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**Re: Medicare and Medicaid Programs: Hospital Condition of Participation:
Prohibiting Sex-Rejecting Procedures for Children (RIN 0938-AV87)**

Thank you for the opportunity to comment on the Centers for Medicaid and Medicare Services' (CMS) proposed rule regarding gender-affirming care¹—medical care for the treatment of gender dysphoria—for minors by Medicare and Medicaid-participating hospitals. *See* 90 Fed. Reg. 59463 (Dec. 19, 2025).

The undersigned are legal and social science scholars affiliated with the Williams Institute at the University of California, Los Angeles School of Law. The Williams Institute is dedicated to conducting rigorous and independent research on sexual orientation and gender identity law and public policy. Relevant to this comment, our portfolio of work includes extensive research and publications on transgender demographics, access to gender-affirming care, mental health, and well-being.² This work includes the collection of original data as well as

¹ We use the term “gender-affirming care” to describe these medical treatments, because this term is accurate in describing the purpose of the treatments and well-precedented in the field. This term “refers to being recognized or affirmed in [one’s] gender identity” via medical interventions. *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT’L J. TRANSGENDER HEALTH S1, S252 (2022). We are not aware of any prior use of the term “sex-rejecting procedures” in medicine, scientific research, laws, or regulations. The use of the term “rejection” indicates a value judgment about the purpose of the procedures. Using a novel and value-laden term to refer to an established field of medicine is suggestive of bias.

² *See, e.g.*, JODY L. HERMAN & ANDREW R. FLORES, WILLIAMS INST., HOW MANY ADULTS AND YOUTH IDENTIFY AS TRANSGENDER IN THE UNITED STATES? (2025), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pop-Update-Aug-2025.pdf>; ABBIE E. GOLDBERG & ELANA REDFIELD, WILLIAMS INST., THE EXPERIENCES OF GENDER-AFFIRMING CARE PROVIDERS IN STATES WITHOUT LAWS RESTRICTING ACCESS TO CARE (2025), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/GAC-Providers-Apr-2025.pdf>; ELANA REDFIELD ET AL., WILLIAMS INST., PROHIBITING GENDER-AFFIRMING MEDICAL CARE FOR YOUTH (2023), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Youth-Health-Bans-Mar-2023.pdf>; CHRISTY MALLORY & WILL TENTINDO, WILLIAMS INST., MEDICAID COVERAGE FOR GENDER-AFFIRMING CARE (2022), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender-Care-Dec-2022.pdf>; JODY L. HERMAN & KATHRYN O’NEILL, WILLIAMS INST., WELL-BEING AMONG TRANSGENDER PEOPLE DURING THE COVID-19 PANDEMIC (2022), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pulse-Toplines-Nov-2022.pdf>; JODY L. HERMAN & KATHRYN O’NEILL, WILLIAMS INST., SUICIDE RISK AND PREVENTION FOR TRANSGENDER PEOPLE: SUMMARY OF RESEARCH FINDINGS (2021), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Suicide-Summary-Sep-2021.pdf>; *see also* SANDY E. JAMES, JODY L. HERMAN, LAURA E. DURSO, AND RODRIGO HENG-LEHTINEN, EARLY INSIGHTS: A REPORT OF THE 2022 U.S. TRANSGENDER SURVEY (2024), https://transequality.org/sites/default/files/2024-02/2022%20USTS%20Early%20Insights%20Report_FINAL.pdf;

the analysis of federal and state government data. Our scholars also use existing government data and advanced statistical modeling to calculate population estimates of LGBT adults and youth, which we then use to estimate the number of LGBT people affected by laws and policies proposed or enacted in the United States.

CMS proposes adding a Condition of Participation (“CoP”) to their regulations that would require participating hospitals to refrain from performing procedures or providing medication for the treatment of gender dysphoria in transgender minors.³ Because our portfolio of work includes research on the experiences of transgender people and healthcare providers with transgender-related medical care, and because of our organization’s fundamental commitment to evidence-based policymaking, the Williams Institute is uniquely positioned to provide information and recommendations to CMS. For the reasons laid out in this comment, we believe the CMS’s proposed rule is inconsistent with the objective application of evidence-based standards and likely violates principles of federalism. We respectfully ask CMS to consider the evidence presented below.

I. The Proposed Rule Is Inconsistent with Evidence-Based Policymaking

The proposed rule is subject to several constraints, including the fundamental expectation that policy governing U.S. healthcare – including the conditions under which hospitals receive federal funding – should be rational, constitutional, and evidence-based. This baseline principle of research and science is expressed throughout the statutory and constitutional requirements imposed upon agencies. The proposed change does not appear consistent with the vast body of evidence regarding gender-affirming treatments for minors, and therefore likely fails to meet these fundamental expectations.

