on the Administration's evidence-free views of safe healthcare for transgender youth.

i. The "Best Interests" and "Quality of Care" Provisions in the SSA Do Not Authorize CMS to Exclude Specific Services from Medicaid.

CMS asserts Sections 1902(a)(19) and 1902(a)(30)(a) of the SSA—referred to as the "best interests" and "quality of care" provisions, respectively—authorize it to prohibit Federal Financial Participation ("FFP") in Medicaid for transgender youth healthcare for individuals under the age of 18. They do not. Section 1902(a)(19) requires states to adopt safeguards to help ensure that covered care is provided "in a manner consistent with simplicity of administration and the best interests of the recipients."[80] Section 1902(a)(30)(A) requires states to adopt "methods and procedures" to ensure that Medicaid payments are "consistent with efficiency, economy, and quality of care."[81] These provisions require the *states* to develop procedural safeguards for their Medicaid programs. Neither provision speaks to the specific type of care or services that states can choose to offer to Medicaid beneficiaries. And neither provision authorizes nor has ever been used by CMS to regulate State Plans in a way that categorically prohibits the use of federal funds for certain healthcare procedures or diagnoses. Further, allowing CMS to rely on these provisions in this manner without clear Congressional authority would invade states' clear purview to regulate the practice of medicine.

As the Supreme Court has made clear, there is always a "best reading of the statute."[82] A straightforward reading of these statutory provisions shows they concern the manner of how states administer medical care, not the substantive nature of the care itself. Specifically, the "best interests" provision sets out that the state must provide such "safeguards" to ensure that "eligibility" for care and services will be "determined" and "provided, in a manner consistent with . . . the best interests of the recipients." Thus, the provision does not relate to the care itself but rather whether the *methods* by which the state determines eligibility for and administers such care

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[79] 42 C.F.R. § 440.230(c); *see also, supra* Section I.b.

[80] 42 U.S.C. § 1396a(a)(19).

[81] 42 U.S.C. § 1396a(a)(30)(A).

[82] *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024); *see also id.* at 385 ("'[I]t is emphatically the province and duty of the judicial [branch],'" not the Executive, "'to say what the law is.'") (quoting *Marbury v. Madison*, 5 U.S. 137, 177 (1803)) (citation modified).

are in the recipient's best interests. The same is true for the "quality of care" provision, which provides that states must implement "such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . to assure that payments are consistent with efficiency, economy, and quality of care." Again, the provision relates not to ensuring quality of care itself but ensuring that the *methods* states set relating to making payments for care are consistent with quality of care. Further, because "[a] word is known by the company it keeps"[83] and the surrounding language in the "quality of care" provision speaks primarily about payments and enacting fiscally responsible policies to protect and conserve limited Medicaid funds,[84] this is further indication that Congress did not intend CMS to use this provision to set substantive clinical guidelines or standards of care.[85]

This interpretation is bolstered by the way the provisions have been historically relied upon. CMS has used the "best interests" provision to define procedural protections for enrollees (e.g., maximum timeframes, verification requirements, etc.) and enhance (not limit) coverage or benefits.[86] When Congress added the "quality of care" provision in the Social Security Amendments of 1967, it summarized it as a payment rule, noting "[t]he amendment requires States to establish methods and procedures designed to safeguard against unnecessary utilization of healthcare and services, as well as to assure that payments (including payments for drugs) do not exceed reasonable charges and that they are made on a basis consistent with efficiency, economy, and quality of care."[87] Congress has repeatedly described the provision as such, including for example, in the Medicare & Medicaid Health Budget Reconciliation Amendments of 1989 where it discussed how "States have discretion in establishing payment rates and methodologies for physician services under their Medicaid programs. Payments to physicians, like payments to other practitioners, must be consistent with efficiency, economy, and quality of care."[88] Indeed, CMS has never tried to rely on these provisions to exclude specific services from Medicaid coverage altogether.

In an attempt to show CMS has "imposed age limitations on the availability of Federal funding for certain procedures in the Medicaid program before," the Proposed Rule refers to regulations prohibiting federal funding for permanent sterilization of individuals under age 21.[89] However, unlike this Proposed Rule, the underlying authorities to promulgate the regulations that

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[83] *Id.*

[84] *Yates v. United States*, 574 U.S. 528, 543 (2015) (under the *noscitur a sociis* canon, "a word is known by the company it keeps . . . to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress").

[85] Importantly, while these provisions do not afford CMS the authority to regulate standards of care, Congress can restrict the use of federal Medicaid funds and has done so explicitly. For example, Congress has long adopted an annual appropriations rider to limit the use of federal health funds, including for the Medicaid program, for abortion services under certain circumstances. As a result, some state Medicaid programs rely on their own funds to cover most abortion services for beneficiaries. Where Congress has authority to limit the use of federal funds and has chosen not to act, CMS cannot circumvent Congress's decision not to disallow the use of federal funds for transgender youth healthcare services via its administrative authority.

[86] *See, e.g., Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 665 (2003); *Alexander v. Choate*, 469 U.S. 287, 303 (1985).

[87] Comm. on Fin. of the U.S. Senate & Comm. on Ways & Means of the U.S. House of Reps., Summary of Social Security Amendments of 1967 21 (Dec. 1967).

[88] *E.g.*, Medicare & Medicaid Health Budget Reconciliation Amendments of 1989: Hearing Before the Subcomm. on Health & the Env't of the Comm. on Energy & Commerce, 101st Cong. 60 (1989).

[89] 43 Fed. Reg. 52146 (1978).

apply to sterilization were neither the "best interests" or "quality of care" provisions. Instead, an independent statutory requirement within the Act that "acceptance of family planning services . . . shall be voluntary" provided the authorization.[90] Further, the reasons animating the sterilization rule were much different than the reasons for putting forward this Proposed Rule. Specifically, the sterilization rule was a response to well-documented forced and coerced sterilization.[91] Indeed, the preamble to the proposed sterilization rule explicitly noted that CMS was "aware of serious allegations of cases in which patients were coerced into being sterilized."[92] The same cannot be said here. Contrary to CMS's unfounded claims, the states provide treatment for gender dysphoria to youth pursuant to robust safeguards that ensure this care is high quality and aligned with the clinical practice standards of major medical associations,[93] including that such care is provided only after a patient provides informed assent and parental or guardian consent when required.[94]

This history makes the Proposed Rule's reliance on these provisions to justify exclusion of coverage for an entire category of medical care an even more extraordinary departure from the plain text of the statute and longstanding agency practice.[95] Through this Proposed Rule, CMS "claim[s] to discover in a long-extant statute an unheralded power representing a transformative expansion of its regulatory authority."[96] Against that background, it is clear that CMS is attempting "to do something that is an extraordinarily big deal, [and therefore] must show that Congress clearly gave it permission to do so in the statutory text."[97] However, as discussed, the "best interests" and "quality of care" provisions do not provide such authority. In fact, longstanding federal law expressly points the other way, prohibiting CMS from exercising direct supervision over the practice of medicine.[98] One section specifically, 42 U.S.C. § 1395, prohibits CMS from promulgating regulations that "direct or prohibit any kind of treatment or diagnosis'; 'favor one

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[90] 42 U.S.C. § 1396d(a)(4)(C).

[91] *Relf v. Weinberger*, 372 F. Supp. 1196, 1199 (D.D.C. 1974) (finding "uncontroverted evidence" that poor people were "improperly coerced into accepting a sterilization operation under the threat that various federally supported welfare benefits would be withdrawn unless they submitted to irreversible sterilization" and that Medicaid childbirth patients were "evidently the most frequent targets of this pressure").

[92] 42 Fed. Reg. 62718, 62719 (1977).

[93] *Infra* Section III.d.

[94] *Supra* Part I.b. notes 26-27; *see also Wylie*, *supra* note 33, at 3878 (noting that clinical criteria for providing transgender youth healthcare includes informed consent); *In Re: Subpoena No. 25-1431-014*, No. 25-mc-00039 (E.D. Pa. Nov. 21, 2025), ECF No. 1, Ex. B, Joint Declaration of Nadia Dowshen, M.D., & Linda Hawkins, Ph.D. ¶ 10 ("Medical treatments [related to transgender youth healthcare] proceed only after informed consent is obtained from parent(s)/legal guardian(s) with medical decision-making authority over the minor patient and the minor patient provides their assent to care"); *Endocrine Society Statement*, *supra* note 38 ("Cisgender teenagers, together with their parents or guardians, are deemed competent to give consent to various medical treatments.").

[95] *See N. Carolina Coastal Fisheries Reform Group v. Capt. Gaston, LLC*, 76 F. 4th 291, 297 (4th Cir. 2023) ("[W]e are more hesitant to recognize new-found powers in old statutes against a backdrop of an agency failing to invoke them previously.").

[96] *See West Virginia v. Env't Prot. Agency*, 597 U.S. 697, 732 (2022) ("'The importance of the issue,' along with the fact that the same basic scheme EPA adopted 'has been the subject of an earnest and profound debate across the country, … makes the oblique form of the claimed delegation all the more suspect.'"). *N. Carolina Coastal Fisheries Reform Group*, 76 F. 4th at 297 ("[W]e are more hesitant to recognize new-found powers in old statutes against a backdrop of an agency failing to invoke them previously.").

[97] *United States v. Freeman*, 147 F. 4th 1, 15-16 (1st Cir. 2025); *see also Gonzales v. Oregon*, 546 U.S. 243, 267 (2006) (Congress does not "hide elephants in mouseholes").

[98] *Supra* Section I.a.; *see also supra* note 11.

procedure over another'; or 'influence the judgment of medical professionals.'"[99] This, combined with Congress's decision to specify Medicaid coverage prohibitions in other circumstances,[100] clearly demonstrates that Congress has not delegated this authority to CMS. In other words, the entire structure of the SSA "conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise."[101]

Moreover, states have wide latitude to protect the health of their citizens, including by determining what constitutes the proper practice of medicine.[102] Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power" and supersede state regulation of the practice of medicine.[103] As discussed above, the plain text of the statute makes clear that these provisions dictate state responsibilities, not CMS's. And as the Supreme Court held in *Gonzales v. Oregon*, where Congress has only spoken in general terms and "the authority desired by [the agency] is inconsistent with the design of the statute in other fundamental respects," it is clear Congress did not intend to regulate or delegate to the agency that authority.[104]

Indeed, the Supreme Court recently reaffirmed state authority over the provision of transgender youth healthcare. In *United States v. Skrmetti*, the Court recognized the states' wide discretion to regulate medical care, including state laws regulating the provision of transgender youth healthcare, emphasizing the need for "legislative flexibility in this area" as it is the subject of "fierce medical and policy debates about [] safety, efficacy, and propriety."[105]

ii. The Proposed Rule Contravenes Medicaid Requirements Related to Early and Periodic Screening, Diagnostic, and Treatment Services.

The Proposed Rule is also at odds with requirements of section 1905(r) (42 U.S.C. § 1396d(a)(4)(B), (r)), requiring that State Plans cover Early and Periodic Screening, Diagnostic, and Treatment Services ("EPSDT"). 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."[106] And it also recognizes that "States may only include tentative limits on services and must take into account

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[99] *Texas v. Becerra*, 623 F. Supp. 3d 696, 732 (N.D. Tex. 2022) (quoting *Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989)), *judgment entered*, No. 5:22-CV-185-H, 2023 WL 2467217 (N.D. Tex. Jan. 13, 2023), and *aff'd*, 89 F.4th 529 (5th Cir. 2024), *and aff'd*, 89 F.4th 529 (5th Cir. 2024).

[100] *See infra* Section II.a.iii.

[101] *Gonzales*, 546 U.S. at 266.

[102] *See, e.g., Medina v. Planned Parenthood S. Atl*., 606 U.S. 357, 357 (2025); *De Buono v. Nysa-Ila Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997); *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977); *Barsky v. Bd. of Regents*, 347 U.S. at 442, 449 (1954).

[103] *United States Forest Serv. v. Cowpasture River Pres. Ass'n,* 590 U.S. 604, 621-22 (2020)*; see also*, *e.g.*, *Sackett v. Env't Prot. Agency,* 598 U.S. 651, 679 (2023); *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764 (2021).

[104] *Gonzales*, 546 U.S. at 272.

[105] 605 U.S. 495, 525 (2025).

[106] 90 Fed. Reg. 59449.

the individual needs of the child."[107] 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.[108]

But the Proposed Rule fails to adhere to the requirement that medical necessity be determined on an individual basis. In discussing why, in its view, the Proposed Rule is consistent with EPSDT, CMS writes that transgender youth healthcare "would no longer be Federally funded as Medicaid-covered services for individuals under the age of 18, or as CHIP-covered services for individuals under the age of 19, because such services may pose a risk of harm to children . . . ."[109] None of the authorities CMS cites support the conclusion that the risks of "sex-rejecting procedures," as the agency describes them, in all cases outweigh the benefits such that they are categorically not medically necessary for anyone under the age of 18. Further, even the clinical practice guidelines relied upon by HHS do not recommend a categorical prohibition on medical treatment for gender dysphoria in youth.[110]

Accordingly, consistent with the clinical guidelines on which it bases its analysis, CMS must recognize that there may be some individual circumstances where medical interventions such as puberty blockers and hormone therapy are medically necessary for the treatment of gender dysphoria in adolescents.[111] The Proposed Rule, however, would prohibit states from offering these services under EPSDT, even where medically necessary.[112] This violates the statute, and it is a stark departure from the agency's longstanding interpretation of the statute and past practice.[113]

Finally, CMS does not even attempt to adequately explain its departure from its long-standing practice of deferring to state determinations of medical necessity in the EPSDT context.[114] The undersigned States are aware of no prior instance in which CMS has categorically denied

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[107] *Id*.; *see also* Ctrs. for Medicare & Medicaid Servs., *EPSDT—A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* 23 (June 2014) [hereinafter *EPSDT Guide*] ("The determination of whether a service is medically necessary for an individual child must be made on a case-by-case basis, taking into account the particular needs of the child.").

[108] *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* Ctrs. for Medicare & Medicaid Servs., State Health Official Letter No.24-005, *Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements* 21 (Sept. 26, 2024) [hereinafter *SHO Letter No. 24-005]* ("[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.").

[109] 90 Fed. Reg. 59452 (emphasis added).

