February 17, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Submitted via https://www.regulations.gov/commenton/CMS-2025-1822-0001

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

Dear Administrator Oz:

GLBTQ Legal Advocates and Defenders ("GLAD Law")[1], the National Center for LGBTQ Rights ("NCLR")[2], and COLAGE[3] submit this comment opposing the Department of Health and Human Services' proposed amendments to the Centers for Medicaid and Medicaid Services' ("CMS'") Hospital Condition of Participation regulation ("proposed rule").[4] This proposed rule would prohibit hospitals from receiving any payments under Medicare or Medicaid for any patient if it provides transgender healthcare (what CMS terms "sex-rejecting-procedures"[5]) to any minor. CMS must withdraw the proposed rule because it is

[1] GLAD Law is a legal rights organization that works throughout New England and nationally to create a just society free of discrimination based on gender identity and expression, HIV status, and sexual orientation. We represent transgender youth and their families in access-to-care matters and regularly engage on Medicaid coverage, Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) compliance, and nondiscrimination in health programs.

[2] NCLR is a non-profit, public interest law firm that litigates precedent-setting cases at the trial and appellate court levels, advocates for equitable public policies affecting the lesbian, gay, bisexual, transgender and queer (LGBTQ) community, provides free legal assistance to LGBTQ people and their advocates, and conducts community education on LGBTQ issues since its founding in 1977.

[3] COLAGE is a national organization that unites people with one or more gay, bisexual, transgender and/or queer parents into a network of peers and supports them as they nurture and empower each other to be skilled, self-confident, and just leaders in our collective communities. For more than three decades, COLAGE has served individuals across generations and geographic regions, many of whom are transgender themselves, are parents of transgender children, or have transgender parents. Because our members and their families are directly affected by policies governing access to medically necessary transgender health care, COLAGE has a strong interest in this rulemaking.

[4] 90 Fed. Reg. 59463 (Dec. 19, 2025).

[5] The invented label "sex-rejecting procedures" has no grounding in clinical nomenclature and is inconsistent with other CMS usage for similar categories of care. For example, CMS' Market Integrity and Affordability Rule uses the term "specified sex-trait modification procedure." 90 Fed. Reg. 27074 (June 25, 2025), codified at 45 C.F.R. §§ 156.115 (Provision of EHB), 156.400 (Definitions). Inconsistent terminology across the federal government, much less a single federal agency, is bound to cause much confusion among recipients.

illegal and regulates the practice of medicine in a manner that will harm adolescents and families.

The various harms to young people and their families that will result if the proposed rule is adopted are manifold[6] and while scantly addressed, even CMS' own estimates in the preamble recognize that the proposed rule would result in the disruption of thousands of existing doctor-patient relationships. CMS estimates thousands of families would experience at least $7 million in costs in the first year as they locate and switch to new healthcare providers. CMS itself acknowledges these numbers are probably an underestimation of the costs to these families from the proposed regulation.[7]

In addition, according to CMS' own estimates, thousands of youth who are currently receiving transgender healthcare at hospitals would no longer be able to receive this care at all because there are no alternative providers available in their regions.[8] While CMS treats the absence of continued care as cost savings, it fails to offer any estimate of the nonquantitative costs that result from the abrupt termination of medically necessary care.

The proposed rule is an unprecedented exercise of federal authority about a matter that has traditionally, and intentionally, been left to the states: the practice of medicine. Although CMS claims this is just another "Condition of Participation" authorized by the Medicare statute, the proposed rule shares nothing in common with the health and safety Conditions of Participation that have been adopted over the past 60 years. Conditions of Participation have long addressed facility processes, staffing, privileging, documentation, patient rights, and quality systems. They have not been used to impose nationwide, indication- and age-based prohibitions on recognized physician-led treatments for defined patient populations.

By conditioning a hospital's eligibility to be paid under Medicare or Medicaid on abstention from providing care that is routine, medically necessary, and otherwise ordered and delivered by licensed clinicians to a select group of patients, the proposed rule seeks to transform program participation standards into a vehicle for the national regulation of the practice of medicine rather than a neutral framework for hospital health and safety.

I. The proposed rule exceeds CMS' Medicare Act authority and unlawfully regulates the practice of medicine.

A. The proposed rule is not authorized by the Medicare Act.

Section 1801 of the Social Security Act (SSA) unequivocally forbids federal officers from exercising "*any* supervision or control over the practice of medicine or the manner in which

[6] *See* discussion *infra* Section III.
[7] 90 Fed. Reg. at 59474-75.
[8] *Id.* at 59474.

medical services are provided."[9] This prohibition echoes traditional federal-state division of authority, which reflect important federalism values. Federalism keeps regulatory decisions closer to affected populations. States face vastly different health challenges, demographics, resources, and values. Each state sets requirements for hospitals, physicians, nurses, and other professionals to practice within its borders. States have primacy over licensure, scope of practice, facility regulation, and patient-rights frameworks.[10] This creates accountability to local populations and allows standards to reflect state-specific priorities, States have exercised this authority to address in various ways the question of appropriate healthcare for transgender youth. Multiple states have adopted shield laws that protect lawful clinical services,[11] and even some states that have prohibited such care have adopted transitional safeguards, such as permitting the continuance of care for adolescents already in treatment.[12]

CMS identifies no unmistakably clear congressional authorization to use hospital participation standards to nationalize contested pediatric standards of care and override state licensure and patient-rights regimes. HHS relies on Section 1861 of the SSA as the basis to establish the regulation.[13] And, to be sure, Section 1861(e)(9) of the SSA defines the term "hospital" to mean an institution that "meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution."[14] But that kind of generic provision, embedded in the statutory definition, cannot be read outside the context of the provisions that precede it.