A. Federal Agency Actions Must be The Product of ‘Reasoned Decisionmaking’

The Secretary of the Department of Health and Human Services (“HHS”) has the authority to prescribe regulations for Medicaid and Medicare that are necessary for the administration of the programs.⁴ This includes prescribing “conditions of participation” that hospitals must accept as a term of their receipt of funding.⁵ The proposed CoP would apply to Medicaid, Medicare, and CHIP:

SANDY E. JAMES, JODY L. HERMAN, ET AL., A REPORT OF THE 2015 U.S. TRANSGENDER SURVEY (2017), <https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf>.

³ 90 Fed. Reg. 59477-78.

⁴ 42 U.S.C. § 1395hh.

⁵ 42 C.F.R. §§ 482.1-.59.

- Medicaid is a need-based program providing healthcare coverage to low-income people and children in the United States.⁶ The program is funded by both federal and state monies.⁷ States that participate in Medicaid must comply with federal requirements, including with CoPs issued by CMS.⁸
- Medicare is a program providing healthcare coverage to people 65 years of age or older and people younger than 65 with certain disabilities.⁹ Medicare is funded by a variety of sources, though most of its funding can be attributed to government contributions, payroll taxes, and premiums paid by the individuals insured.¹⁰ CMS also issues CoPs to states participating in Medicare.¹¹
- The Children’s Health Insurance Program (CHIP) is a need-based program providing healthcare coverage to uninsured children who live in low-income families but whose income is too high to qualify for Medicaid.¹² To receive funding for this program, states must comply with the requirements under 42 U.S.C. §§ 1397aa et. seq.¹³

The Secretary must satisfy certain baseline criteria to ensure that agency actions, including the proposed CoP, are objective, reasonable, and evidence based. These principles are made clear in the Administrative Procedure Act and the Evidence Act.

The Administrative Procedure Act (APA) governs the regulation-making procedures that federal agencies must follow, and grants federal courts oversight over all agency actions.¹⁴ The APA's provisions are designed to ensure due deliberation and fairness in agency actions.¹⁵ Described by the senator who co-sponsored the bill as “a bill of rights for the hundreds of thousands of Americans whose affairs are controlled or regulated,” the APA ensures public

⁶ Robin Rudowitz et al., *Medicaid 101*, KAISER FAM. FOUND. (Oct. 8, 2025), <https://www.kff.org/medicaid/health-policy-101-medicare/?entry=table-of-contents-introduction>.

⁷ *Id.*

⁸ *Id.*; *Conditions for Coverage (CfCs) & Conditions of Participation (CoPs)*, CTRS. MEDICARE & MEDICAID SERVS. (Sept. 10, 2024, 6:21 PM), <https://www.cms.gov/medicare/health-safety-standards/conditions-coverage-participation>.

⁹ SOC. SECURITY ADMIN., MEDICARE 1 (2026), <https://www.ssa.gov/pubs/EN-05-10043.pdf>.

¹⁰ Juliette Cubanski et al., *Medicare 101*, KAISER FAM. FOUND. (Oct. 8, 2025), <https://www.kff.org/medicare/health-policy-101-medicare/?entry=table-of-contents-what-is-medicare>.

¹¹ CTRS. MEDICARE & MEDICAID SERVS., *supra* note 8.

¹² Robin Rudowitz, Samantha Artiga & Rachel Arguello, *Children’s Health Coverage: Medicaid, CHIP and the ACA*, KAISER FAM. FOUND. (Mar. 26, 2014), <https://www.kff.org/affordable-care-act/childrens-health-coverage-medicare-chip-and-the-aca/>.

¹³ See Alison Mitchell, *Federal Financing for the State Children’s Health Insurance Program (CHIP)*, CONG. (May 23, 2018), <https://www.congress.gov/crs-product/R43949>.

¹⁴ 5 U.S.C. §551-9; see also *Summary of the Administrative Procedure Act*, U.S. ENV’T PROT. AGENCY (July 9, 2025), <https://www.epa.gov/laws-regulations/summary-administrative-procedure-act>.