[110] *Supra* note 32 at 151 (describing Finland treatment guideline that recommends medical treatment for "adolescents with persistent, childhood-onset gender dysphoria, no major psychiatric comorbidities, and stable identity development through adolescence"); *id.* at 153 (describing Sweden's treatment guidelines which allows medical treatment of gender dysphoria, including surgeries, in "exceptional circumstances"); *id.* at 155 (describing policy changes introduced after the Cass Review permitting medical treatment for gender dysphoria for youth "contingent upon strict eligibility criteria and detailed assessment protocols"); *see also infra* Section III.

[111] 90 Fed. Reg. 59445 (citing to the Sweden, Finland, and United Kingdom practice guidelines).

[112] 90 Fed. Reg. 59452.

[113] *See SHO Letter #24-005* at 21 ("[W]hile services available to adults may include limits on the amount, duration, and scope of services that can never be exceeded (i.e., a 'hard limit'), states are not permitted to apply these kinds of limits to any service covered under EPSDT in either a FFS or managed care delivery system."); *see also N. Carolina Coastal Fisheries Reform Group v. Capt. Gaston, LLC*, 76 F. 4th 291, 297 (4th Cir. 2023).

[114] *See EPSDT Guide, supra* note 108 at 24 (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); *see also supra* Section II.a.

EPSDT coverage for a service used to treat a medical condition that a state has determined is medically necessary. Simply put, the Proposed Rule's categorical removal of the states' discretion to cover medical treatment of gender dysphoria, even where it has been determined to be medically necessary for a particular patient, is at odds with the law, CMS's own past practice, and the reasonable reliance of the states that have developed Medicaid programs that cover these services.

iii. The Proposed Rule Contravenes Additional Medicaid Regulations.

CMS claims that the Proposed Rule is consistent with other Medicaid regulations, specifically referring to regulations that allow state Medicaid agencies flexibility in administering their Medicaid programs (42 C.F.R. § 440.230) and prohibit them from arbitrarily denying or reducing access to care because of an individual's diagnosis, type of illness, or condition (42 C.F.R. § 440.230(c)) also known as the comparability requirement). CMS is wrong that the Proposed Rule is consistent with these regulations, and such inconsistency further demonstrates that the "authority desired by [CMS] is inconsistent with the design of the statute in other fundamental respects."[115]

With respect to flexibility, 42 C.F.R. § 440.230 has long allowed states to set state-specific standards regarding the amount, duration, and scope of Medicaid-covered services; to set criteria for determining medical necessity; and to adopt procedures to control the utilization of Medicaid-covered services. 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.[116] CMS now claims this flexibility is not absolute because CMS reviews State Plan Amendments for compliance with certain guidelines when determining the amount, duration, and scope of covered services.[117] Historically, however, CMS has reviewed State Plan Amendments to affirm the sufficiency of the services that states provide, not to exclude coverage of clinical services that states have determined are medically necessary.[118]

The EPSDT requirements further demonstrate the flexibility given to state Medicaid agencies. As explained above, CMS has historically deferred to state determinations of medical necessity in the EPSDT context.[119] CMS even acknowledges that its Proposed Rule "would limit States' longstanding flexibility to develop State-specific processes for determining when a service is medically necessary for an EPSDT-eligible beneficiary under section 1905(r)(5) of the Act."[120] 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 CMS's rule, medical treatment for gender dysphoria would be available for 18-year-olds under the Medicaid program but categorically medically unnecessary for all 17-year-olds. This strains credulity. States should,

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

[116] *Pharm. Rsch. & Mfrs. Of Am. v. Walsh*, 538 U.S. 644, 665 (2003).

[117] 90 Fed. Reg. 59451.

[118] Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health, 81 Fed. Reg. 5530, 5534 (Feb. 2, 2016) ("We agree that states may limit covered services to only include medically necessary services. This flexibility is already provided in regulation at § 440.230(d). Medical necessity is not determined by us, but is determined by medical professionals."); *SHO Letter #24-005*, *supra* note 109 at 2 ("CMS and the states have a unique partnership in operating Medicaid and CHIP: CMS ensures that states meet federal requirements, but federal law also gives states options for implementing their Medicaid and CHIP programs in a manner tailored to their communities' needs.").

[119] *Supra* Section II.a.ii.

[120] 90 Fed. Reg. 59452.

therefore, continue exercising their statutorily granted flexibility to determine whether treatment for gender dysphoria is medically necessary in individual cases.

State Medicaid agencies are also 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."[121] To comply with this comparability requirement, state Medicaid programs must generally cover medically necessary treatments prescribed by clinicians following expert standards of care without arbitrary distinctions such as those based on indication.[122] In other words, the comparability provision prohibits states from discriminating among Medicaid beneficiaries based on diagnosis or age.[123] As the Second Circuit has explained, "the comparability provision does not protect categorically needy beneficiaries simply by prohibiting States from treating them less favorably than the medically needy. It also prohibits States from discriminating among the categorically needy by providing benefits to some categorically needy individuals, but not to others."[124]

CMS asserts that the Proposed Rule is consistent with this prohibition because the agency has considered the risk/benefit profiles of different uses of transgender youth healthcare.[125] But this does not resolve the inconsistency as it still requires state Medicaid agencies to discriminate among their beneficiaries on the basis of diagnosis and 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 youth healthcare.[126] Further, CMS's reliance on the discredited HHS Report does not resolve this tension.[127] The Proposed Rule would thus require state Medicaid agencies to discriminate against individuals under the age of 18 with gender dysphoria in violation of the comparability provision by allowing available, necessary medical services to some beneficiaries but not others on the basis of diagnosis and age.[128]

The Proposed Rule's inconsistencies with these longstanding Medicaid regulations make clear that CMS has not previously understood that Congress authorized the agency to exclude from coverage an entire category of medical care under Medicaid.[129] And the agency's past

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[121] 42 C.F.R. § 440.230(c); 42 U.S.C. § 1396a(a)(10)(B).

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

[123] *Skrmetti* does not require a different result. While the Supreme Court held in *Skrmetti* that a law restricting certain surgical and chemical interventions for minors 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.

[124] *Davis*, 821 F.3d at 255–56 (quoting *Rodriquez v. City of New York*, 197 F.3d 611, 615 (2d Cir. 1999)).

[125] 90 Fed. Reg. 59452.

[126] 90 Fed. Reg. 59454.

[127] *Infra* Section III.d.

[128] *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 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).

[129] *See, e.g., West Virginia v. Env't Prot. Agency,* 597 U.S. 697, 721 (2022) (Congress must speak clearly when authorizing an agency to exercise power in areas of vast economic and political significance, and where it has not done so there is reason to assume Congress did not mean to provide such broad authority to regulatory agencies).

interpretation is consistent with the plain text of the statute as described above,[130] which limits the best interest and quality of care provisions to ensuring the adequacy of state processes to safeguard those interests as part of the careful state-federal division of labor over the administration of Medicaid. Further indication that Congress has not delegated this authority to CMS is that Congress itself has tried, but failed, on numerous occasions in the past year to take this very action legislatively. Specifically, an early version of H.R.1 sought to prohibit federal Medicaid and CHIP funding for "gender transition procedures" for youth; this provision was not included in the final text of the legislation.[131] The U.S. House of Representatives later sought to prohibit federal Medicaid payment for specified gender transition procedures for individuals under the age of 18, which also failed.[132] Having seen its Congressional allies unable to make the necessary statutory changes to effect the change it favors to federal funding for transgender youth healthcare, HHS now seeks impermissibly to alter the meaning of longstanding and settled law to accomplish the same goal.[133]

b. The Proposed Rule Violates the Medicaid Drug Rebate Program.

In the Proposed Rule, CMS spends less than a paragraph discussing the Medicaid Drug Rebate Program ("MDRP") and the effects the Proposed Rule would have on states' participation in the program. Instead, CMS incorrectly asserts that because the Proposed Rule will not exclude Medicaid coverage of any pharmaceuticals in their entirety, the Proposed Rule is lawful. The question, however, is whether the Proposed Rule impinges coverage of drugs with medically accepted indications in violation of the Medicaid pharmacy benefit, which it explicitly does. In limiting treatment that states are required to cover using Medicaid dollars, CMS is forcing states to violate federal law and decades of precedent while risking suit from citizens who expect coverage of transgender youth healthcare via Medicaid.

Although states have wide discretion in administering their own Medicaid programs, they must abide by certain federal standards.[134] Under Section 1927 of the SSA, Congress established clear requirements for (1) the coverage of nearly all outpatient drugs when a drug manufacturer has entered into a rebate agreement with HHS and (2) the exclusion of drugs when used for specified purposes. Section 1927 requires any state that participates in the Medicaid pharmacy benefit (which all states do) to cover all FDA-approved covered outpatient drugs ("CODs"), with narrow, explicitly defined exceptions.[135] The pharmacy benefit requires that a state that chooses to cover any CODs within its Medicaid program, subject to national drug rebate agreements, must

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[130] *Supra* Section II.a.i.

[131] H.R. 1, 119th Cong. § 44125 (2025).

[132] H.R. 498, 119th Cong. § 2(a)(3) (2025).

[133] Yet another example where Congress underscored that states, not the federal government, are responsible for the regulation of medicine and setting standards of care is 42 U.S.C. § 18122, 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).

[134] *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 323 (2015) ("Medicaid offers the States a bargain: Congress provides federal funds in exchange for the State's agreement to spend them in accordance with congressionally imposed conditions.").

[135] Ctrs. for Medicare & Medicaid Servs., Medicaid Drug Rebate Program, MEDICAID.GOV, https://perma.cc/5L7R-DDXF (last visited Jan. 26, 2026).

cover all FDA-approved uses found on the drug's FDA-approved label and medically accepted indications as listed within specified pharmaceutical compendia.[136] This requirement is known as the MDRP. CODs in the pharmaceutical compendia described in Section 1927(g)(1)(B)(i) include indications for both "on-label" and "off-label" uses.[137] Any "on-label" indications must be covered even if they are not included in the compendia.[138]

Under Section 1927(d)(2), Congress did not identify specific drugs that may be excluded from the Medicaid program. Instead, Congress identified a narrow list of "drugs or classes of drugs, or their medical uses" that can be excluded.[139] Said another way, Congress has already established a very limited list of excludable indications under the Medicaid program.[140] Drugs used in the medically necessary treatment of gender dysphoria are not part of this narrow list of exclusions, and CMS now attempts to create a new exclusion where one does not exist.[141]

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[136] *Id*. To be covered as part of the MDRP, that "medically accepted indication" needs to be included in one of three, statutorily recognized pharmaceutical compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information system. The United States Pharmacopeia-Drug Information is no longer available. Abbi Coursolle, *More Transparency Needed to Ensure Medicaid Beneficiaries Have Access to Necessary Off-Label Prescription Drugs* 3, NAT'L HEALTH L. PROGRAM (Apr. 7, 2022). The compendium has been replaced by successive publications, including DrugPoints. However, CMS has not announced whether DrugPoints is, in its view, a successor to United States Pharmacopeia-Drug Information and as a result, states vary in their recognition of DrugPoints as a compendium for purposes of determining off-label coverage in Medicaid. *Id*.

[137] Many, if not most, drugs have "off-label" uses which may also be in the compendia. As the Utah Study explained, "Off-label use of medications in general is particularly common among children, with off-label use rates as high as 38% of prescriptions and 79% of children. Since a majority of drugs are studied and approved by the FDA in adults before children, drug companies rarely go to the effort to obtain FDA approval for use in children without a financial incentive. Because off-label use is legal and common, it is also unusual to seek FDA approval for new indications once a drug has been approved by the FDA." Transgender Medical Treatments and Procedures Amendments (S.B. 16, 2023): Report to the Utah Legislature Health and Human Services Interim Committee, 6 (May 2025), https://perma.cc/4KU3-ZC8U [hereinafter *Utah Study*].

[138] *Supra* note 136.

[139] 42 U.S.C. § 1396r-8(d)(2). In only a few instances has Congress named specific drug classes that can be excluded. Section 1927(d)(2) expressly allows the exclusion of only prescription vitamins and mineral products; and over-the-counter drugs (with some exceptions). 42 U.S.C. § 1396r-8(d)(2)(F)-(G) (2024).

[140] Section 1927(d)(2) allows drugs to be excluded based on a very limited number of indications. For instance, the statute does not exclude specific weight loss drugs, but Congress allows drugs to be excluded "*when used for* anorexia, weight loss, or weight gain[.]" *Id*. § 1396r-8(d)(2)(A) (2024) (emphasis added). Similar restrictions apply for drugs "*when used to* promote fertility," "*when used for* the symptomatic relief of cough and colds," and "*when used to* promote smoking cessation," among other excludable indications. *Id*. § 1396r-8(d)(2)(B), (D)-(E) (2024); *see also Hillman v. Maretta*, 569 U.S. 483, 496 (2013) ("We have explained that [w]here Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.") (internal quotation marks omitted); *cf. Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotation marks omitted).

[141] The Secretary can, under limited circumstances, periodically update the list of excludable drugs identified in subparagraph (d)(2). *See* 42 U.S.C. § 1396r-8(d)(3). In doing so, the Secretary must collect drug utilization review and surveillance data from state Medicaid programs; analyze this data; and make an evidence-based determination that the drug, drug class, or medical use is being used improperly. CMS has neither invoked this legal authority nor collected the requisite data from states that would be needed to make such a determination under subparagraph (d)(3).

Indeed, drugs used in the treatment of gender dysphoria among youth are included in these compendia for that indication and thus have long been covered by state Medicaid programs. For example, gonadotropin-releasing hormone agonists, such as leuprolide, are included in at least one compendia as a treatment of gender dysphoria in youth.[142] By banning Medicaid coverage of medically accepted indications of this drug, even if the drug itself may still be covered for other purposes, CMS is forcing states to violate the terms of their participation in the MDRP.

Requiring states to deny coverage for treatments they are required to provide by law not only runs afoul of Section 1927's coverage requirement, it also reflects a reversal by CMS of its long-held position without adequate justification.[143] CMS has consistently prohibited states from excluding coverage of FDA-approved drugs to participate in the MDRP. In 2017, Massachusetts requested authority for a Section 1115 demonstration project.[144] This project would have allowed Massachusetts to exclude coverage of some prescription drugs under its Medicaid program.[145] CMS denied Massachusetts's application because Section 1927 does not allow states to exclude coverage of FDA-approved drugs.[146] As CMS explained, if Massachusetts wanted to exclude coverage of any CODs, the state would no longer be able to provide Medicaid coverage for any CODs under the State Plan.[147] The state would instead have to negotiate directly with manufacturers "and forgo all manufacturer rebates available under the federal Medicaid Drug Rebate Program."[148] That is still true today—Section 1927 does not allow states to exclude coverage of CODs for any medically accepted indications, nor does it allow CMS to mandate states exclude coverage of CODs or indications.