"[W]here, as here, a more general term follows more specific terms in a list, the general term is usually understood to embrace only objects similar in nature to those objects enumerated by the preceding specific words."[15] This is particularly true where Section 1861(e)(9) refers to "such other" requirements, signaling that the requirements that come before in subsections (e)(1)-(8) dictate the bounds of any authority in (e)(9). These preceding subsections show that CMS' (e)(9) authority embraces only administrative requirements or requirements that relate to the operation of the hospital – such as "provid[ing] 24-hour nursing service," "maintain[ing] clinical records on all patients," or having "bylaws in effect."[16] The unnumbered language following Section 1861(e)(9) likewise confirms the nature of such conditions: it anticipates "personnel requirements" and "fire and safety requirements" pursuant to (e)(9).[17] And the Supreme Court's decision in *Biden v. Missouri* simply permitted the agency to take steps under (e)(9) to ensure that hospital

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[9] 42 U.S.C. § 1395 (emphasis added).
[10] *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243 (2006).
[11] 90 Fed. Reg. at 59469-70 (citing *Equality Maps: Transgender Healthcare "Shield" Laws*, Movement Advancement Project, https://www.lgbtmap.org/equality-maps/healthcare/trans_shield_laws).
[12] 90 Fed. Reg. at 59470 (noting that 12 states provide tapering off periods while 10 have clauses primarily allowing adolescents to continue receiving treatment if they were already receiving it).
[13] *Id.* at 59464.
[14] 42 U.S.C. § 1395x(e)(9).
[15] *Epic Systems Corp. v. Lewis*, 584 U.S. 497, 512 (2018) (internal quotation marks omitted).
[16] 42 U.S.C. §§ 1395x(e)(2), (3), (5).
[17] *Id.* at §§ 1395x(e)(9)(B), (C),

employees were not exposing their patients to a contagious disease.[18] The Court did not suggest the agency could regulate the medical treatment of patients of the hospital.

Section 1861(e)(9) of the SSA does not authorize the CMS to exclude from participation in Medicare[19] any hospital that refuses to abide by categorical bans on entire classes of medical interventions for a defined diagnosis and age group. Yet the proposed rule does just that — it declares a recognized set of physician-ordered interventions harmful and ineffective for minors in hospital settings and forbids their use by hospitals participating in Medicare.[20] The proposed rule itself purports to rely on clinical evidence and ethics to justify its prohibition. Such quintessential medical judgments about standards of care cannot be recast to meet the permissible statutory bounds of Conditions of Participation requirements.

B. The proposed rule regulates the practice of medicine in violation of Section 1801.

The brazenly false and conclusory assertion in the preamble to the proposed rule that transgender healthcare for minors is "not healthcare" does not change the fact that the proposed rule seeks to regulate the practice of medicine.[21] By requiring medical professionals to curtail their practice when caring for clients with a diagnosis of gender dysphoria, CMS inserts itself into the clinical decision-making process. That is supervision over how medical services are provided and thus squarely within Section 1801's prohibition. Regardless of how CMS frames its action, by permitting care for one class of diagnoses while prohibiting it for another, it is engaging in impermissible regulation of the practice of medicine.

The architecture of the proposed rule further undermines the claim that the services at issue are "not healthcare." The proposed Conditions of Participation adopt novel definitions of "sex," "male," and "female," and define the prohibited category of care by clinical purpose, sweeping in puberty suppression, hormone therapy, and surgeries when performed to align traits with gender identity while allowing the same modalities for other indications. Implementation therefore depends on clinical appraisal of differential

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[18] 595 U.S. 87, 94 (2022) (per curiam) ("[T]he Secretary routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves. And the Secretary has always justified these sorts of requirements by citing his authorities to protect patient health and safety." (citations omitted)).

[19] This restriction also applies to hospitals that provide inpatient and outpatient services to Medicaid enrollees, which are required to meet the Medicare Conditions of Participation to participate in Medicaid. 42 C.F.R. §§ 440.10(a)(3)(iii) (inpatient services) and 440.20(a)(3)(ii) (outpatient services).

[20] *Id*.

[21] 90 Fed. Reg. at 59471.

diagnoses, indications, and psychosocial goals. Hospitals could not comply with the proposed rule without making medical judgments at the point of care.

C. The proposed rule's reliance on clinical judgments to justify a categorical prohibition confirms substantive regulation of the practice of medicine.

The preamble's core justification for the regulation is medical. It evaluates risk–benefit profiles,[22] invokes medical ethics,[23] critiques professional guidelines,[24] and concludes that a class of physician-ordered interventions lacks sufficient evidence of benefit and poses unacceptable risks for minors in hospital settings.[25] That is a blanket clinical conclusion that particular treatments should never be furnished to a defined population and is not a neutral facility judgment.