¹⁵ *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001) (quoting *Smiley v. Citibank (s.D.)*, N.A., 517 U.S. 735, 741 (1996)).

transparency, input, and accountability in the rulemaking process.¹⁶ Courts reviewing agency actions under the APA will examine the agency’s justification to ensure it is not, *inter alia*, “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”¹⁷

The touchstone of “arbitrary and capricious” review is whether the action was the product of “reasoned decisionmaking.”¹⁸ To meet this threshold, agencies must “examine the relevant data and articulate a satisfactory explanation for its action, including a ‘rational connection between the facts found and the choices made.’”¹⁹ A reviewing court must “consider whether the decision was based on consideration of the relevant factors and whether there has been a clear error of judgment.”²⁰ Although “a court may not set aside an agency’s policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration’s priorities,”²¹ agencies are nonetheless expected to “examine the relevant data,”²² act in good faith,²³ and—fundamental to the questions raised by the proposed CoP— must not ignore evidence simply just because it runs counter to their position.²⁴

Additionally, federal agencies, including HHS, are subject to the Foundations for Evidence-Based Policymaking Act of 2018 (the Evidence Act).²⁵ Designed to remedy the

¹⁶ Virginia Huth, *Celebrating the 75th anniversary of the Administrative Procedure Act*, U.S. GEN. SERV. ADMIN. (June 11, 2021), <https://www.gsa.gov/blog/2021/06/11/celebrating-the-75th-anniversary-of-the-administrative-procedure-act>.

¹⁷ 5 U.S.C. § 706(2)(A).

¹⁸ *Altera Corp. & Subsidiaries v. Cmm’r.*, 926 F.3d 1061, 1081 (9th Cir. 2019), citing *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983) [hereinafter *State Farm*].

¹⁹ 5 U.S.C. § 706; *State Farm*, *supra* note 18, at 43 [internal citations omitted].

²⁰ *State Farm*, *supra* note 19, at 43 [internal citations omitted].

²¹ *See generally* *DOC v. New York*, 588 U.S. 752, 756 (2019) (Regarding efforts to add a citizenship question to the Decennial Census: “It is hardly improper for an agency head to come into office with policy preferences and ideas, discuss them with affected parties, sound out other agencies for support, and work with staff attorneys to substantiate the legal basis for a preferred policy. Yet viewing the evidence as a whole, this Court shares the District Court’s conviction that the decision to reinstate a citizenship question cannot adequately be explained in terms of DOJ’s request for improved citizenship data to better enforce the Voting Rights Act”).

²² *See, e.g., State Farm*, *supra* note 18, at 43 (“Normally, an agency rule would be arbitrary and capricious if the agency...entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before it, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” [emphasis added])

²³ *See* *DOC v. New York*, *supra* note 21, at 75 (“[a court] may inquire into the ‘mental processes of administrative decisionmakers’ upon a ‘strong showing of bad faith or improper behavior.’” [internal citations omitted]).

²⁴ *State Farm*, *supra* note 18, at 43; *see also* *Genuine Parts C. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (when considering a claim under 5 U.S.C. § 706(2)(A), “in their application to the requirement of factual support, the substantial evidence test and the arbitrary and capricious test are one and the same...an agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence...an agency cannot ignore evidence contradictory to its position” [internal citations omitted]); *Landry v. FDIC*, 204 F.3d 1125 (D.C. Cir. 2000) (resolving a dispute under the “substantial evidence” standard, “it is well established that the substantial evidence rule requires consideration of the evidence on *both* sides; evidence that is substantial viewed in isolation may become insubstantial when contradictory evidence is taken into account.”)

²⁵ *Implementing the Foundations for Evidence-Based Policymaking Act at the U.S. Department of Health & Human Services*, OFF. ASSISTANT SEC’Y PLAN. & EVALUATION, <https://aspe.hhs.gov/topics/data/evidence-act-0> (last visited Feb. 10, 2026).

problem federal agencies face when they “lack the data and evidence necessary to make critical decisions about program operations, policy, and regulations,” the law builds on existing federal policy and infrastructure to “advance data and evidence-building functions in the Federal Government by statutorily mandating Federal evidence-building activities, open government data, and confidential information protection and statistical efficiency.”²⁶ In compliance with the Evidence Act, the Biden administration implemented the Federal Evidence Agenda for LGBTQ Equity, which included a substantial commitment by HHS to understanding transgender health needs and implementing evidence based policies to meet those needs.²⁷

By contrast, on the first day of the new administration, President Trump issued an executive order announcing that transgender and nonbinary people would no longer be recognized by the federal government.²⁸ The Biden-era executive order creating the LGBTQ+ Evidence Agenda was also rescinded, and agencies (including HHS) quickly began removing transgender-specific data from most federally-administered surveys and data collections, pulling down federal websites and resources documenting transgender and nonbinary experiences (including research on transgender health), and most federal research grants for transgender health needs were abruptly discontinued.²⁹

The Administration’s complete abandonment of Evidence Act protocols – including many by HHS – must be considered when reviewing CMS’s proposed CoP and the evidence it relies upon. Rigorous and systematic collection of data on a national scale is a powerful tool that can be used increase the certainty of research findings, maximize understanding, and provide the best quality evidence for policymaking regarding gender-affirming care.³⁰ New research from Australia demonstrates this: in a recent study discussed below, researchers were able to analyze

²⁶ Memorandum from Russel T. Vought to Heads of Executive Departments and Agents (July 10, 2019) (<https://www.whitehouse.gov/wp-content/uploads/2019/07/M-19-23.pdf>).