The requirements of Section 1927 were again made clear in litigation over state Medicaid coverage of direct acting antivirals ("DAAs") for Hepatitis C Virus ("HCV") treatment. In 2013,

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[142] *See* AHFS Compendia ("GnRH agonists such as leuprolide also have been used for pubertal hormone suppression in transgender persons undergoing gender-affirming hormone therapy [off-label].") (citing *supra* note 33).

[143] *F.C.C. v. Fox Television Stations, Inc*., 556 U.S. 502, 537 (2009) (Thomas, J., concurring) ("An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate.").

[144] A 1115 demonstration project is an area within Medicaid in which CMS has the greatest authority to approve changes to how states want to operate their Medicaid programs. Nearly all states have 1115 waivers that let them operate differently from the statutory requirements within a window of reasonability. *See*, *About Section 1115 Demonstrations*, MEDICAID.GOV, https://perma.cc/D6X5-42DM (last visited Jan. 28, 2026).

[145] As part of a larger restructuring of its statewide prescription coverage, Massachusetts sought flexibility to "select preferred and covered drugs through a closed formulary" and to "procure a selective and more cost effective specialty pharmacy network." Letter from Marylou Sudders, Sec'y, Executive Office of Health & Human Servs., to Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs., Re: Request to Amend Massachusetts' Section 1115 Demonstration: MassHealth (11-W-00030/1) 3 (Sept. 8, 2017), https://perma.cc/SV2L-V9NS [hereinafter *Sudders Letter*].

[146] "CMS would be willing to consider a demonstration that would give the state the ability to exclude certain Medicaid covered outpatient drugs from coverage under its Medicaid program, as requested, on the condition that the state would drop optional State plan drug coverage under section 1902(a)(54) of the Social Security Act (the Act) so that individuals currently receiving coverage under section 1902(a)(54) could receive coverage of outpatient drugs under the expenditure authority in section 1115(a)(2). This would mean that, with respect to such individuals, drug coverage would no longer be provided in accordance with the provisions outlined in Section 1927 of the Social Security Act." Letter from Tim Hill, Acting Dir., Ctr. For Medicaid & CHIP Servs., to Daniel Tsai, Assistance Sec'y, MassHealth 2, (June 27, 2018), https://perma.cc/TB8B-4SGD.

[147] *Sudders Letter*, *supra* note 145, at 2.

[148] *Id.*

the FDA approved a new, highly effective treatment for HCV.[149] Though both an effective treatment and cost effective, "the substantial cost of these drugs combined with a high prevalence of disease" placed a strain on both public and private payers.[150] To mitigate these costs, state Medicaid programs placed various eligibility restrictions that limited access to DAAs.[151] Since 2015, national guidelines promulgated by major medical associations have recommended DAA treatment without the imposition of these restrictions.[152] In spite of these guidelines, many states kept their restrictions in place. Private citizens sued states that restricted access alleging violations of the Medicaid Act for failing to cover medically necessary DAAs for Medicaid enrollees.[153] As of 2022, multiple lawsuits have overturned Medicaid DAA coverage and eligibility restrictions in several states because, when a state opts into the MDRP and covers CODs, that state must cover all CODs for medically indicated purposes.

If CMS adopts this policy to prohibit state coverage of specific drug indications, it would impose substantial administrative burdens on states, providers, and Medicaid Managed Care Organizations by disrupting current practice. Outpatient retail pharmacy claims do not currently include diagnosis codes, preventing pharmacies from verifying Medicaid coverage for the affected drugs based on their intended use.[154] States would therefore need to implement prior authorization requirements for all affected medications, creating costly and burdensome processes for managed care plans, pharmacies, and prescribing providers. Critically, this administrative burden would extend far beyond treatment for gender dysphoria, affecting all patients taking these medications for any purpose—including individuals using these medications to treat perimenopause,[155] endometriosis,[156] or hypogonadism.[157] The resulting delays in medication access and increased administrative costs would impact a broad patient population while straining an already overburdened prior authorization system.

In addition, many other essential drugs are covered for off-label use in Medicaid, as required under the statute. For example, many chemotherapeutic drugs are used off label—as many as half of all courses of chemotherapy are prescribed off-label.[158] The Proposed Rule would set

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[149] Sonya Davey et al., *Changes in Use of Hepatitis C Direct-Acting Antivirals After Access Restrictions Were Eased by State Medicaid Programs*, 5 JAMA HEALTH FORUM 4 (Apr. 5, 2024).

[150] *Id*.

[151] *Id*. These restrictions include requiring prior insurance authorizations, sobriety, and confirmation that the individual seeking treatment has fibrosis, or liver damage, before approving treatment. *See "Resources,"* HEPATITIS C, STATE OF MEDICAID ACCESS, https://perma.cc/72LR-KBKX (last visited Jan. 26, 2026).

[152] *Davey*, *supra* note 149.

[153] *See B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, (W.D. Wash. May 27, 2016); *see also, Postawko v. Missouri Dep't of Corr.*, 910 F.3d 1030 (8th Cir. 2018) (summarizing the state of Hepatitis C diagnosis and care in the United States).

[154] *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Part D Prescription Drug Event (PDE) Data Elements* (Apr. 8, 2008), https://perma.cc/V6Y9-MUXL (showing the components of a prescription drug claim which do not include diagnosis, Current Procedural Terminology ("CPT"), or International Classification of Diseases ("ICD") codes).

[155] *See* PubChem, "Estradiol," NAT'L LIBR. OF MED., NAT'L CTR. FOR BIOTECH. INFO. (last visited Feb. 11, 2026), https://perma.cc/3XD3-A3M4.

[156] *See* Mark D. Hornstein, *Endometriosis: Long-Term Treatment with Gonadotropin-Releasing Hormone Agonists*, UPTODATE (Mar. 21, 2023).

[157] *See* Arthi Thirumalai, et al., *Treatment of Hypogonadism: Current and Future Therapies*, 68 F100RESEARCH 6 (Jan. 24, 2017).

[158] *See* J.F. Powers & M.B. Osswald, *Off-Label Chemotherapy Use in a Military Treatment Facility*, 27 J. CLINICAL ONCOLOGY 6631 (May 20, 2009).

the precedent that CMS—or states—could restrict access to these critical drugs, in clear conflict with the intent of the statute.

If the Proposed Rule takes effect, CMS will require states to stop covering CODs solely when used for transgender youth healthcare under Medicaid. This exposes states to litigation risk and suggests the agency believes it was somehow Congress's intention that state Medicaid programs be required to refuse coverage of prescription drugs that they are in fact required under Medicaid to cover.

c. SSA Provisions Related to CHIP Plans Do Not Allow CMS to Prohibit Medical Treatment for Gender Dysphoria.

CMS should withdraw the Proposed Rule because it lacks authority to prohibit the coverage of medical services in CHIP plans that are provided according to state law, and, even if such authority existed, lacks a reasonable basis for prohibiting transgender youth healthcare.

In the proposed rule, CMS refers to section 2110(a)(24) but fails to grapple with its text.[159] Section 2110(a) defines the services that child health assistance (i.e., federal payments for child health benefits) may be used to provide. It explicitly includes in subparagraph (a)(24) "[a]ny other medical, diagnostic, screening, preventative, restorative, remedial, therapeutic, or rehabilitative service . . . *if recognized by State law* . . ." (emphasis added). The statute then requires that those services be "prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by state law," be "performed under the general supervision or at the direction of a physician," or be "furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license." In other words, under the plain language of section 2110(a)(24), states may include in their CHIP plans any service that is "recognized by State law," including transgender youth healthcare, as long as the service is provided consistently with state law and provided by or under the supervision of a licensed professional.

Notwithstanding this clear statutory language, CMS makes no attempt to explain why it may prohibit transgender youth healthcare in states, like many of the undersigned States, that have state laws that recognize such care.[160] Instead, it says only that the "flexibility" offered by section 2210(a)(24) may be overridden by CMS's own determination of what is "efficient and effective and in the best interests of children." 90 Fed. Reg. 59453. But CMS cites no statutory provision that enables it to override the specific permission granted by Congress in section 2110(a)(24) to include medical services "recognized by State law," just because a particular service is not permitted within a Medicaid plan, or is excluded from the definition of Essential Health Benefit, or is excluded from health coverage provided to federal employees.

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[159] 90 Fed. Reg. 59453, *citing* 42 USC § 1397jj(a)(24).

[160] *See, e.g.*, Wash. Rev. Code §74.09.675; Cal. Code Regs. tit. 10 §2561.2, subd. (a) (2012); Cal. Civ. Code § 1798.301; 3 Code Colo. Regs. §702-4, Reg. 4-2-42, §5(A)(1)(o); Del. Code tit. 18, §2304; 215 Ill. Comp. Stat. 5/356z.60(b); 50 Ill. Adm. Code §2603.35; Me. Rev. Stat. tit. 22, §3174-MMM; Md. Code Ann., Ins. §15-1A-22; Mass. Gen. Laws ch. 272, §§92A, 98; Minn. Stat. §62Q.585; N.J. Stat. Ann. §17:48-6oo; N.Y. Comp. Codes R. & Regs. tit. 11, §52.75; Or. Admin. R. 836-053-0441; Vt. Stat. Ann. tit. 8, §§4724, §4088m; Mass. Div. of Ins. Bulls. 2021-11, 2014-03; R.I. Health Ins. Bull. 2015-03; *see also* 90 Fed. Reg. 59444 (acknowledging that many states permit the provision of medical treatment for gender dysphoria).

CMS appears to rely on section 2101(a),[161] but this section sets out the Congressional purpose in establishing CHIP and imposes no substantive requirement on State Plans, nor does it permit CMS to override specific statutory authority elsewhere in Title XXI of the SSA. And, while part of the purpose is to coordinate CHIP "with other sources of health benefits coverage for children," CMS makes no attempt to survey or quantify the sources of health benefits for children that do permit transgender youth healthcare for those under 19. Notably, the health benefits plans offered to many state employees (such as the employees of the many undersigned States), provide this coverage. And, of course, a set of health benefits consistent with the coverage provided to state employees is also a permitted benchmark benefits package.[162] So, even if section 2101(a) did give CMS the statutory authority to exclude a service from possible inclusion in a state CHIP plan to make benefit plans consistent (and it does not), CMS has not shown that doing so plausibly "coordinates" the sources of youth health benefits.

CMS also relies on a claimed authority to exclude services from state CHIP plans, notwithstanding section 2101(a)(24) where, in CMS's judgment, the service poses a "significant risk of harm."[163] But, as just discussed, the statutory scheme prioritizes states' judgment about what services to include and does not give CMS the authority to exclude services, permitted by state law, that a state chooses to include. And, as discussed elsewhere in this letter, the evidence upon which CMS relies is contravened by the weight of authority.[164] Moreover, nothing cited by CMS supports a categorical exclusion of transgender youth healthcare for all patients.[165] In short, CMS lacks authority to categorically prohibit states from covering medical treatment for gender dysphoria when such care is available in state CHIP plans and recognized by state law.

d. The Proposed Rule Runs Counter to ACA Sections 1554 and 1557.

While the SSA and its implementing regulations alone demonstrate the Proposed Rule exceeds CMS's authority, various provisions of the Affordable Care Act ("ACA") also reinforce this conclusion. Indeed, the Proposed Rule would violate both Sections 1554 and 1557 of the ACA, further demonstrating the Proposed Rule contravenes Congress's clear directive that federal rules cannot interfere with patient access to healthcare or discriminate against vulnerable populations.

First, Section 1554 of the ACA 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 health care services;" or "limits the availability of health care treatment for the full duration of a patient's medical needs."[166] 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."[167]

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[161] 42 U.S.C. § 1397aa.
[162] 42 U.S.C. § 1397cc(b)(2).
[163] 90 Fed. Reg. 59452.
[164] *See infra* Section III.d.
[165] *See id.*
[166] 42 U.S.C. § 18114.
[167] *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).

The Proposed Rule violates Section 1554 by creating unreasonable barriers and impeding timely access to treatment for gender dysphoria.[168] The Proposed Rule imposes clear barriers to transgender youth healthcare by impacting the ability of patients and their families, who do not have the means to obtain other health insurance or privately pay for these services, to receive such care—a fact acknowledged by CMS.[169] Further, these are not "reasonable" barriers nor is this healthcare "inappropriate" per the terms of the statute. For reasons discussed in this letter, transgender youth healthcare is widely accepted as evidence-based, safe, and effective.[170] As such, the Proposed Rule's categorical prohibition on the use of federal funds for such safe and effective healthcare is clearly not reasonable. The Proposed Rule also violates Section 1554 by prohibiting care only for youth with certain diagnoses, thereby limiting the availability of treatment for the full duration of a patient's medical needs, and by impeding timely access to healthcare services by forcing states, managed care entities, and providers to develop and adapt to new systems that risk disruption to coverage and care.

This is not a novel interpretation of Section 1554. At least two courts have found that restrictions on care and coverage violate 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 limits on [a provider's] ability to act."[171] And in *Planned Parenthood of Maryland, Inc. v. Azar*, a Maryland district court held that another HHS rule violated Section 1554.[172] The rule, the plaintiffs argued, created a barrier to paying for insurance—through lost coverage, fewer insurers offering abortion coverage, and higher premiums—that would impede timely access to healthcare and limit access to treatment. The district court agreed, finding that the rule "directly affect[ed] how consumers pay for medical care" and the record showed that the rule was "likely to cause enrollee confusion and [could] lead to some enrollees losing health insurance."[173]

Second, 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 . . ."[174] The Proposed Rule acknowledges that Section 1557 incorporates Title IX's prohibition on sex discrimination but relies on one district court case to argue that such prohibition

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[168] Transgender youth healthcare falls squarely within the statute's definition of "medical care" because this care is offered for the "mitigation" and "treatment" of gender dysphoria—a diagnosable medical condition defined in the Diagnostic and Statistical Manual of Mental Disorders. This care also "affect[s] any structure or function of the body." While CMS attempts to invent a cramped new definition of "health care" related to restoring bodily health and biological function in its Conditions of Participation Proposed Rule, 90 Fed. Reg. 59463, 59471, federal law includes no such limit.