Further, the proposed design and enforcement mechanisms reinforce the conclusion that this rule is attempting to regulate the practice of medicine. As stated previously, the definitions and exceptions require clinicians to assess purpose and diagnosis at the bedside to determine whether an intervention falls within or outside the prohibition. Program-participation sanctions make these clinical judgments coercive by threatening termination from Medicare and Medicaid for hospitals that permit provision, compelling changes in privileging, order sets, and care pathways so that physicians cannot furnish a recognized modality for a particular diagnosis. These features demonstrate federal supervision over the manner in which medical services are provided, contrary to Section 1801.

II. The proposed rule fundamentally conflicts with Medicaid Act requirements for beneficiary access and provider participation.

The proposed rule cannot be reconciled with how Medicaid actually operates or the Act's statutory structure that governs provider participation and beneficiary access. By barring from Medicare and Medicaid hospital settings that states have relied on to meet pediatric needs, the rule converts approved coverage into illusory benefits and narrows beneficiary choice and rewrites provider eligibility in a manner the statute does not permit.

The proposed rule directly conflicts with Medicaid program operations approved by CMS. Many states cover the targeted services for minors under defined criteria and have centered delivery in hospital-based centers of excellence embedded in children's hospitals. By categorically prohibiting hospital provision of those covered services if the hospital wants to participate in Medicare, the proposed rule leaves those benefits as only

[22] 90 Fed. Reg. at 59465-67, 59470-71.
[23] *Id.* at 59465.
[24] *Id.* at 59465-70.
[25] *Id.* at 59470.

available on paper and forecloses the settings where pediatric capacity exists.

The proposed rule fails to address how states are to comply with Medicaid's State plan obligations[26] and network adequacy benchmarks[27] if hospital-anchored programs choose withdraw from Medicaid participation rather than comply with the proposed Condition of Participation. Nor does it reconcile the collision with beneficiaries' free-choice-of-provider protections.[28] The proposed rule would narrow beneficiary choice and indirectly redefine provider eligibility by excluding otherwise qualified and willing hospital providers for the act of providing routine medical care.

The proposal would also destabilize Medicaid State plans and delivery systems that CMS has approved and that center pediatric capacity in hospital-based programs. States use hospital-embedded Centers of Excellence to coordinate endocrinology, adolescent medicine, surgical subspecialties, pharmacy, and behavioral health for adolescents with complex needs. By foreclosing covered services in those settings, the rule would force states to reengineer networks on short notice, renegotiate managed-care contracts, and reroute referrals to an uncertain supply of non-hospital providers. The preamble's own assumptions — that many adolescents will stop care and that hospitals may need to create separate facilities — underscore the likelihood of access gaps and prolonged wait times.

These outcomes threaten compliance with network adequacy and timely access standards and are incompatible with beneficiaries' statutory right to obtain services from any qualified and willing provider. Maintaining coverage while disabling hospital-based providers who are most qualified to deliver care is inconsistent with program design and narrows practical access for low-income and rural families who rely on hospital-anchored networks.

III. The proposed rule reflects arbitrary and capricious decision-making.

Assuming CMS has the authority to engage in rulemaking in this area (which it does not), a federal agency acts arbitrarily when it fails to consider important aspects of the problem and offers explanations counter to the evidence. The proposed rule fails to engage in either of these requirements. It further compounds this omission by treating denial of care as a benefit and by assuming, without empirical grounding, that half of affected adolescents will cease treatment due to access barriers, while failing to account for offsetting costs associated with untreated or abruptly discontinued care. Further, the proposal relies

[26] *See generally*, 42 C.F.R. Part 431, Subpart B (State Medicaid Agency) (providing requirements such as comparability of service, free choice of provider); 42 C.F.R. Part 438, Subpart B (Managed Care) (same).
[27] 42 C.F.R. § 438.68.
[28] 42 U.S.C. § 1396a. Implementing regulations at 42 C.F.R. § 431.51(b)(1) require a state plan to allow a beneficiary to obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is (i) qualified to furnish services and (ii) willing to furnish them to that particular beneficiary.

primarily on a single departmental umbrella review[29] that offers no clinical or policy recommendations and treats that document as if it compelled a nationwide prohibition. It discounts contrary evidence and longstanding clinical guidance from mainstream professional organizations, and it selectively invokes foreign policy adjustments while ignoring calibrated approaches that add oversight or concentrate access in research settings.