²⁷ SUBCOMMITTEE ON SEXUAL ORIENTATION, GENDER IDENTITY, AND VARIATIONS IN SEX CHARACTERISTICS (SOGI) DATA, NAT’L SCI. & TECH. COUNCIL, FEDERAL EVIDENCE AGENDA ON LGBTQI+ EQUITY (2023), <https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/01/Federal-Evidence-Agenda-on-LGBTQI-Equity.pdf>; Exec. Order No. 14075, 87 Fed. Reg. 37189 (June 21, 2022); Adrian Shanker & Melissa Korniejczuk, *Collecting Data on Sexual Orientation and Gender Identity: A Promising Practice for Improving Population Health and Advancing Health Equity*, PUB. HEALTH REPS. (2024).

²⁸ Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, Exec. Order No. 14168, 90 Fed. Reg. 8615 (Jan. 30, 2025).

²⁹ Initial Rescissions of Harmful Executive Orders and Actions, Exec. Order No. 14148, 90 Fed. Reg. 8237 (Jan. 28, 2025); Angela Watercutter, *Researchers Rush to Save US Government Data on Trans Youth—Before It Disappears*, WIRED (Mar. 21, 2025, 5:30 AM), <https://www.wired.com/story/researchers-rush-to-save-data-on-trans-youth-before-it-disappears/>; Theresa Gaffney, *CDC Will No Longer Process Transgender Data*, STAT NEWS (Feb. 25, 2025), <https://www.statnews.com/2025/02/25/cdc-will-no-longer-process-transgender-data/>; Sara Reardon, *New NIH Grant Terminations Target Transgender Studies—Even in Mice*, SCI. (Mar. 6, 2025, 2:30 PM), <https://www.science.org/content/article/new-nih-grant-terminations-target-transgender-studies-even-mice>.

³⁰ See Sari L. Reisner, et al., *Advancing Methods for US Transgender Health Research*, 23 CURRENT OP. ENDOCRINOLOGY, DIABETES & OBESITY 198 (2016) (describing the types of research needed to better understand the effects of gender-affirming care, including “four main systematic approaches: 1) general population-based, 2) health systems-based, 3) clinic-based, and 4) venue-based.”).

twelve years of public health data collected from approximately 32,000 individuals – an enormous sample –to evaluate effects of gender-affirming care on mental health care utilization.³¹ The current U.S. Administration’s categorization of evidence of the effects of gender-affirming care as “low-quality,” as discussed below, must be understood in conjunction with the Administration’s intentional destruction of data on transgender health and choice to discontinue efforts to improve evidence quality using proven methods that were already underway.

B. The Proposed CoP is Based on Evidence That Is Not Objective, Comprehensive, or Reliable

CMS has curated an evidence base in support of its proposed actions. However, there are several reasons why this base of evidence does not support the intervention proposed by CMS. First, the evidence relied upon by CMS is flawed and raises substantial concerns about bias and reliability. Second, a more comprehensive review of evidence shows substantial benefits of access to gender-affirming care for transgender youth. Third, CMS fails to discuss or apparently consider the potential harms caused by the denial of gender-affirming care to transgender minors. Finally, CMS fails to weigh collateral consequences: denial of care for transgender adults, the risks of disrupting the entire healthcare system, and the preclusion of future research to properly assess and understand risks and benefits and improve the overall base of knowledge about transgender health and well-being.

1. The Evidence Base Relied Upon by CMS Is Flawed and Raises Substantial Concerns

a. HHS Has Not Applied Scientific Principles Objectively Regarding Gender-Affirming Care for Minors

Much of the Administration’s policymaking on gender-affirming care began with an executive order. Executive Order (E.O.) 14187, “Protecting Children from Chemical and Surgical Mutilation,” characterizes gender-affirming medications and surgeries as “mutilation,” broadly describes the entire body of existing research on benefits and harms as “junk science” (before the review of such evidence had taken place), and categorically rejects the international standards of care for treating transgender people.³²

³¹ See generally Karinna Saxby et al., *Mental Health Treatment Among Transgender and Gender Diverse People Following Gender Affirming Hormone Therapy: Evidence from Whole-of-Population Australian Administrative Data*, *ECLINICALMEDICINE* 103765 (2026).