[169] 90 Fed. Reg. 59441, 59449 ("We also recognize that Medicaid and CHIP beneficiaries and their families would be impacted by this Proposed Rule. Families of these beneficiaries may look to obtain other health insurance or privately pay for these services. Medicaid and CHIP beneficiaries who are unable to find alternative means to pay for these services may either have to rely on other methods of intervention such as psychotherapy or mental health counseling, or never begin receiving these services because of this proposed rule, if finalized.").

[170] *Supra* Section III.d.

[171] 973 F.3d 258, 288 (4th Cir. 2020).

[172] No. CV CCB-20-00361, 2020 WL 3893241 (D. Md. July 10, 2020).

[173] *Id.* at *9.

[174] 42 U.S.C. § 18116(a).

does not extend to discrimination on the basis of gender identity because gender is not synonymous with sex under Title IX.[175]

But the Proposed Rule fails to acknowledge that the majority of courts that have addressed whether 1557's protection extends to gender identity—including the Fourth and Ninth Circuit Courts of Appeals—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.[176] The Proposed Rule contends that *Skrmetti*[177] supports CMS's view that excluding transgender youth healthcare from reimbursement under Medicaid and CHIP does not discriminate unlawfully on the basis of sex under Section 1557.[178] This overstates the holding in *Skrmetti.* There, the Court considered only whether a state ban on transgender youth healthcare violated the Equal Protection Clause of the Fourteenth Amendment, not any statute, including Title IX or Section 1557.[179] Indeed, the Court expressly declined to address whether the reasoning in *Bostock v. Clayton County* would apply to other statutes.[180]

In any event, the Proposed Rule also runs afoul of Section 1557's prohibitions on age and disability discrimination. As the Court recognized in *Skrmetti*, a ban on transgender youth healthcare classifies on the basis of both age and medical use.[181] 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.[182] This provision applies to discrimination against the young as much as the elderly.[183] 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

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[175] 90 Fed. Reg. 59450-51 (citing *Tennessee v. Kennedy*, 1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025)).

[176] 590 U.S. 644 (2020); *see also 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 (2025), and *cert. granted, judgment vacated*, 145 S. Ct. 2838 (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 gender-affirming 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).

[177] This includes, by extension, the district court's decision in *Tennessee*, 2025 WL at *10.

[178] 90 Fed. Reg. 59451.

[179] *United States v. Skrmetti*¸ 605 U.S. 495, 500 (2025).

[180] *See id*. at 519-20.

[181] *Id*. at 511.

[182] 42 U.S.C. § 6102.

[183] *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).

those circumstances are not present, the distinction must be justified by a legitimate, nondiscriminatory reason.[184] As explained below in Section III, 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."[185] For this reason, a categorical ban on federal reimbursement for transgender youth healthcare impermissibly violates Section 1557.[186]

e. The Proposed Rule Contravenes the Tenth Amendment and the Spending Clause.

Apart from the statutory provisions 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. The Tenth Amendment reserves for the states all rights and powers "not delegated to the United States" federal government.[187] 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."[188] Since at least 1889, the authority to regulate the practice of medicine has been recognized as among these powers.[189] As discussed above, the undersigned States exercise their traditional authority to regulate the practice of medicine in myriad ways.[190] Most recently in *Skrmetti*, the Supreme Court recognized the states' authority 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.'"[191] The Proposed Rule flouts Tenth Amendment jurisprudence, as it single-handedly seeks to prohibit Medicaid reimbursement for healthcare that a multitude of states affirmatively permit and protect.[192]

The Proposed Rule's egregious overreach in an area of state concern is compounded by the surprise retroactive conditions the Proposed Rule imposes, in violation of the Spending Clause. 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

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[184] 89 Fed. Reg. 3604-5.

[185] 29 U.S.C. § 705(20)(B); *but see supra* note 3 (discussing HHS's third proposed rule from December 2025 seeking to exclude "gender dysphoria" from the definition of "disability" under the Rehabilitation Act).

[186] *See Williams v. Kincaid*, 45 F.4th 759, 774 (4th Cir. 2022) (holding that gender dysphoria is a covered disability under the ADA).

[187] U.S. Const. amend. X.

[188] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996); *see also Slaughter-House 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").

[189] *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 ....").

[190] *See supra* Section I.

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

[192] 90 Fed. Reg. 59441, 59442-43.

"'surpris[e] participating States with post acceptance or retroactive conditions.'"[193] The Executive Branch is likewise forbidden from imposing surprise retroactive conditions when carrying out Spending Clause legislation.[194] As the Supreme Court has observed, it "strains credulity" to think that a state would have had notice of and agreed to unambiguous funding conditions, when the administering agency announces those conditions for the first time well into a long-settled program.[195]

Here, the new conditions announced in the Proposed Rule constitute surprise, retroactive conditions of Medicaid that none of the administering states or their state-run hospitals agreed to at the programs' outset, or even during the approval process of State Plans.[196] The SSA gives no notice, much less clear or unambiguous notice, that acceding to the President's or federal government's policy preferences for medical treatment—and thereby forcing state Medicaid agencies to carry out a discriminatory federal policy motivated by animus—is a condition for reimbursement of care that has already been approved of in a State Plan.[197] Congress promised states the opposite: the federal government would not interfere in the practice of medicine and would defer to states' exercise of their traditional police powers, as provided by the Tenth Amendment, to regulate acceptable forms of healthcare for their residents.

CMS's Proposed Rule is therefore an unlawful and improper attempt to regulate medicine in the absence of clear Congressional intent and in contravention of the structure and limitations of federalism.

III. CMS Lacks a Reasoned Basis to Usurp the States' Authority to Regulate Healthcare for Transgender Youth Beneficiaries of Medicaid and CHIP.

In an unprecedented departure from its statutory role and traditional practice, CMS has issued a Proposed Rule that excludes from Medicaid reimbursement a specific category of care provided by mainstream medical professionals and healthcare providers.[198] Indeed, this decision was foreordained by Executive Orders signed nearly a year before the proposal was issued, and is reinforced by the actions and statements of senior administration officials that show an entrenched hostility toward the continuation of transgender youth healthcare.[199] Several aspects of the Proposed Rule demonstrate that the agency has already made up its mind to ban transgender youth healthcare and that its proposal lacks a reasoned basis.

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[193] *See Nat'l Fed'n of Indep. Bus.* ("NFIB") *v. Sebelius*, 567 U.S. 519, 584 (2012) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 25 (1981)); *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (in Spending Clause legislation, funding "conditions must be set out unambiguously") (quotation marks omitted).

[194] *See Solid Waste Agency of N. Cook Cnty. v. Army Corps of Eng'rs*, 531 U.S. 159, 172-73 (2001) (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.").

[195] *Pennhurst*, 451 U.S. at 25.

[196] *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").

[197] Further, contrary to Spending Clase requirements, the Proposed Rule's language itself is impermissibly ambiguous. For example, the Rule is ambiguous in defining which medical treatments are and are not "sex-rejecting," particularly in light of how CMS defines that term differently in separate actions. *See infra* III.a.

[198] *See generally* 90 Fed. Reg. 59441.

[199] *Id*.

First, the Kennedy Declaration—and the fact that it purported to take immediate effect and was issued contemporaneously with the NPRMs—creates an unworkable regulatory scheme that could effectively foreclose all transgender youth healthcare. Second, the Proposed Rule ignores states' significant reliance interests in providing transgender youth healthcare as part of their Medicaid and CHIP systems. CMS also fails to offer any explanation as to why reasonable alternatives that would account for states' reliance interests would not work. Third, CMS does not explain how it is not pretextual to continue federal funding for cisgender youth to receive the very treatment CMS asserts it must ban from reimbursement for transgender youth to protect against long-term and irreversible harm. Finally, CMS bases its extraordinary Proposed Rule on its own HHS Report, which is discredited and unscientific, while ignoring broad medical consensus as to the safety and efficacy of transgender youth healthcare and strong state law guardrails to ensure informed parental consent and knowing patient assent. Working backwards from its decision to ban care, CMS's portrayal of transgender youth healthcare as unsafe is dishonest, incomplete, and incorrect.

a. The Proposed Rule Is the Result of CMS's Impermissibly Closed Mind to Ban Transgender Youth Healthcare.

It is impossible to understand the true effect of the Proposed Rule without consideration of how the Rule would operate alongside two of the additional actions HHS announced on December 18—the Conditions of Participation Proposed Rule and the Kennedy Declaration. Despite the fact the agency announced it was undertaking "a series of proposed regulatory actions" simultaneously and for the purpose of "carry[ing] out President Trump's Executive Order directing HHS to end the practice of sex-rejecting procedures on children,"[200] the preamble and Regulatory Impact Analysis for this Proposed Rule do not acknowledge any of the other actions. And despite their coordinated release, HHS has made no attempt to explain how the Conditions of Participation Proposed Rule and this Rule would interact with the Kennedy Declaration,[201] if both are finalized while the Kennedy Declaration is in effect. That is because, based on the plain language of the three separate actions, there is no way to read them as creating a coherent regulatory framework for transgender youth healthcare and HHS could not have intended for them to do so.[202]

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[200] U.S. Dep't of Health & Human Servs., *HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children*, HHS (Dec. 18, 2025), https://perma.cc/CFR7-6A7A; *see also* U.S. DEP'T OF HEALTH & HUM. SERVS., *Protecting Children*, at 15:03 (YouTube, Dec. 18, 2025), https://perma.cc/6539-6G8Q (Dr. Mehmet Oz, Administrator for CMS, noting that CMS is "taking major steps . . . to stop a funding process that has led to irreversible medical interventions with two major actions").

[201] The Kennedy Declaration, while the most definitive, was not even the first or only indication of HHS's commitment to this predetermined outcome. As described above, in March and April 2025, respectively, CMS issued a quality and safety special alert memo to hospitals and other covered entities and a letter to state Medicaid directors raising concerns about treatment for gender dysphoria in youth and warning against continued provision of this care by hospitals and coverage of this care by state Medicaid programs. *Supra* note 52; CTRS. FOR MEDICARE & MEDICAID SERVS., State Medicaid Director Letter, RE: Puberty blockers, cross-sex hormones, and surgery related to gender dysphoria (Apr. 11, 2025), https://perma.cc/N6ZM-HXWG. The White House also celebrated the chilling effect that its Executive Orders and other threats had on healthcare providers who stopped offering the treatment for gender dysphoria that many young people rely on. Brooke Migdon, *White House Celebrates Reports of Hospitals Pausing Gender-Affirming Care*, THE HILL (Feb. 3, 2025), https://perma.cc/PQ6K-27LU.

[202] CMS acknowledges as much in its Conditions of Participation Proposed Rule, noting that the "effect attributable to this proposed rule might be lower in magnitude than the aggregate presented here if other actions, such as the HHS/CMS proposal titled 'Prohibition on Federal Medicaid and Children's Health Insurance Program

Specifically, the Kennedy Declaration claims that the provision of transgender youth healthcare "fail[s] to meet professional recognized standards of health care" and serves as grounds for exclusion of providers from participating in Medicaid and Medicare.[203] At the same time, the Proposed Rule asserts that it would not "prevent States from providing coverage for [transgender youth healthcare] with State-only funds outside of the federally-matched Medicaid program or CHIP."[204] However, the Proposed Rule fails to acknowledge that under the Kennedy Declaration, any provider who continues to offer such care with state-only funds would face a draconian threat of lifetime exclusion from participation in *any* federally funded medical programs for providing any type of medical care, not just transgender youth healthcare.[205] It is true that some states may have the ability to fund care for the small population of transgender youth diagnosed with gender dysphoria who require treatment. But CMS does not acknowledge that most healthcare providers would likely be unwilling to continue to provide transgender youth healthcare if doing so would subject them to a risk of a lifetime ban from participating in federally funded medical programs such as Medicaid and Medicare, or from working in a hospital setting that depends on Medicaid and Medicare for continued operation. CMS does not even seek comment on whether providers might be willing to limit their professional careers to practicing in a setting that receives no federal financial support. The agency must at a minimum offer its reasoned explanation for how CMS anticipates the Proposed Rule would interact with the Kennedy Declaration.[206]

Several inconsistencies among the three actions are further evidence that CMS has not intended to create a workable regulatory scheme related to transgender youth healthcare.[207] As one example, the definitions in this Proposed Rule, the Conditions of Participation Proposed Rule, and the Kennedy Declaration do not uniformly describe what constitutes "sex-rejecting procedures." And this Proposed Rule, which includes a directed question requesting comment on the challenges to operationalizing the proposed definitions, fails to share its reasoned explanation of how states and all impacted parties should understand the varying definitions, including the different definitions of "sex-rejecting procedures" that are proposed in each of HHS's December 18, 2025, regulatory actions.

Through this Proposed Rule, the Conditions of Participation Proposed Rule, and the Kennedy Declaration, HHS has revealed its true purpose—a prior decision to ban transgender youth healthcare. CMS offers no other reasoned explanation for HHS's simultaneous announcement of these regulatory actions or how they are intended to interact.[208] At the very least,

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Funding for Sex-Rejecting Procedures Furnished to Children' are finalized before finalization of this proposal." 90 Fed. Reg. 59475.

[203] *Kennedy Declaration*, *supra* note 5, at 9.

[204] 90 Fed. Reg. at 59454.

[205] *Id*.

[206] *See Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co*., 463 U.S. 29, 42, 46-48, 51 (1983).

[207] *See Air Transport Ass'n of America Inc. v. National Mediation Bd*., 663 F.3d 476, 486-87 (D.C. Cir. 2011) ("Decisionmakers violate the Due Process Clause and must be disqualified when they act with an 'unalterably closed mind' or are 'unwilling or unable' to rationally consider arguments.") (citing *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170, 1174 (D.C. Cir. 1979)).

[208] *Cf. ANR Storage Co. v. FERC*, 904 F.3d 1020, 1024 (D.C. Cir. 2018) (noting that to determine if agency action is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law the agency's reasoning "cannot be internally inconsistent"); *see also United Food & Com. Workers Union, Loc. No. 663 v. United States Dep't of Agric*., 532 F. Supp. 3d 741, 769–70 (D. Minn. 2021) (finding that the agency's rule was arbitrary and capricious in part because of an internal inconsistency in the Final Rule).

CMS's failure to consider the combined effect of the three actions demonstrates a "failure to consider an important aspect of the problem."[209]

b. CMS Disregards States' Longstanding Reliance Interests.