Further, the proposed rule is procedurally flawed because the agency failed to engage in required consultation under Section 1863 of the Act. Specifically, when, as here,[30] the Secretary purports to "carry[] out" acts "relating to determination of conditions of participation of services, under subsection[] (e)(9)," the Secretary "*shall* consult with appropriate State agencies and recognized national listing or accrediting bodies."[31] The mandatory nature of the consultation requirement is confirmed because the sentence goes on to provide that the Secretary "may consult with appropriate local agencies." "When a statute distinguishes between 'may' and 'shall,' it is generally clear that 'shall' imposes a mandatory duty."[32]

It is well-settled that merely notifying persons of the opportunity to comment on an NPRM is not sufficient to meet a statutory obligation to "consult" with them.[33] There is no indication in the preamble or otherwise that the agency engaged in the "considerable consultation" required for a federal program that requires close cooperation between state and federal authorities,[34] and there is no justification offered for foregoing such consultations prior to issuing the NPRM.[35]

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[29] *U.S. Dep't of Health & Hum. Servs., Office of Population Affairs*, Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices (May 1, 2025), https://opa.hhs.gov/gender-dysphoria-report.
[30] 90 Fed. Reg. at 59464 (citing Section 1861(e)(9) as authority for the regulation).
[31] 42 U.S.C. § 1395z (emphasis added).
[32] *Kingdomware Technologies, Inc. v. United States*, 579 U.S. 162, 172 (2016); *see also Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 887 (D.C. Cir. 2024) (interpreting Medicare Act) ("And where a statute uses 'shall' in some provisions and 'may' in others, as § 1395ww does here, Congress likely used 'shall' to 'impose[ ] a mandatory duty' that is 'impervious to discretion.'").
[33] *See, e.g.*, *California Wilderness Coal. v. U.S. Dep't of Energy*, 631 F.3d 1072, 1087 (9th Cir. 2011) (statutory obligation to "consult" means "more than notice-and-comment"; agency must "confer" with relevant parties before undertaking a course of action); *Campanale & Sons, Inc. v. Evans*, 311 F.3d 109, 118 (1st Cir. 2002) (statutory requirement to consult "must mean something more than general participation in the public comment process;" "otherwise the consultation requirement would be rendered nugatory"); *Confederated Tribes & Bands of Yakima Indian Nation v. FERC*, 746 F.2d 466, 475 (9th Cir. 1984) (regulatory requirement to consult was not met merely by giving notice; "The consultation obligation is an affirmative duty.").
[34] *Evelyn V. v. Kings Cnty. Hosp. Ctr.*, 956 F. Supp. 288, 298 (E.D.N.Y. 1997) ("Not insignificantly given the cooperative aspect of these programs, the [Medicare] statute contemplates considerable consultation between federal and state authorities as the Secretary carries out these mandates.") (citing Section 1683).
[35] *Compare Biden v. Missouri*, 595 U.S. 87, 97 (2022) (when agency showed good cause for adopting interim regulation without notice-and-comment, "consultation during the deferred notice-and-comment process is permissible").

A. The impact analyses fail to adequately address harms and burdens caused by the proposed rule.

The analysis of paperwork burdens and economic effects is unsupported and fatally incomplete. By failing to account for the real-life impacts of foreclosing the provision of an entire field of physical healthcare altogether for a subset of minors, the regulatory impact analysis fails to provide a sufficiently accurate accounting by which the true costs of the proposed rule can be considered.

For example, the preamble estimates that a treating clinician can prepare a notice and answer questions in approximately one hour per patient. Ending active pediatric treatment plans typically requires record review, multidisciplinary consultation, development of alternative plans, consent discussions, tapering protocols where indicated, referral coordination, and monitoring for adverse effects across multiple encounters with substantial documentation, often including behavioral health integration.[36] The physician-only one-hour estimate is therefore unrealistic and understates the resources necessary to execute safe transitions.

The preamble's estimate for the total costs for healthcare providers to notify youth and their parents that they are no longer providing transgender healthcare is based on the assumption that the cost should be limited to those families that reside in states without restrictions on transgender healthcare.[37] This assumption is plainly incorrect. CMS reasons that the number of youth who reside in states that restrict transgender healthcare is not a "large number" based on the unfounded premise that youth enrolled in Medicaid or CHIP would not travel out of state to receive the transgender healthcare that they need and based on the driving times to the nearest clinic in a state without restrictions.[38]

Review-time and policy-updating costs for hospitals likewise are understated, because participation-level changes that touch patient rights, surgical services, medical records, and state-law coordination require extensive engagement from legal, compliance, clinical, information technology, and education teams, including electronic health record updates and training.

This economic analysis also does not consider the time and expense families are willing to spend to ensure their children receive the care they need. Relying on switching-cost estimates borrowed from primary-care contexts in assessing the cost families would experience under the proposed rule understates the reality of transitioning pediatric care, where networks are narrower, wait times longer, and therapeutic relationships more fragile.

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[36] *See., e.g.*, American Medical Association, *1.1.5 Terminating a Patient-Physician Relationship*, AMA Principles of Medical Ethics: I, VI (explaining that physicians have a fiduciary duty to their patients to support the continuity of care for their patients), https://code-medical-ethics.ama-assn.org/ethics-opinions/terminating-patient-physician-relationship.

[37] 90 Fed. Reg. at 59472-73.

[38] *Id.* at 59472.

If the proposed rule goes into effect, then these families will need to go to even greater lengths, incurring even greater expense, to find nonhospital providers for their children's care. The current state restrictions on transgender healthcare have already increased waitlists, caused concern about the continued ability to access care, families paying more attention to where they choose to live so that they can continue to access care. These backlogs and worries will only grow more severe if this proposed rule goes into effect. The preamble itself acknowledges that many adolescents will cease care due to access barriers.[39]

Further, the preamble vastly underestimates the possible costs involved because it inconsistently addresses the preemptive nature of the proposed rule. As the preamble acknowledges: "Nothing in this proposed rule prohibits or permits the basic legality of SRPs."[40] Instead, the proposed rule would "no longer … allow[] facilities that engage in [SRPs] to receive Medicare and Medicaid funds."[41] But later in the preamble, it asserts that the proposed rule "preempts the applicability of any state or local law providing for SRPs to the extent such law provides broader grounds for these procedures than provided for by" the proposed rule.[42]

It is not clear that Medicare has the preemptive effect CMS inconsistently claimed. It has been argued that federal government's authority under the Spending Clause does not extend to preempting state laws otherwise regulating private parties simply because that private party voluntarily accepts payments from the federal government.[43] Under that view, a hospital (other than a federally-operated hospital, such as those run by the Veterans Administration or the Department of Defense) located in a state is governed by the laws of that state, even if compliance with those laws makes the hospital ineligible to receive federal payments.

Approximately 30 percent of Medicare/Medicaid certified hospitals are located in the 17 states and D.C. that CMS identifies as having shield laws or executive orders protecting gender transition procedures.[44] Depending on the outcome of a preemption analysis, the proposed rule could mean that the almost 1500 hospitals located in those states (30

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[39] *Id.* at 59474.
[40] *Id.* at 59472.
[41] *Id.*
[42] *Id.* at 59476.
[43] *Cf. Moyle v. United States*, 603 U.S. 324, 357-358 (2004) (dissenting opinion of Alito, J., joined by Thomas, J., and Gorsuch, J.) ("The Government has not identified any decision holding that a federal law enacted under the Spending Clause preempts a state criminal law or public health regulation."); *id.* at 334 (concurring opinion of Barrett, J., joined by Roberts, C.J., and Kavanaugh, J.) (describing as a "difficult and consequential argument" whether "Congress, in reliance on the Spending Clause, can obligate recipients of federal funds to violate state criminal law").
[44] 90 Fed. Reg. at 59469-70 & n.68 (identifying States with shield laws or executive orders protecting these procedures); KFF, *Number of Medicare Certified Hospitals, by State (2023 timeframe)*, https://www.kff.org/medicare/state-indicator/number-of-medicare-certified-hospitals/.

percent of the 4,832 hospitals identified by CMS as Medicare/Medicaid certified)[45] will not be able agree to the conditions absent changes to state law. Exiting Medicaid is not a sustainable option for children's hospitals and safety-net institutions that depend on Medicaid reimbursement and that anchor state network adequacy; withdrawal would trigger contract terminations across managed care and fee-for-service, collapse access for all Medicaid patients served by those institutions and jeopardize the states' compliance with state and federal access and timeliness standards under Medicaid.

These are all costs of the proposed rule that CMS should have, but did not, address in the preamble.

B. Reliance on a deeply flawed, agency generated report is insufficient justification for this rulemaking.

Reliance on the HHS pediatric gender dysphoria report cannot justify the proposed exclusions and funding restrictions. The report was commissioned under an Executive Order aimed at ending transgender health care for minors and defunding related research,[46] and its development departed from scientific norms.[47] The initial publication named no authors, and more than one fifth of its references were drawn from lay media and social media rather than peer-reviewed literature, undermining transparency and credibility.[48] Leading medical organizations, including the American Academy of Pediatrics (AAP), immediately objected that the report misrepresents medical consensus, cites AAP policy inaccurately, and prioritizes opinions over a comprehensive review of the evidence.[49]

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[45] 90 Fed. Reg. at 59473 & n.89 (number of certified hospitals).
[46] Executive Order 14187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8771 (Jan. 28, 2025).
[47] Nadia Dowshen, et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, Journal of Adolescent Health (2025) at 1-2, https://www.jahonline.org/article/S1054-139X(25)00246-0/pdf.
[48] G. Nic Rider, et al., *Scientific Integrity and Pediatric Gender Healthcare: Disputing the HHS Review*, Sexuality Research and Social Policy (Oct. 13, 2025), https://link.springer.com/content/pdf/10.1007/s13178-025-01221-5.pdf.
[49] American Academy of Pediatrics (AAP), Press Release, AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria (May 1, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-hhs-report-treatment-for-pediatric-gender-dysphoria ("Patients, their families, and their physicians—not politicians or government officials —should be the ones to make decisions together about what care is best for them based on evidence-based, age-appropriate care"); American Psychological Association, APA Statement on Access to Treatment for Transgender, Gender Diverse, and Nonbinary People (May 1, 2025), https://updates.apaservices.org/statement-on-access-to-treatment-for-transgender-gender-diverse-and-nonbinary-people ("The lack of transparency regarding authorship, expertise, and methodology in the recent HHS report undermines scientific rigor and contradicts standards for evidence-based policymaking."); American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association, American Psychiatric Association, Leading Physician Groups Oppose Infringements on Medical Care, Patient-Physician Relationship (May 1, 2025), https://www.acponline.org/sites/default/files/acp-policy-library/statements/joint_statement_on_hhs_gender_affirming_care_report_2025.pdf ("[A]ll patients must