The Proposed Rule ignores the states' significant reliance interests in administering their Medicaid and CHIP programs under their existing frameworks. In doing so, CMS also fails to consider states' interests against a full range of "significant and obvious alternatives" to prohibiting Medicaid and CHIP coverage for transgender youth healthcare. CMS cannot ignore these significant reliance interests nor shirk its obligation to consider alternatives—including alternatives presented by the states in this comment and to the Office of Information and Regulatory Affairs ("OIRA"), Office of Management and Budget ("OMB")—as part of the good-faith rulemaking process.[210]

Many of the states' Medicaid programs cover transgender youth healthcare, and several states require by law that all health plans do so.[211] 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 an understanding that the federal government may not regulate the practice of medicine within their states.[212] They have long received FFP for claims related to the treatment of gender dysphoria, and CMS has never rejected or disapproved an undersigned State's Plan based on the inclusion of transgender healthcare. This longstanding structure reflects states' 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. CMS cannot disturb these sovereign interests absent Congressional authority, which it lacks.[213]

In addition to the states' sovereign interests, if the Proposed Rule ends Medicaid and CHIP coverage of transgender youth healthcare, this will drastically alter the costs and practical availability of such care, and therefore impact state Medicaid program design and rates and impede states' abilities to meet their legal obligations under federal and state law. In response to these fiscal injuries and concerns, CMS only mentions that, in its view, the possible harm of providing this healthcare "outweighs the possible financial costs some States may experience if they begin

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[209] *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co*., 463 U.S. 29, 42, 46-48, 51 (1983).

[210] Some of the undersigned States provided CMS ample evidence regarding the safety and efficacy of this care during an August 6, 2025, meeting with OIRA and OMB in which HHS and CMS officials participated. *See also State Farm*, 463 U.S. at 51; *Farmers Union Cent. Exchange, Inc. v. F.E.R.C.*, 734 F.2d 1486, 1511 (D.C. Cir. 1984) ("It is well established that an agency has a duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives.").

[211] *Supra* Section I.a.; *see also supra* notes 20-21.

[212] *United States v. Skrmetti*, 605 U.S. 495, 524 (2025) ("We afford States wide discretion to pass legislation in areas where there is medical and scientific uncertainty.") (internal quotation marks omitted); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) ("[W]e begin by noting that the historic police powers of the State include the regulation of matters of health and safety.").

[213] *Evelyn v. Kings County Hosp. Center*, 819 F. Supp. 183 (E.D.N.Y. 1993) ("Such deference to the states is consistent with Congress's express directive that Medicaid and Medicare not become vehicles for federal 'supervision or control over the practice of medicine or the manner in which medical services are provided.'").

to pay with State funds the full costs" of the healthcare.[214] This reflects CMS's inadequate consideration of the states' interests and does not reasonably address the states' fiscal harms.[215]

CMS also fails to address the technical and operational complexity of implementing the Proposed Rule. For example, under the Proposed Rule, state Medicaid agencies would have to operationalize the policy by processing claims based on specific diagnosis codes, which most claims processing platforms are not designed to do.[216] And because diagnosis codes may be incomplete, nonspecific, or vary across providers, the state Medicaid agency would also need to implement prior authorization or other utilization management controls to reliably capture clinical intent before services are rendered. Implementing prior authorization for this purpose would require state Medicaid agencies to develop new clinical criteria, update provider manuals and billing guidance, retrain staff and managed care organizations, revise contracts, and enhance oversight and appeals processes. These and other necessary system modifications, operational workflows, and compliance considerations make the Proposed Rule burdensome and costly for state Medicaid agencies to administer.

CMS had to consider these reliance interests, costs, and harms against regulatory alternatives to the Proposed Rule.[217] Yet the agency acknowledges in the Regulatory Impact Analysis that the only alternative it considered was "taking no action."[218] In doing so, CMS fails to consider the range of existing regulatory alternatives that fall in between taking no action—which the undersigned States believe adamantly is the correct course for all the reasons set out in this letter and strongly urge CMS to withdraw this Rule as unnecessary and inconsistent with federal law—and a total ban. For example, CMS has not explained why any of the requirements specific to transgender youth healthcare that are in place in some states[219] and that were

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[214] 90 Fed. Reg. 59448.

[215] *See Farmers Union Cent. Exchange, Inc. v. F.E.R.C.*, 734 F.2d 1486, 1511 (D.C. Cir. 1984) (An agency has "a duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives.") (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co*., 463 U.S. 29, 47-58 (1983)) and *Pub. Citizen v. Steed*, 733 F.2d 93, 94 (1984) (failing to pursue or explain why an agency did not purse obvious alternatives is arbitrary and capricious)).

[216] American Medical Association, *National Correct Coding Initiative Technical Guidance Manual for Medicaid Services* (Feb. 28, 2022), https://perma.cc/X97M-X2XN; T-MSIS, *CMS Technical Instructions: Diagnosis, Procedure Codes*, MEDICAID.GOV (last visited Feb. 14, 2026), https://perma.cc/LG44-PM9Q.

[217] This letter further details CMS's failure to consider significant costs and harms imposed by this Proposed Rule on states, transgender youth, their families, and health care providers, as well as other impacted parties such as state-regulated insurers, managed care providers, and drug manufacturers, in the discussion of the Regulatory Impact Analysis in Section V, below.

[218] *See* 90 Fed. Reg. 59441, 59549 ("[a]s an alternative to this proposed rule, we considered taking no action.").

[219] *See*, *e.g.*, N.Y. State Dep't of Health, Office of Health Ins. Programs, Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria (Sept. 1, 2018), https://perma.cc/L823-ZY8W (requiring Medicaid managed care plans to use evidence-based and guideline-supported criteria for gender-dysphoria treatment; mandating state agency submission and approval of utilization-management standards; and establishing procedural guardrails for coverage decisions including timely determinations, peer-to-peer consultation before adverse decisions, review by clinicians with gender-dysphoria expertise, and denial notices that provide specific medical-necessity rationales tied to the individual's diagnosis and documented clinical need); Wash. Admin. Code § 182-531-1675 (2025) (conditioning Apple Health coverage for gender-affirming interventions on medical necessity and clinical documentation requirements, including a qualifying diagnosis by an appropriate provider; requiring prior authorization for most gender-affirming surgeries; and tying surgical approval to evidence-based, guideline-informed criteria such as behavioral health assessments, hormone-therapy prerequisites when clinically indicated, and documented informed

recommended by the University of Utah College of Pharmacy's Drug Regimen Review Center study[220] would be inadequate to meet the agency's goals of avoiding harm to youth.[221] CMS must explain why these alternatives, which afford guardrails that ensure the highest standards of care, are evidence-based, specific to gender-dysphoria treatment, and consistent with clinical guidance from major medical authorities, would not better safeguard the health and well-being of transgender youth.[222]

c. CMS's Justification for Banning Medicaid and CHIP Reimbursement for Transgender Youth Healthcare Is Pretextual.

CMS attempts to justify its proposal to bar Medicaid reimbursement for transgender youth healthcare based on a purported lack of evidence for this care. But CMS expressly provides that such treatment will remain available under some circumstances, including for purposes other than to treat gender dysphoria.[223] CMS does not acknowledge that its reasons for barring reimbursement for this care when provided to treat gender dysphoria would necessarily extend to the provision of this care for other diagnoses, and fails to explain why this care is safe in one context but not another. For example, CMS argues that transgender youth healthcare may be irreversible and complicate reproductive activity in the future. However, it does not address how cisgender youth relying on the same treatment for a diagnosis other than gender dysphoria would not be at risk of the same harms. Further, CMS does not explain how this healthcare is different from other types of treatment, such as cancer treatment in youth, that could have similar effects but that are still approved for Medicaid reimbursement under the Proposed Rule. Similarly, CMS reasons that physical interventions, such as hormone therapies, are not medically necessary treatment for gender dysphoria—which it deems to be nothing more than psychological distress. 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 and transcranial magnetic stimulation for treatment-resistant depression and major depressive disorder.[224]

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consent addressing risks, alternatives, and reproductive effects); 130 Mass. Code Regs. 450.204 (2024) (defining "medical necessity" for MassHealth coverage and payment; requiring services to meet professionally recognized standards and be substantiated by medical records; addressing exclusions for experimental or unproven services); MICH. DEP'T OF HEALTH & HUM. SERVS., Medicaid Provider Bulletin No. MSA 21-28: Coverage of Gender Affirmation Services (Sept. 30, 2021), https://perma.cc/WV9Q-X6YT (Michigan Medicaid covers gender-affirming medical, surgical, and pharmacologic treatments for beneficiaries diagnosed with gender dysphoria; providing that such care is not "elective" or "cosmetic" when medically necessary; and requiring medical-necessity determinations and provider qualifications to follow current clinical practice guidelines, including WPATH and the Endocrine Society). The Cass Review itself highlights these standards. In the U.K., treatment is recommended on a case-by-case basis after an individual seeking treatment has been assessed by a multidisciplinary team of providers over the course of multiple sessions. *See generally*, Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Apr. 2024), https://perma.cc/S8UT-3GXJ [hereinafter *Cass Review*].

[220] *Utah Study*, *supra* note 137 at 11-14 (recommending enhanced training requirements for providers of transgender youth healthcare, creating and maintaining a database of certified providers, and implementing interdisciplinary teams of providers with expertise in transgender youth healthcare as the sole providers who can offer treatment in the state).

[221] 90 Fed. Reg. 59448.

[222] *See supra* Section III.b., at n. 208.

[223] 90 Fed. Reg. 59454.

[224] *See* Joao L. de Quevedo, *Electroconvulsive Therapy (ECT) for Children and Adolescents*, MCGOVERN MED. SCH. AT UTHEALTH, (Feb. 10, 2025), https://perma.cc/ZV3W-SH63; Leah Kuntz, *FDA Clears Deep*

CMS has no justifications or explanations for the line it draws in the Proposed Rule, because no non-pretextual explanations rooted in science or any other nondiscriminatory basis exist. Instead, CMS pursues the Administration's agenda to deny the existence of transgender individuals by forcing states to choose between providing Medicaid coverage for this vital care or foregoing equally vital Medicaid and CHIP dollars.[225]

Further, beyond demonstrating pretext for the Proposed Rule, CMS's differentiation between transgender youth who require this treatment and cisgender youth who may require the same treatment discriminates on the basis of transgender status in violation of the Equal Protection Clause. The Equal Protection Clause prohibits government policies that express negative attitudes or fear in connection with people viewed as "different."[226] Indeed, the courts that have examined actions taken by the federal government targeting transgender youth healthcare to date have found that this discriminatory animus motivates their actions seeking to restrict access to such care.[227]

d. CMS Ignores Strong Evidence that Undermines the Need for its Proposed Rule.

Rather than providing a reasoned justification and examining all relevant data, CMS pursues the Secretary's anti-science agenda through this Proposed Rule. CMS supports its politicized views of medicine by repeatedly pointing to its own commissioned, discredited, and unlawful study, the HHS Report, to attack credible sources, without ever addressing myriad medical and scientific evidence that contradicts its predetermined view.

i. Strong Evidence Supports the Safety and Efficacy of Transgender Youth Healthcare.

Transgender youth healthcare, like all healthcare for youth, is delivered by medical professionals who base treatment recommendations on recognized clinical standards that are

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Transcranial Magnetic Stimulation for Adolescents with MDD, PSYCHIATRIC TIMES, (Nov. 14, 2025), https://perma.cc/A3LG-YMQJ.

[225] *See supra* Section III.a.

[226] *City of Cleburne v. Cleburne Living Ctr*., 473 U.S. 432, 448 (1985); *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"); *id*. at 449 ("Vague, undifferentiated fears about a class of persons further no legitimate state interest and cannot be used to validate a policy of different treatment.").

[227] *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 re2025 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'").

founded in evidence-based medicine.[228] This includes requiring providers to consider any relevant health risks associated with specific treatment for individual patients.[229] Additionally, states have established robust safeguards to ensure high-quality care that aligns with clinical practice standards.[230] For example, states require that all decisions about treatment and care are made with informed parent consent and patient assent.[231]

Patients who receive transgender youth healthcare overwhelmingly report high levels of satisfaction with their care and its positive impacts on their mental and physical health.[232] These accounts are plentiful.[233] Indeed, the care that CMS proposes to exclude from Medicaid and CHIP reimbursement has been studied and shown to dramatically improve mental health outcomes in individuals with gender dysphoria.[234] Hormone therapy in particular, is an essential part of addressing these serious mental health concerns and reducing the risk of suicide in transgender individuals.[235] The Utah Study further supports this consensus.[236] The Utah Study examined 134 studies "representing more than 28,056 transgender minors from all over the world" which conducted a review of gender dysphoria treatment and subsequently recommended offering transgender youth healthcare with comprehensive, interdisciplinary teams and "an enhanced and explicit informed consent and assent process."[237] The conclusions of the Utah Study are consistent with a systematic literature review of "all peer-reviewed articles published in English between 1991 and 2017" related to transgender adults that found 93% agreement that hormonal and surgical transgender healthcare "improves the overall well-being of transgender people." The remaining 7% found mixed or no conclusive findings, not negative findings.[238] Across both the literature review and the Utah Study, not one study found care harmed transgender youth. Like all other healthcare, transgender youth healthcare is based on a model of harm prevention and reduction, and the Utah Study concluded that the way to address uncertainties, where they exist, is through "careful assessment and reassessment of the whole person," not through delaying, minimizing, or outright refusing treatment.[239]

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[228] *Coleman*, *supra* note 37.

[229] *Poteat*, *supra* note 40.

[230] *Supra* Section I.b.

[231] Abigail English & Rebecca Gudeman, *Minor Consent and Confidentiality: A Compendium of State and Federal Laws. National Center for Youth Law* (Nat'l Ctr. for Youth L. 2024), https://perma.cc/QJX2-NP5U.

[232] *Supra* Section I.c.

[233] *See supra* notes 47-50.

[234] *See* Lucas Schelemy et al., *Systematic Review of Prospective Adult Mental Health Outcomes Following Affirmative Interventions for Gender Dysphoria*, 26 INTL. J. TRANSGENDER HEALTH 480 (2024); Giuliana Grossi, *Suicide Risk Reduces 73% in Transgender, Nonbinary Youths with Gender-Affirming Care*, HCPLIVE (Mar. 9, 2022), https://perma.cc/87UG-75AW (citing Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, Pediatrics (Feb. 25, 2022) https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789423.

[235] *Supra* Section I.c.

[236] *See Utah Study*, *supra* note 137.

[237] *See generally*, *id*.

[238] *What Does the Scholarly Research Say about the Effect of Gender Transition on Transgender Well-Being?*, WHAT WE KNOW, Cornell Univ. (2018), https://perma.cc/AX5K-CUBQ.

[239] *Id*., at 9.

Additionally, available research reports lower rates of regret and dissatisfaction with transgender healthcare[240] than with other common medical procedures.[241] Rates of regret after obtaining transgender healthcare are very low.[242] One study reported that only 0.6% of transgender women and 0.3% of transgender men experienced regret.[243] Another study reported that regret was documented in only 1.1% of adult gender-diverse patients.[244] Studies of youth who receive transgender healthcare as minors report similar findings. One study of over 200 youth who received transgender youth healthcare found that five years after the start of treatment using puberty-blockers, only 4% of the youth reported having some regret, and even fewer reported stopping treatment.[245]

CMS wholly ignores this evidence and instead insists that the harms and risks to transgender youth outweigh any benefits of clinically warranted, safe, and legal healthcare.[246] However, CMS lacks an adequately reasoned basis to disregard the evidence that undermines its conclusions regarding the safety and efficacy of transgender youth healthcare. 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, including the Utah Study, violates basic principles of administrative law.[247]

ii. CMS Relies on Poor Quality, Unscientific Studies and Misinterprets Data to Support its Foregone Conclusion to Ban Transgender Healthcare.

In ignoring the evidence that undermine its conclusion,[248] CMS relies on its own self-serving assessment, the HHS Report, to assert that "the evidence does not support conclusions about the effectiveness of medical and surgical interventions in improving mental health or reducing gender dysphoria symptoms."[249] However, the HHS Report is without scientific merit, has been widely rejected by medical experts in fields including pediatric and family medicine, psychology, obstetrics and gynecology, and endocrinology, and, as noted below, fails to comply

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[240] *See Wiepjes, supra* note 46, at 585 (reporting that 0.6% of transgender women and 0.3% of transgender men experienced regret); 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* 5, BJPSYCH OPEN (2021) (reporting a regret rate of approximately 1.1%); Olson, *supra* note 46.

[241] Sarah M. Thornton et al., *A Systematic Review of Patient Regret After Surgery—A Common Phenomenon in Many Specialties but Rare Within Gender-Affirmation Surgery*, 234 AM. J. OF SURGERY 68, 68-73 (2024).

[242] *Wiepjes, supra* note 46, at 582-590.

[243] *See id*.

[244] *See Hall, supra* note 237.

[245] *See Olson*, *supra* note 46, at 1354-61; *see also* Pranav Gupta et al., *Continuation of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Individuals: A Systematic Review*, 30 ENDOCR. PRACT. 1206, 1206-11 (2024); Maria Anna Theodora Catharina van der Loos et al., *Continuation of Gender-Affirming Hormones in Transgender People Starting Puberty Suppression in Adolescence: A Cohort Study in the Netherlands*, 6 LANCET CHILD & ADOLESCENT HEALTH 869, 869-875 (2022).

[246] *See* 90 Fed. Reg. 59443-47.

[247] *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co*., 463 U.S. 29, 51, 57 (1983).

[248] *See supra* Section I.c. (discussing the longstanding practice of transgender youth healthcare in the United States in line with the recommendations of reputable major medical associations).

[249] 90 Fed. Reg. 59444.

with the Federal Advisory Committee Act.[250] Not only is the evidence in the HHS Report poor, it also does not support CMS's Proposed Rule. The HHS Report does not conclude that transgender youth healthcare is unsafe or that it fails to ameliorate gender dysphoria. The Report's authors found "limited evidence regarding the harms of sex-rejecting procedures in minors."[251] Indeed, the HHS Report itself refers to evidence of harms as "sparse."[252] While HHS might conclude (by ignoring contrary evidence) that there is no *benefit* to treatment for gender dysphoria in young people, the Proposed Rule's unprecedented and extraordinary action to ban the use of federal Medicaid and CHIP funds for an entire category of healthcare, must be supported by something more than "sparse" evidence, which could not even be documented in its own Report.[253]

In addition to relying on its own unscientific Report, CMS cites to the United Kingdom's Cass Review, which was used in the U.K. to justify restructuring the treatment protocol for transgender youth healthcare from the accepted and medically indicated method of psychotherapy followed by hormone therapy and surgical intervention to focus solely on "psychosocial support."[254] Similar to the HHS Report, the Cass Review does not support the claims made in the Proposed Rule. For example, CMS uses the Cass Review to affirm that there is a "lack of robust evidence regarding the effectiveness of interventions such as puberty blockers and cross-sex hormones to treat gender dysphoria and incongruence in children and adolescents."[255] The Cass Review does not say this. Indeed, the Cass Review explicitly states that "for some, the best outcome will be transition."[256]

Because the evidence it relies on is insufficient to support its proposal, CMS also presents misinformation and distorts well-established facts regarding transgender youth healthcare.

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[250] *See* Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. ADOLESCENT HEALTH 3, 342-345 (Sept. 2025); *see also* Mary Kekatos, *HHS finalizes report on gender-affirming care for youth, medical groups push back*, ABC NEWS (Nov. 20, 2025, 04:13 ET), https://perma.cc/C4XH-5CSB; Susan J. Kressly, *AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria*, AM. ACAD. PEDIATRICS (May 1, 2025), https://perma.cc/6VPB-DQGM; Jen Christensen & Jamie Gumbrecht, *Trump Administration Releases 400-Page Review of Gender Dysphoria Treatment for Youths But Won't Say Who Wrote It*, CNN (May 1, 2025), https://perma.cc/FRB4-GH3Q; *Leading Physician Groups Oppose Infringements on Medical Care, Patient-Physician Relationship*, AM. COLL. PHYSICIANS (May 1, 2025), https://perma.cc/WNQ4-XQE2. *See also infra* Section IV.

[251] 90 Fed. Reg. 59444 (citing *HHS Report*, *supra* note 32 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 Conditions of Participation Proposed Rule that seeks to 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/63L6-NKYH; Ian Lopez, *Gender Care Pullback Led by Trump's HHS Moves Boldly Into 2026*, BLOOMBERG LAW (Jan. 5, 2026, 4:05 AM), https://perma.cc/5XPT-7AFK.

[252] *HHS Report, supra* note 32, at 13.

[253] *See, e.g.*, Dowshen, *supra* note 250 ("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.").

[254] 90 Fed. Reg. 59445 n.42 (citing *Cass Review*, *supra* note 220).

[255] 90 Fed. Reg. 59449 n.80.

[256] *Cass Review, supra* note 220, at 21.

Specifically, in the preamble of the Proposed Rule, CMS accuses healthcare professionals of widespread inaccurate diagnosing of youth with gender dysphoria. This assertion is false. CMS presents no evidence that rates of misdiagnosis of gender dysphoria among youth exceed the rates of misdiagnosis for other medical conditions. Rather than support its assertion with data, CMS attacks the medical profession's treatment and diagnosis of gender dysphoria among youth. However, medical experts develop clinical practice guidelines, including guidelines for treatment of gender dysphoria among youth, using a rigorous systematic review of evidence and literature.[257] Trustworthy guidelines are developed by multidisciplinary clinicians, researchers, and stakeholders with expertise on the issue.[258] Practice guidelines are transparent about the evidence they rely on and disclose both the quality of the evidence as well as the strength of the guidelines' recommendations.[259] Clinical practice guidelines do not encourage health providers to do anything other than practice evidence-based medicine, as they are already obligated to do.[260] Standards of care set by professional medical organizations and endorsed by numerous medical associations ensure that the delivery of transgender youth healthcare is safe, individualized, and centered around the patient.[261] In the United States in particular, individuals who receive transgender care must be informed of all the risks and are carefully evaluated by their healthcare providers who assess what care is medically necessary.[262]

Further, CMS misrepresents the studies it cites to create the impression that other countries have banned transgender youth healthcare, but this is also not true.[263] None of the countries cited by HHS, such as the United Kingdom, Sweden, and Finland, have adopted blanket bans on medical treatment for gender dysphoria; rather, treatment remains available on a case-by-case basis and in a manner that is consistent with the standard of care in the United States. For example, in the United Kingdom, hormone therapy is available for young people 16 and older "with a diagnosis of gender incongruence or gender dysphoria" to be used alongside psychological support.[264] CMS also overlooks the fact that treatment for gender dysphoria continues to be widely available in other European countries such as Spain, Italy, and Germany, and that U.S. legislators banning care are "at odds with European recommendations."[265]

IV. The Proposed Rule Fails 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 a report of an advisory committee established by HHS (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.

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[257] *See* M. Hassan Murah, *Clinical Practice Guidelines: A Primer on Development and Dissemination*, 92 Mayo Clinic Proceedings 3, 423-33 (Mar. 2017).

[258] *Id*. at 425.

[259] *Id*.

[260] *Id.*

[261] *See supra* Section I.c.; *see also, supra* note 258.

[262] *Coleman, supra* note 37.

[263] *See* 90 Fed. Reg. 59445 Section I.B.1.

[264] Treatment: Gender Dysphoria, NHS England (last visited Jan. 27, 2026), https://perma.cc/P2KM-ZJJB.

[265] Joshua P. Cohen, *Increasing Number of European Nations Adopt a More Cautious Approach to Gender-Affirming Care Among Minors*, Forbes (June 6, 2023, 7:08 PM), https://perma.cc/7PPX-5F4K.

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."[266] 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.[267] 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."[268] 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 HHS wholly failed to comply with the FACA requirements.[269] 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."[270] HHS also did not publish a notice in the Federal Register announcing the author group,[271] submit a Membership Balance Plan to GSA describing HHS's "plan to attain fairly balanced membership,"[272] 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.[273] 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,[274] and that an agency make available "all materials that were made available to or prepared for or by an advisory committee,"[275] 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.[276] 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."[277] 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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[266] 5 U.S.C. § 1001(2).

[267] *HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures,* U.S. DEP'T OF HEALTH & HUMAN SERVS. (Nov. 19, 2025), https://perma.cc/SK5N-VUXG.

[268] *HHS Report*, *supra* note 32, at 11.

[269] 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.

[270] *See* 41 C.F.R. 102-3.60(b)(1)-(2).

[271] *Id.* 102-3.65(a).

[272] 89 Fed. Reg. 27673, 277682 (Apr. 18, 2024).

[273] *Id.* § 102-3.60(b)(2).

[274] 5 U.S.C. § 1009(a)(2)-(3).

[275] *Food Chem. News v. Dep't of Health & Human Servs*., 980 F.2d 1468, 1469 (D.C. Cir. 1992).

[276] 5 U.S.C. § 1009(b).

[277] *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020).

V. CMS's Regulatory Impact Analysis Is Inadequate.

a. The States Will Bear Significant Costs if CMS's Proposed Rule Takes Effect, Which the RIA Largely Ignores.

The Regulatory Impact Analysis ("RIA") fails to consider the full range of costs and harms of the Proposed Rule, including costs it will impose on the states, their residents, and all participants in state-regulated healthcare. The RIA is also procedurally deficient. Specifically, CMS fails to identify a reasonable baseline against which to compare the costs and benefits of the Proposed Rule, including alternative approaches to the baseline. The RIA should explain whether CMS concluded the regulations maximized net benefits, including potential economic, public health and safety, and other advantages. Instead, CMS considered only one side of the equation—savings, not costs—and factored into its analysis *only* consideration of cost savings that align with CMS's goal to end transgender youth healthcare. In fact, CMS concedes it improperly excluded one tangible economic and public health cost from its consideration—increases in other federally-funded healthcare services related to gender dysphoria.[278]

Finally, the RIA relies on analytical assumptions but does not provide any way for the states and commenters to assess the reasonableness of those assumptions and if they were based on a reliable and unbiased data for spending projections. Instead of shedding light on how CMS developed its analysis, the RIA admits the agency relied on no impact analyses on the effects of prohibiting these procedures, instead simply assuming without justification that "some individuals would ultimately receive these services once eligible and believ[ing] 50 percent is reasonable."[279]

i. The RIA Ignores the Costs States Will Incur Defending Their Sovereign Interests.

States' sovereign injuries. Despite acknowledging states' longstanding reliance interests in the preamble,[280] the RIA does not assess states' costs of defending their own laws and regulations to protect transgender youth and their healthcare providers, as described above. Nor does the RIA recognize or quantify the costs states will incur from taking legal action to protect their interests in maintaining the integrity of the medical authorities and regulatory bodies that resolve questions about the practice of medicine under state law as an exercise of state sovereignty.[281]

States will pay a steep price to ensure transgender youth continue to receive medically necessary healthcare. Although the Proposed Rule solicits comment on whether states will continue to provide transgender youth healthcare without FFP, the RIA does not consider or

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[278] 90 Fed. Reg. 59459.

[279] 90 Fed. Reg. 59458.

[280] 90 Fed. Reg. 59451-52 (discussing how CMS has long afforded state Medicaid agencies flexibility to establish the amount, duration, and scope of covered Medicaid services and to develop state-specific processes for determining when a service is medically necessary for an EPSDT-eligible beneficiary).

[281] Several of the undersigned States have already filed suit to stop implementation of the Kennedy Declaration. *See Oregon v. Kennedy*, 6:25-cv-02409, (D. Or. Jan. 6, 2026), ECF No. 28 ¶¶ 65–77 (Am. Compl.); *id*., ECF No. 32 (Pls.' Mot. Summ. J.). The complaint and the States' motion for summary judgment set out the sovereign injuries that states are already suffering from the Kennedy Declaration. CMS's RIA must acknowledge, address, and make a reasonable effort to estimate costs to the states that result both from the Kennedy Declaration itself, its interaction with the Proposed Rule, and the costs of the litigation states have brought to reverse the harms that have occurred and to prevent further harm.

estimate the direct costs states would incur if they alone were to pay for transgender youth healthcare. These costs include securing, setting up, and administering a new state-only funding stream for transgender youth healthcare; creating a new reimbursement system; and issuing guidance to providers. And because federal and state laws impose a legal obligation on custodial entities to provide all necessary healthcare to youth in their custody, the Proposed Rule will force states alone to incur costs in their capacity as legal custodians of youth in foster care, juvenile detention, or other forms of state custody who need transgender youth healthcare.[282]

ii. The RIA Also Ignores the Costs Imposed on Patients, Their Families, and Providers, as well as State Regulated Insurers and Managed Care Providers.