The report's methods and inferences are materially unsound.[50] It functions as an umbrella review that amplifies bias from prior contested reviews and over-relies on the Cass Review while failing to address detailed critiques of that review and even its own acknowledgment that medical interventions are appropriate for some adolescents.[51] It discounts longitudinal and cohort studies showing improvements in mental health, appearance congruence, life satisfaction, and reductions in depression, anxiety, and suicidality associated with transgender medical care, including multi-site health-system data demonstrating substantial reductions in suicidality-related hospital utilization among treated youth.[52] It grades benefits as "weak" largely because randomized trials do not exist, while disregarding the practical and ethical barriers to randomized control trials in this context and the fact that much of pediatrics relies on longitudinal and observational evidence of similar quality to guide care.[53] It also emphasizes hypothetical harms despite acknowledging "sparse" evidence of harm, even though puberty blockers and hormone therapies have long safety histories in other pediatric indications and are used within protocols that require individualized risk-benefit assessment and fertility counseling.[54]

The report mischaracterizes current standards of care and endorses practices at odds with ethical norms.[55] Contrary to the report's portrayal, established guidelines from professional societies describe a cautious, multidisciplinary model in which comprehensive biopsychosocial assessment and ongoing mental health care are foundational, and medical interventions are reserved for a subset of adolescents with persistent, clinically significant dysphoria after rigorous evaluation.[56] This stands in stark contrast to the systematic medical evidence review conducted on behalf of the Utah Department of Health and Human Services, which resulted in a report finding that hormonal transgender healthcare can be safely provided to youth experiencing gender dysphoria.[57]

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have access to evidence-based, comprehensive medical care, and that physicians must be able to practice medicine that is informed by their education, training, and experience without threat of criminalization."); American Medical Association and AAP, Press Release, AMA and AAP Joint Statement on Evidence-Based Health Care (Nov. 19, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/ama-and-aap-joint-statement-on-evidence-based-health-care/ ("We reject characterizations of our approach to gender-affirming care as negligent or ideologically driven, and take particular issue with the false assertion that our members have committed 'malpractice' or betrayed their oath in any way. These claims, rooted in politics and partisanship, misrepresent the consensus of medical science, undermine the professionalism of physicians, and risk harming vulnerable young people and their families.").

[50] Dowshen, et al., *supra* note 47, at 1-2.

[51] Rider, et al., *supra* note 48, at 2.

[52] Dowshen, et al., *supra* note 47, at 1.

[53] Rider, et al., *supra* note 48, at 2.

[54] Dowshen, et al., *supra* note 47, at 1.

[55] *Id.* at p. 2; Ian D. Wolfe et al., *7 Pediatric Bioethicists: Proposed Ban on Medicaid Funding for Hospitals Providing Gender-Affirming Care for Minors Is Deeply Unethical*, STAT (Jan. 30, 2026), https://www.statnews.com/2026/01/30/gender-affirming-care-why-experts-oppose-proposed-ban/.

[56] Dowshen, et al., *supra* note 47, at 1.

[57] University of Utah College of Pharmacy, Drug Regimen Review Center, Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria (Aug. 6, 2024) (prepared for the Utah Department of

The report promotes a psychotherapy-only approach despite acknowledging there is no evidentiary base that psychotherapy alone resolves adolescent gender dysphoria. It further platforms "gender exploratory therapy," which experts have described as a conversion-style practice aimed at steering youth toward not being transgender.[58] Such practices are widely considered unethical and are restricted or banned in many jurisdictions, including the District of Columbia,[59] creating a direct conflict between the report's recommendations and prevailing legal and ethical standards.

Because the proposed rule rests on a report that lacks scientific independence, misstates the evidence base, mischaracterizes clinical standards, and promotes ethically problematic practices, CMS should not rely on it to support Conditions of Participation or funding exclusions. At a minimum, CMS should withdraw or substantially revise the proposal, undertake a transparent and methodologically rigorous evidence review that meaningfully engages relevant professional societies, and align program policy with the conservative, multidisciplinary, evidence-informed standards that currently govern pediatric care.

IV. The proposed rule would result in impermissible coercion, prohibited under the Spending Clause.

The proposed rule presents hospitals with a false choice that amounts to unconstitutional coercion under the Spending Clause. Hospitals cannot realistically forgo Medicare and Medicaid participation — American Hospital Association data shows that 96 percet of hospitals derive at least half their inpatient revenue from these programs, with over 82 percent depending on them for two-thirds or more of patient days, all while receiving reimbursement rates below actual costs.[60] Conditioning continued access to this indispensable funding on the termination of evidence-based care for transgender youth exemplifies the coercive federal overreach the Supreme Court invalidated in *National*

Health and Human Services) (analyzing 134 primary clinical studies representing more than 28,000 transgender minors worldwide).

[58] *Id.* at 1; Rider, et al., *supra* note 48, at 3; *U.S. Dep't of Health & Hum. Servs., Substance Abuse & Mental Health Servs. Admin.*, Moving Beyond Change Efforts: Evidence and Action to Support and Affirm LGBTQI+ Youth (2023), https://storage.googleapis.com/trevor-web-public/2025/11/f6b47c66-samhsa-lgbtqia-youth-report.pdf.