CMS proposes this sweeping change despite conceding a lack of peer-reviewed findings and data to support an analysis of the economic and noneconomic impact its categorical ban on Medicaid and CHIP reimbursement will have on patients, families, providers, and insurers.[283] The agency also excluded from its RIA any estimates of the cost-effectiveness of transgender youth healthcare, despite studies that show care is cost-effective and allows transgender youth to avoid psychological distress, including anxiety, depression, and suicidal ideation, which, if left untreated can be extremely costly to states.[284]

Costs the Proposed Rule would impose on transgender youth and their families/guardians. CMS did not analyze the economic and noneconomic costs of denying transgender youth healthcare, including, for example, greater future healthcare costs and greater risk of harm for impacted individuals who would lose access to transgender youth healthcare.[285] CMS ignored these costs even though much is known about the costs and harms from denying transgender youth healthcare, or when the supply of care is severely restricted.[286] The estimated average cost of not covering healthcare for a transgender individual is approximately $23,619 for a 10-year period, reflecting the medical costs of negative health outcomes including depression, substance use, and suicide.[287] Termination or delays of care will not only put patients at risk for psychological distress, but cause more acute symptoms of gender dysphoria that could be avoided with consistent treatment.[288] Care denial removes the protective benefits of gender congruence,

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[282] *See Massachusetts v. Trump*, 1:25-cv-12162, ECF No. 87, Ex. 9 (Aledort Decl.) ¶¶ 41–46; Ex. 6 (Bagdasarian Decl.) ¶¶ 26–28, 31–33; Ex. 7 (Mueller Decl.) ¶¶ 21–22; Ex. 8 (Maehr Decl.) ¶¶ 12–13 (D. Mass. Dec. 22, 2025).

[283] 90 Fed. Reg. 59441, 59458-62.

[284] *Supra* Section I.c.

[285] 90 Fed. Reg. 59459 ("We have not estimated if there would be any other impacts on Federal expenditures (for example, increases in other healthcare services related to gender dysphoria).").

[286] Myeshia Price-Feeney et al., *Understanding the Mental Health of Transgender and Nonbinary Youth*, 66 J. ADOLESCENT HEALTH 684, 684-690 (2020).

[287] William V. Padula et al., *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis*, 31 J. Gen. Intern. Med. 394, 398 (2016).

[288] *Massachusetts*, 1:25-cv-12162-AK, ECF 87-21, ¶ 30 (explaining patients whose care has been terminated have suffered "more acute symptoms of gender dysphoria" and noting multiple patients in such scenarios " had worsening dysphoria and mental health" with one patient needing "to start an intensive outpatient psychiatric program to cope with the setback" from termination of care). Diane Chen et al., *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*, 388 NEW ENG. J. MED. 240 (2023); Johanna Olson-Kennedy et al., *Emotional Health of Transgender Youth 24 Months After Initiating Gender-Affirming Hormone Therapy*, 77 J. ADOLESCENT HEALTH 41 (2025).

causing deteriorating anxiety, depression, suicidality, gender dysphoria, quality of life, and social and occupational functioning.[289]

CMS's Proposed Rule would not only deny coverage to new patients but could require abrupt termination of care for those already receiving it if they cannot afford out of pocket costs, which is likely to be the case for low-income Medicaid beneficiaries and their families. There are significant risks to abruptly stopping most medical treatments, including treatment of gender dysphoria.[290] The costs would likely extend beyond the direct consequences of stopping treatment mid-stream. It could also lead to downstream consequences like reticence to engage with healthcare providers for other types of medical care, including mental healthcare, primary care services, and emergency care, resulting in more significant, and costly, future healthcare needs.[291]

Further, if patients face barriers to receiving transgender youth healthcare, the undersigned States' costs to maintain public health will be impacted. Investing in coverage for individuals and ensuring necessary healthcare services are covered has a well-documented, measurable, positive impact on health outcomes.[292] Transgender youth who are denied transgender youth healthcare are likely to require additional, more costly physical and mental healthcare, now and later in life.[293] The restriction of access to pubertal suppression and hormone therapy for transgender youth is correlated with these negative health outcomes that manifest as additional costs to payers.[294] Early treatment also may reduce the need for riskier and more costly interventions later in life such as surgical interventions, which are not excluded from coverage for Medicaid-eligible adults by this Proposed Rule.[295] The expense of more costly procedures and treatments when transgender youth healthcare is unavailable will be borne by the states, as administrators of healthcare plans.[296]

The RIA should have considered these known costs and harms and estimated the Proposed Rule's economic and noneconomic toll on transgender youth, including the costs of treatment delays, long waiting periods, and expenses to cover continued transgender youth healthcare. CMS should also factor into the RIA the time it will take families to navigate their coverage options and

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[289] Joanne LaFleur et al., *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* (Utah Dep't of Hum. Servs. Aug. 6, 2024), https://perma.cc/F76H-YN2Z.

[290] Kristen L. Eckstrand et al., *Mental Health and Care Denial in Transgender Youth,* 83 JAMA PSYCHIATRY 9, 10 (2026); *see*, *e.g.*, *In Re: Subpoena No. 25-1431-014*, No. 25-mc-00039 (E.D. Pa. Nov. 21, 2025), ECF No. 1, Ex. B, Joint Decl. of Nadia Dowshen, M.D., & Linda Hawkins, Ph.D. ¶ 1; *see also id*., at 69-72, Decl. of Dr. Joseph St. Geme III.

[291] 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").

[292] *See, e.g.,* Samuel Mann et al., *Access to Gender-Affirming Care and Transgender Mental Health: Evidence from Medicaid Coverage* (Aug. 7, 2022), https://perma.cc/4BHT-TUSU.

[293] *Outlawing Trans Youth: State Legislatures and the Battle over Gender-Affirming Healthcare for Minors,* 134 HARV. L. REV. 2163 (2021), https://perma.cc/GC7P-HWXE (explaining how puberty blockers and hormone replacement therapies allow transgender youth to avoid intense psychological distresses, including anxiety, depression, and suicidal behavior).

[294] *Annelou, supra* note 44, at 705.

[295] Gilbert Gonzales & Kyle A. Gavulic, *The Equality Act Is Needed to Advance Health Equity for Lesbian, Gay, Bisexual, and Transgender Populations*, 110 AM. J. PUB. HEALTH 801 (2020).

[296] AM. MED. ASS'N, *Health Insurance Coverage for Gender-Affirming Care of Transgender Patients* (2025), https://perma.cc/SH6C-MYRT.

the burden of paying for care out of pocket, for the small number of low-income families who might find alternative funding to afford this care if the Proposed Rule is finalized.

Finally, the Proposed Rule will have significant, harmful redistributive effects on low-income children who are beneficiaries of Medicaid and CHIP and who are more likely to be from communities of color. Transgender people are more likely to have lower incomes than cisgender people and will not be able to afford out of pocket costs, which could result in denial of care all together.[297] Yet CMS fails to acknowledge or address the effects of its proposal to restrict access to transgender youth healthcare solely in the Medicaid and CHIP programs. The RIA must estimate the costs to beneficiaries and the states of a rule that would restrict access to transgender youth healthcare solely among individuals whose care is covered by Medicaid or CHIP.

Costs the Proposed Rule will impose on providers of transgender youth healthcare. The RIA fails to consider or estimate a range of economic and professional costs and harms the Proposed Rule will impose on providers. Some of the costs and harms the states anticipate include lost income, professional and career injuries, and injuries that result from impaired patient-provider relationships. The RIA acknowledges that providers of transgender youth healthcare will lose income from Medicaid and CHIP reimbursement, but asserts funding can be recouped from other sources.[298] The RIA fails to estimate how much income will be lost and what other funding sources are available to replace lost income beyond suggesting that states might fund transgender youth healthcare.

CMS further fails to analyze the Proposed Rule's potential impacts on care provided throughout hospital networks, in either the preamble or RIA. The RIA must consider this as well as the impact, including economic strains, the Proposed Rule will have on providers of transgender youth healthcare who continue to provide care. These providers' practices will see increased operating costs from new patients seeking healthcare from across the country if most providers stop care.

The RIA also fails to consider the costs to providers who stop providing transgender youth healthcare, including any costs to transition to a different practice area, develop new skills, and pursue additional training, board certification, and licensure. Hospitals, including state hospital system, clinics, and private practice groups, will also lose talent as practitioners who can no longer provide care seek work elsewhere.

In addition to such expenses, the RIA fails to describe the harm to providers who will have to stop providing care on which they have built their careers, professional relationships, and reputation. These harms include the inability to fulfill their doctor-patient duties consistent with an ethical obligation to provide healthcare to patients who are transgender youth participating in Medicaid and CHIP.

Costs the Proposed Rule will impose on state-regulated insurers and managed care providers. The Proposed Rule would impose costs and harms on insurers and managed care providers in the states that the RIA did not identify or quantify. Insurers and managed care providers will experience increased administrative burdens related to adjusting to new systems, issuing new guidance, educating providers, and developing different claims, billing, and other

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[297] Lindsey Dawson, et al., *Trans People in the U.S.: Identities, Demographics, and Wellbeing*, KFF (Sept. 28, 2023), https://perma.cc/Z564-C7G7.

[298] 90 Fed. Reg. 59441, 59448-49.

procedures. For example, the RIA should have developed a model to estimate costs to each insurance provider that will have to adjust rates because of the Proposed Rule. Although many states set rates at specific times of the year, the Proposed Rule might 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.

Costs the Proposed Rule will impose on drug manufacturers. The RIA fails to acknowledge or account for the economic impact the Proposed Rule will have on manufacturers of hormone therapies and other drugs. CMS must also assess the costs the Proposed Rule will have on the MDRP. If the Proposed Rule were to take effect, these changes will open the door for other drugs to be excluded from the MDRP on indication, which is a significant cost to drug manufacturers that the RIA fails to acknowledge or assess.

iii. Even the Costs CMS's RIA Acknowledges Are Grossly Underestimated.

CMS's estimates for state policy review and revisions are underinclusive of all states, underinclusive of all costs and burdens, and an inadequate estimate of the time to comply with the rule. CMS incorrectly asserts that the Proposed Rule will impact only those states that have enacted laws or regulations that protect healthcare for transgender youth. Instead of acknowledging and accounting for the Proposed Rule's impact on all states, the preamble makes the faulty assertion that for the "27 States and one Territory [that] have enacted laws restricting some or all of the [] procedures that would be covered by this proposed rule . . . we do not anticipate State staff will need to conduct a review of policy documents for Medicaid or CHIP as these procedures are currently banned (or will be banned)."[299] However, even states with laws that restrict "some" relevant care will have to review their policies. And states with laws restricting all relevant care will likely have to review their policies to confirm that all relevant policy documents have been updated in compliance with new federal requirements. For example, all states will likely have to reach out to their contracted managed care plans, review managed care contracts, provider directories, provider manuals, and other state operations documents to ensure compliance.

Yet the proposed information collection offers wildly inaccurate estimates of the time it will take 28 states and territories to review and revise policies. CMS estimates it will take two people a total of 3 staff hours to review all Medicaid and CHIP policy documents. This extremely low estimate fails to anticipate the review of proposed policy changes by managers, senior leadership, or a state's legal team. It also fails to assume any time associated with communications with external stakeholders about the new policy and related changes. It is likely that a state would have some engagement with consumer organizations, the state legislature, provider organizations, Medicaid advisory committees, and others.

CMS further underestimates the first step of internal review, which is to review state managed care contracts, provider manuals, and other state operations documents to ensure compliance. None of these costs are factored into the proposed information collection or the RIA. This review will likely be undertaken by many people within individual state agency divisions (e.g. at least one person each from within the managed care division, the quality division, the fee-for-service division, the legal team, the communications team etc.). CMS also fails to estimate any staff time associated with additional steps following the review. Across state agencies, employees

[299] 90 Fed Reg. 59448.

will revise contracts, policies, and procedures that are out of compliance with the new federal policy. Their revisions will be approved by managers, lawyers, and the Medicaid director. States will also engage stakeholders in making any required changes, which will necessitate additional senior-level engagement and communications support. The revisions may also require engagement with the state legislature, which would require government affairs and legal team engagement. To ensure effective implementation of these changes, states will develop internal and external guidance documents to ensure the changes required by the Proposed Rule are understood by all who are impacted.

Finally, CMS fails to acknowledge or estimate costs that state managed care providers will incur from changing their policy documents and written materials to align with the requirements of the Proposed Rule. Managed care provider staff, including health services, compliance, and communications staff, will review the final rule and any state guidance issued by the Medicaid agency on how to implement the changes. They will revise their plan materials, translate them into all languages spoken by their members, and ensure the documents are reviewed before they are disseminated to members. Managed care providers will also train member services staff to respond to questions about coverage that members will have because of the new rule. All these efforts will be undertaken by every Medicaid plan in each state, resulting in costs that CMS fails to include in its estimates.

State plan review and revisions. CMS acknowledges in the preamble that all states and territories "would be required to submit SPAs specifically indicating adherence to the prohibition on claiming Federal funding of sex-rejecting procedures for individuals under the age of 18… [sic]."[300] The agency repurposes its extremely low and inaccurate policy review estimates to calculate how many people and how much time all states will spend reviewing their State Plans—2 hours at $87.52/hour for a Business Operations Specialist to prepare an initial SPA and 1 hour at $128.00/hour for a General Operations Manager to review and approve the SPA for submission to CMS—for a total of 3 hours of staff time. Again, CMS fails to anticipate review by managers, senior leadership, or state lawyers who will be involved in making these changes.

Finally, CMS's estimate fails to assume any time associated with states' communications with the agency about the new plans. Even when a state adopts a SPA template in its entirety, CMS conducts a "same-page review" of other policies on the same page of the State Plan that the state is requesting to amend. This "same-page review" can be a lengthy and time-consuming process, which can consume hundreds of hours of state and CMS staff time, and require involvement from the state's legal team and senior leadership. CMS must include estimates of these costs in its RIA and information collection request.

CMS's estimated cost savings are flawed. The RIA projects a $130 million reduction in state Medicaid spending from fiscal year 2027 through fiscal year 2036 in 2027 dollars.[301] The estimate is based on a population under age 17. Again CMS asserts that the Proposed Rule would not prohibit payment by a state Medicaid agency for transgender healthcare to individuals age 18 and above without factoring into its estimate the impact of the Kennedy Declaration or the Conditions of Participation Proposed Rule on continued care.[302] The RIA should have projected a

[300] 90 Fed. Reg. 59457.

[301] 90 Fed. Reg. 59458.

[302] As part of this overall estimate, CMS "assumed about 3 percent of spending would be delayed until individuals reach age 18…", 90 Fed. Reg. 59458, but did not provide any support for this extremely low estimate.

higher number in saved state Medicaid spending based on these other regulatory actions, which could impact transgender healthcare to Medicaid beneficiaries of any age. States will not spend money on this care through their Medicaid participation, but they will not save these funds either. The cost of transgender youth healthcare will be born fully by the states where care remains legal and available. Those costs more than offset the savings to states from not covering this care through Medicaid. And any "savings" would be further offset by the increased costs for other healthcare and expenses that states will incur when transgender youth lose access to clinically warranted, and in some cases lifesaving, healthcare. CMS did not try to estimate those costs or consider them as an offset to the projected savings.

b. CMS's RIA Must Estimate the Costs its Concurrent Regulatory Actions Will Impose on Providing Transgender Youth Healthcare Where Such Care Is Legal.

As discussed above, the states cannot anticipate the real-world costs and effects of HHS's concurrent regulatory actions if the agency does not explain how the Proposed Rule would function alongside the Conditions of Participation Proposed Rule and the Kennedy Declaration. Without clarity on the interaction of HHS's actions with each other and state law, states and all impacted stakeholders will have to spend time and money to attempt to understand the complete regulatory framework developed by HHS. They will also incur costs to ensure they are not acting unlawfully, in part because these actions propose different definitions and competing requirements, many of which would create potential conflicts with state law.

Trying to calculate the compliance costs is extremely difficult because states will have to navigate this complex web of federal regulations and state law to assess if compliance is even possible. Yet the RIA does not anticipate any time for state lawyers; agency program, policy, and administrative staff; and legislators and their staff to figure out how this unprecedented and complex set of federal rules and requirements works and whether it is legal. Similarly, patients and their families will incur costs navigating how to obtain healthcare consistent with the Kennedy Declaration and both Proposed Rules. CMS does not acknowledge this challenge. Nor does CMS anticipate the costs to healthcare providers who would be impacted by both Proposed Rules and the Kennedy Declaration. Providers will incur significant costs assessing how, if at all, they can continue to provide lawful transgender youth healthcare. They will expend resources consulting with attorneys, insurers, and professional licensing boards on how they can lawfully continue to practice medicine consistently with these agency actions and state law.

Finally, the RIA for this Proposed Rule and the Conditions of Participation Proposed Rule RIA rely on conflicting estimates that further complicate estimating the costs of complying with each Proposed Rule. Whereas the Conditions of Participation Proposed Rule declined to estimate the cost of care for patients living in states with restrictions on transgender youth healthcare, noting that the care in those states is not "significant," the RIA for this Proposed Rule asserts that "States that had not banned gender dysphoria treatments for children as of 2023 accounted for 76 percent of spending…" CMS thus in this Proposed Rule asserted that 24% of spending on transgender youth healthcare occurs in states with restrictions. This is either the result of a definitional tension between the analysis CMS offers 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 inconsistencies make it impossible for the states to assess the reasonableness of the cost estimates in the two proposed regulatory impact analyses HHS released on the same day.

c. The RIA Fails to Consider the Cost Effectiveness of Reasonable Alternatives to a Categorical Ban on Federal Reimbursement for Transgender Youth Healthcare.

CMS concedes in the RIA that it considered no regulatory alternatives to a categorical ban on federal reimbursement for transgender youth healthcare.[303] Among the alternatives the agency fails to consider in its cost benefit analysis are numerous alternative European approaches that afford broader protection for transgender youth healthcare, such as Spain[304] and Italy[305]; and the diversity of approaches adopted by the undersigned States,[306] that the preamble described.[307]

d. The Regulatory Flexibility Statement Is Dismissive of the Costs and Harms the Proposed Rule Imposes on Small Entities.

The Proposed Rule asserts, without any analysis, that "we estimate that almost all hospitals and other healthcare providers are small entities as that term is used in the RFA."[308] But HHS has done no analysis of which hospitals and other healthcare providers offer transgender youth healthcare, and whether those entities are in fact small entities as determined by the Regulatory Flexibility Act ("RFA") and relevant regulations, even though the RFA requires that the agency estimate the number of small entities to which the Proposed Rule will apply.[309] Rather than conduct that necessary, rigorous analysis, HHS instead merely assumed that all providers are small providers. By determining, without basis, that all providers are small providers, HHS spread the costs to actual small entity providers across all providers, regardless of their size. Their inclusion artificially deflates the change in revenue. CMS must calculate the economic impact on small businesses 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 not be used to disguise a significant impact on a subset."[310] The agency is permitted to rely on average impact only where "the economic impact is expected to be similar for all affected small entities, and if those entities have similar costs and revenues."[311] CMS's faulty calculations

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[303] *See* 90 Fed. Reg. 59441, 59549.

[304] 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 & Pepita Gimenez-Bonafe, *Comparative Study of Trans Healthcare Models in Catalonia*, 10 HELIYON 18 (Sept. 30, 2024).

[305] The Interdisciplinary Group for Gender Incongruence ("GIIG") model, employed by a healthcare center in Padua Italy, utilizes mental health support, medical and surgical treatments, screening programs, and regular follow-up to ensure treatment safety and efficacy. *See* Alberto Scala, et al., *Improving Care for Individuals with Gender Incongruence: Establishing a Multidisciplinary Approach in Italy*, 48 J. ENDOCRINOL INVEST., 8, 1839-1848 (June 6, 2025).

[306] *Supra* notes 263-66.

[307] *See* 90 Fed. Reg. at 59447-59459.

[308] 90 Fed. Reg. 59459.

[309] 5 U.S.C. § 603(3).

[310] *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services*, DEP'T OF HEALTH & HUMAN SERVS. 7 (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.").

[311] *Id*.

cannot support its conclusion that the Proposed Rule will not have a significant economic impact on small entities.

In addition to grossly underestimating the impact of the Proposed Rule on small entities, the Regulatory Flexibility Statement contains analytic failures that prevent CMS from accurately calculating the costs on small entities or considering alternatives that would minimize those costs. As noted above, CMS asserts that nearly all providers are small entities.[312] It calculates that the Proposed Rule will reduce revenue to affected small entities by $31.6 million, via reduced transfers from the federal government and state governments.[313] The Regulatory Flexibility Statement asserts that because this number is less than a 1% change in revenue for the small entities, the threshold of 3 to 5% change in revenue for a significant impact is not met.[314]

But this oversimplified analysis fails to address the actual effect of the Proposed Rule on healthcare providers. For example, many healthcare providers offer more than one service to their patients, and some patients see a single provider for all of their healthcare. Thus, providers of transgender youth healthcare often offer their patients healthcare that is unrelated to the transgender youth healthcare they provide, such as primary care services, emergency care, and mental healthcare. If those providers stop offering transgender youth healthcare to patients, those patients will likely also stop receiving other types of healthcare with that provider, thereby diminishing revenues from the federal and state governments for providers far more than the cost of transgender healthcare alone.

CMS's analysis also 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.[315] This Proposed Rule is likely to impose significant burdens in many of those categories upon impacted providers and small entities, but CMS failed to consider any of these measures.

Finally, the Proposed Rule fails to consider any impact it will have on healthcare providers in small practice settings that will experience enormous strain from immediate spikes in patient demand—often far greater than the practice is equipped to handle—if the Proposed Rule goes into effect. While these increased burdens challenge healthcare practices of all sizes, they are particularly burdensome for small practices that have far fewer patients, staff, and resources. 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.

CMS's Regulatory Flexibility Statement analysis makes no effort to account for these and other predictable effects of the rule. By limiting its analysis solely to the cost of transgender youth healthcare, the agency has not met its obligations under the Regulatory Flexibility Act.

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[312] *See* 90 Fed. Reg. 59459.
[313] *See id.* at 59461.
[314] *Id.* at 59461-62.
[315] *Supra* note 311, at 5.

VI. The Proposed Rule Fails to Comply with Executive Order 13132.

The Proposed Rule also fails to comply with Executive Order 13132.[316] The Proposed Rule acknowledges that it triggers EO 13132 because it "will have a substantial direct effect on the ability of States to receive federal Medicaid funds for sex-rejecting procedures furnished to children under age 18 and on the ability of States to receive Federal CHIP funds for sex-rejecting procedures furnished to children under age 19."[317] Despite acknowledging that the Proposed Rule triggers EO 13132, it blatantly violates the EO's procedural consultation requirements. EO 13132 specifically requires consultation with state and local officials "early in the process of developing the proposed regulation,"[318] 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."[319] HHS did not engage in any such consultation or discussion with state or local officials about whether the agency's objectives could be attained through other means. 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.

VII. Effective Date

In the Proposed Rule, CMS states that the costs in the RIA were projected based on an October 1, 2026, effective date.[320] It is not clear if this is the Proposed Rule's intended effective date. If it is, October 1, 2026, would not provide nearly enough time for CMS to consider and address the many significant deficiencies with the Proposed Rule.[321] And because the Proposed Rule is "significant," as determined by OIRA,[322] the Office has up to 90 days to review CMS's final rule and circulate it to other federal agencies.[323] After OIRA's review, CMS can publish the final rule but it cannot go into effect for at least 30 days following publication.[324] Given these statutory requirements, CMS would have about three months, or until June 1, 2026, to meaningfully review all comments, consider all substantial alternatives, and make necessary changes before its draft of the final rule would be due to OIRA for publication.

Even if CMS were able to address all concerns raised by commenters in that short period of time, CMS has not explained why an October 1 effective date outweighs other effective date alternatives.[325] As explained throughout this letter, the impact of this Proposed Rule on youth who receive transgender healthcare will be devastating—particularly for individuals who are already receiving such care.[326] Indeed, because of the health risks associated with the sudden cessation of transgender youth healthcare, even states that have legislated to ban or restrict transgender youth

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[316] Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999).

[317] 90 Fed. Reg. 59462.

[318] 64 Fed. Reg. 43258.

[319] *Id.* at 43256.

[320] 90 Fed. Reg. 59458.

[321] Agencies are required to respond to "significant" comments under the APA. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

[322] Exec. Order No. 12886, 58 Fed. Reg. 51735, 51742.

[323] *Id*.

[324] *See* 5 U.S.C. § 553(d); *Administrative Procedure Act: Legislative History*, S. Doc. No. 248, 79th Cong., at 201 (1946).

[325] *See supra* Section V.c ("Failure to consider any regulatory alternatives, let alone 'significant and obvious alternatives' . . . is enough to invalidate final agency action.").

[326] *Supra* Section I.c.

healthcare have enacted provisions that allow waivers or periods to taper off care for patients who currently receive treatment for gender dysphoria.[327] CMS has not explained why its Proposed Rule does not contain such a waiver provision or at the very least a period of time for patients to taper off their treatment under their providers' care to minimize risks. Further, CMS has given no indication of how much time states, patients, and entities will have after the effective date to comply with the Rule.[328] As such, medical providers and their patients are not able to appropriately plan whether and how to safely and ethically taper treatment.

The effective date would also not provide sufficient time for impacted entities, including state Medicaid agencies and providers, to implement the changes directed by the Proposed Rule. For example, states develop annual budgets and plan for agency funding statewide and at times set by statute. In states that wish to reallocate funding to continue to cover transgender youth healthcare, an October 1 effective date may not coincide with the culmination of that process. And many state agencies, including agencies that administer state Medicaid programs, would face administrative burdens related to adjusting to new systems, issuing new guidance, educating providers, and developing different claims, billing, and other procedures.[329] Medical providers would have to reassign their cases to mental healthcare providers, creating a shift in demand and resources in the transgender youth healthcare system. Because so many individuals and entities, including the undersigned States, will be impacted by Proposed Rule's drastic changes to the transgender youth healthcare landscape, the lack of a proposed effective date, and the assumption in the RIA that October 1 might be the effective date, is impractical and unreasonable.

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For all the reasons discussed in this letter, we oppose the Proposed Rule and request that the Secretary and CMS withdraw it. Banning the use of federal Medicaid and CHIP funds for an entire category of healthcare not only undermines the essential rights of youth living with gender dysphoria, it also interferes with the undersigned States' power to protect the health and safety of their citizens. If HHS can usurp states' authority to regulate transgender youth healthcare in this unlawful manner, the agency can unlawfully regulate any other clinically recommended healthcare nationwide.

Sincerely,

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[327] *Supra* Section III.c (discussing different approaches to regulating the provision of transgender healthcare for youth among the states). Among states that ban transgender healthcare, 18 states include either tapering or waiver provisions. *See* MOVEMENT ADVANCEMENT PROJECT, *Bans on Best Practice Medical Care for Transgender Youth, Table 1: Legislation/Regulations and Exceptions*, https://perma.cc/FPN7-K6N6.

[328] *See Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 449 (3d Cir. 2011) ("Among the purposes of the APA's notice and comment requirements are '(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.'") (quoting *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.,* 407 F.3d 1250, 1259 (D.C. Cir. 2005)).

[329] *Supra* Section V.a.iii.

William Tong
Attorney General of Connecticut

Kwame Raoul
Attorney General of Illinois

Andrea Joy Campbell
Attorney General of Massachusetts

Letitia James
Attorney General of New York

Nicholas W. Brown
Attorney General of Washington

Kris Mayes
Attorney General of Arizona

Rob Bonta
Attorney General of California

Philip J. Weiser
Attorney General of Colorado

Brian L. Schwalb
Attorney General of the District of Columbia

Kathleen Jennings
Attorney General of Delaware

Aaron M. Frey
Attorney General of Maine

Anthony Brown
Attorney General of Maryland

Dana Nessel
Attorney General of Michigan

Keith Ellison
Attorney General of Minnesota

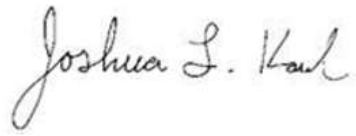
Aaron D. Ford
Attorney General of Nevada

Jennifer Davenport
Acting Attorney General of New Jersey

Dan Rayfield
Attorney General of Oregon

Peter Neronha
Attorney General of Rhode Island

Charity R. Clark
Attorney General of Vermont



Joshua L. Kaul
Attorney General of Wisconsin