[59] Twenty-three states and the District of Columbia currently ban licensed mental health professionals from subjecting minors to conversion therapy, through either statutes or statewide professional-licensing rules. Movement Advancement Project, "Equality Maps: Conversion Therapy Laws," https://www.lgbtmap.org/equality-maps/conversion_therapy. *But see*, *Chiles v. Salazar*, No. 24-539 (argued Oct. 7, 2025) (challenging Colorado's conversion therapy ban); *Cath. Charities of Jackson, Lenawee, & Hillsdale Ctys. v. Whitmer*, 162 F.4th 686 (6th Cir. 2025) (preliminarily enjoining Michigan's conversion therapy ban).

[60] American Hospital Association, *Fact Sheet: Majority of Hospital Payments Dependent on Medicare or Medicaid* (May 2024), https://www.aha.org/system/files/media/file/2022/05/fact-sheet-majority-hospital-payments-dependent-on-medicare-or-medicaid-congress-continues-to-cut-hospital-reimbursements-for-medicare.pdf.

Federation of Independent Business v. Sebelius, which held that Congress cannot employ financial pressure "so coercive as to pass the point at which pressure turns into compulsion."[61] The Court in *South Dakota v. Dole*,[62] similarly recognized that permissible conditions must amount to "relatively mild encouragement" rather than threats to essential funding streams.

The NPRM compounds this coercion by applying Conditions of Participation "regardless of payor" to institutions where "nearly all" participate in federal programs, effectively commandeering hospital-wide clinical policy rather than merely attaching conditions to federal dollars.[63] This "regardless of payor" provision transforms what might otherwise be a condition on federal funds into a de facto national mandate. Unlike traditional Spending Clause conditions that affect only federally-funded services, this proposed rule reaches private-pay patients, commercially-insured patients, and state-funded services that have no connection to federal Medicare or Medicaid dollars. A hospital that wishes to provide lawful, medically-indicated care to a privately-insured adolescent using private resources cannot do so without forfeiting all federal program participation — a consequence that bears no relationship to the federal funds at issue and that converts voluntary program participation into wholesale regulatory control. This regulatory overreach mirrors the unconstitutional conditions doctrine's prohibition on leveraging federal funds to regulate conduct beyond the scope of the federal program. The Supreme Court has repeatedly held that conditions on federal spending must be related to the federal interest in national projects or programs, yet the proposed rule extends federal control to every patient in a participating hospital regardless of funding source. Such expansive reach exceeds the permissible bounds of Spending Clause authority and effectively conscripts hospitals as instruments of federal policy enforcement across their entire operations.

V. Coordinated same-day HHS actions demonstrate impermissible animus rather than neutral program administration.

The proposed rule did not arise as an isolated health-and-safety measure but as part of a synchronized departmental campaign directed at a single population and a single category of physician-ordered care.[64] On the same day that CMS issued this proposed rule, the agency also unveiled a companion Medicaid proposed rule (Medicaid NPRM) that would deny Federal Financial Participation for the same defined set of purpose-based uses in minors.[65] The preamble to the proposed rule grounds its prohibition in an executive directive and a departmental umbrella review, recasts recognized modalities under a novel

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[61] 567 U.S. 519 (2012).
[62] 483 U.S. 203 (1987).
[63] 90 Fed. Reg. at 59464.
[64] Press Release, *U.S. Dep't of Health & Hum. Servs.*, HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children (Dec. 18, 2025) [hereinafter, HHS Press Release], https://www.hhs.gov/press-room/hhs-acts-bar-hospitals-performing-sex-rejecting-procedures-children.html.
[65] 90 Fed. Reg. 59441 (Dec. 19, 2025).

label and declares the targeted uses categorically inconsistent with hospital health and safety. The preamble to the Medicaid NPRM, released concurrently, relies on the same materials to withdraw federal matching funds for those uses, even where a clinician determines the service is medically necessary, while encouraging psychotherapy as a substitute and acknowledging that coverage withdrawal may "prevent or delay" care and prompt families to "look to obtain other insurance" or pay out of pocket.[66] Public messaging by the Department the very day of publication amplified that both actions were intended to bar hospitals from performing the defined interventions on youth,[67] underscoring that the thrust of the campaign was to eliminate access through overlapping pathways rather than to calibrate facility processes.

Internal cross-references across the two proposals confirm their coordinated design. The impact analysis in the proposed rule expressly states that its estimated effects "might be lower" if the Medicaid and CHIP prohibition is finalized first,[68] a candid admission that the rules are engineered to work in tandem. The Medicaid NPRM preamble likewise situates its prohibition within a yearlong sequence of departmental steps, including State Medicaid Director guidance and hospital letters seeking adverse-event data and financial disclosures, and then projects immediate cessation of federal reimbursement upon effectiveness.[69] That choreography — linking an across-the-board hospital participation bar with a simultaneous financing cut-off and coordinated communications — reads as a single project to extinguish access to care for individuals with a defined diagnosis and treatment purpose, not a neutral application of participation standards to remedy identified facility-level safety failures.

The terminology choices and the structure of the prohibitions reinforce the inference of animus. Both rules adopt a nonclinical label to define the targeted care by purpose, then carve out the very same drugs and procedures when used for other pediatric indications or to treat intersex conditions. In the preamble to the proposed rule, CMS defines "sex," "male," and "female" in reproductive terms and treats the targeted uses as categorically unsafe for minors in hospitals; in the preamble to the Medicaid NPRM, CMS relies on the same umbrella review to conclude that the targeted uses lack an adequate evidence base for youth and that psychotherapy should be favored, while simultaneously assuring coverage of identical interventions for other diagnoses. The effect is to disallow treatment when, and only when, the purpose is to address gender dysphoria, even as the agency preserves the modalities for non-transgender youth and other clinical contexts. That

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[66] *Id.* at 59449, 59459.
[67] HHS Press Release, *supra* note 64.
[68] 90 Fed. Reg. at 59475.
[69] *Id.* at 59450 (citing Letter from Drew Snyder, Deputy Administrator and Director, CMS, to State Medicaid Directors (Apr. 11, 2025), https://www.cms.gov/files/document/letter-stm.pdf and Mehmet Oz, Administrator, CMS, Memorandum regarding Urgent Review of Quality Standards and Gender Transition Procedures (May 28, 2025), https://www.cms.gov/files/document/hospital-oversight-letter-generic.pdf).

asymmetry functions as a diagnostic proxy while denying that any diagnosis-based distinction exists, a hallmark of pretext rather than principled health-and-safety regulation.

Contemporaneous descriptions of the rollout further reflect the agency's targeting posture. Coverage emphasized the Department's rapid, same-day release of multiple actions aimed at curtailing access to care for transgender adolescents, its unusual recasting of established modalities as outside the scope of "medicine" when used for a particular diagnosis, and its reliance on a single departmental review to justify categorical national bans while discounting contrary positions from mainstream medical organizations. Those features mirror what the preambles themselves reveal: synchronized timing anchored to an executive directive, novel terminology deployed to reframe clinical interventions for one group, explicit cross-references designed to ensure that hospital participation and financing prohibitions are mutually reinforcing, and a public narrative that counts denial of care as a regulatory good. In administrative law terms, the coordinated release, the disparate treatment of identical interventions across patient groups, and the integration of communications and rule text to target a defined population are classic indicia of bias and pretext. They confirm that the proposed rule advances an animating objective to prohibit a class of care for transgender youth, rather than to address any neutral, evidence-based deficiency in hospital participation standards.

Furthermore, HHS's actions reflect the administration's animus against transgender individuals and its coordinated effort across the federal government to end transgender healthcare for minors. For example, all of the federal district courts that have reviewed administrative subpoenas issued by the Department of Justice (DOJ) to healthcare providers seeking personal health information of minor patients receiving transgender healthcare have rebuked DOJ's attempts to enforce those subpoenas.[70] Several courts have held that these subpoenas were issued for the improper purpose of "pressuring providers to cease offering gender-affirming care rather than to investigate specific

[70] *See In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-mc-00041-JHC, 2025 WL 3562151, at *12 (W.D. Wash. Sept. 3, 2025); *Queerdoc PLLC v. U.S. Dep't of Just.*, No. 2:25-mc-00042, 2025 WL 3013568, at *7 (W.D. Wash. Oct. 27, 2025), *appeal docketed*, No. 25-7384 (9th Cir. Nov. 24, 2025); *In re Admin. Subpoena No. 25-1431-019*, No. 1:25-MC-91324-MJJ, 2025 WL 2607784, at *6 (D. Mass. Sept. 9, 2025), *appeal docketed*, No. 25-2092 (1st Cir. Nov. 14, 2025); *In re Subpoena No. 25-1431-014*, No. MC 25-39, 2025 WL 3252648, at *13 (E.D. Pa. Nov. 21, 2025); *In re 2025 UPMC Subpoena*, No. 2:25-mc-01069-CB, 2025 WL 3724705, at *2 (W.D. Pa. Dec. 24, 2025). *See also In re: Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063-SKC-CYC, 2026 WL 33398, at *4 (D. Colo. Jan. 5, 2026) (magistrate judge recommendation to the federal district court stating "the Subpoena never attempts to satisfy its burden as to limited scope" and that the subpoena's requests "which seek personal health data … are not, therefore, relevant in purpose to an [Federal Food, Drug, and Cosmetic Act] investigation").

unlawful conduct,"[71] and that "the government's demand for deeply private and personal patient information carries more than a whiff of ill-intent."[72]

Conclusion

The proposal repurposes hospital participation standards to impose a categorical, national clinical prohibition on a defined group of adolescents while redefining medical care as "not healthcare" to evade statutory constraints and minimizing the real-world harms from abrupt discontinuation and narrowed provider choice. Its legal theory, evidentiary foundation, preemption posture, and economic analysis are deficient, and its practical operation would upend Medicaid delivery systems and undermine beneficiaries' free-choice protections. CMS should withdraw the proposal in its entirety.

[71] *Queerdoc*, 2025 WL 3013568, at *7.
[72] *In re 2025 UPMC Subpoena*, 2025 WL 3724705, at *2.