³² Protecting Children from Chemical and Surgical Mutilation, Exec. Order No. 14187, 90 Fed. Reg. 8771 (Feb. 3, 2025).

As directed by the executive order, HHS produced a subsequent review of evidence that aligns with the ideological statements in the order.³³ The panel of individuals that conducted the HHS Review did not include any clinicians that actively provide gender-affirming care, or researchers who study gender-affirming care, from a neutral or supportive perspective.³⁴ In fact, the authors of the report were openly partisan: eight of nine authors of the HHS review have a public history of opposition to gender-affirming care.³⁵ The authors include a co-founder of the “Society for Evidence-Based Gender Medicine” – an organization dedicated to undermining the evidence base for gender-affirming care³⁶ – and the author of “Trouble with Gender: Sex Facts, Gender Fictions,” an outspoken critic of gender-affirming care.³⁷ The composition of the panel and the predetermination of the findings in the report have raised critical questions about intellectual conflicts of interest, bias, and lack of objectivity.³⁸

In contrast to the findings of the HHS Review, a 2024 nonpartisan review by independent researchers at the University of Utah (with expertise in pharmacoepidemiology and no prior

³³ EVGENIA ABBRUZZESE, DEP’T HEALTH & HUM. SERVS., TREATMENT FOR PEDIATRIC GENDER DYSPHORIA: REVIEW OF EVIDENCE AND BEST PRACTICES (2025), <https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf>; Protecting Children from Chemical and Surgical Mutilation, *supra* note 32, §§ 3(a)(ii); *see also* § 3(b) (“The Secretary of HHS...shall use all available methods to increase the quality of data to guide practices for improving the health of minors with gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion, or who otherwise seek chemical or surgical mutilation.”).

³⁴ *Id.* at 17-18.

³⁵ The authors of the report are Alex Byrne (see ALEX BYRNE, TROUBLE WITH GENDER: SEX FACTS, GENDER FICTIONS (2023)), Evgenia Abbruzzese (see Evgenia Abbruzzese, Stephen B. Levine & Julia W. Mason, *The Myth of “Reliable Research” in Pediatric Gender Medicine: A Critical Evaluation of the Dutch Studies-and Research That Has Followed*, 49 J. SEX & MARITAL THERAPY 673 (2023)); Dr. Farr Curlin (see Farr Curlin, *Transgender Treatments Distort the Purpose of Medicine*, WALL ST. J. (June 23, 2025), <https://www.wsj.com/opinion/transgender-treatments-distort-the-purpose-of-medicine-ccd6e513>); Moti Gorin (see Moti Gorin, *What Is the Aim of PEDIATRIC “Gender-Affirming” Care?*, 54 HASTINGS CTR. REP. 35 (2024)); Dr. Kristopher Kaliebe (see GENSPECT, *The PERFECT Storm Behind Social Media’s Impact on Children* (YouTube, Nov. 20, 2024), <https://www.youtube.com/watch?v=D1L2nfwYz1c>); Dr. Michael Laidlaw (see HERITAGE FOUND., *Medical Risks of Hormonal and Surgical Interventions for Gender Dysphoric Children* (YouTube, April 4, 2019), <https://www.youtube.com/watch?v=rYtGPLpW-g8>); Dr. Kathleen McDeavitt (see Kathleen McDeavitt, J. Cohn & Chan Kulatunga-Moruzi, *Pediatric Gender Affirming Care Is Not Evidence-Based*, 17 CURRENT SEXUAL HEALTH REPS. 11 (2025)); Leor Sapir (see Leor Sapir, *A Cause, Not a Cure*, CITY J. (May 10, 2022), <https://www.city-journal.org/article/a-cause-not-a-cure>); and Yuan Zhang. Mr. Zhang has not taken a public position on gender-affirming care but has made statements critical of institutions providing such care (see Yuan Zhang, @Real_YuanZhang, X (Oct. 9, 2025, at 1:36 PM), https://x.com/Real_YuanZhang/status/1976386241512996883?s=20).

³⁶ Teresa Gaffney, *Author of Reviews of Gender Affirming Care Decries ‘Egregious Misuse’ of the Findings to Justify Bans*, STAT NEWS (Sept. 22, 2025), <https://www.statnews.com/2025/09/22/evidence-based-medicine-gender-affirming-care-gordon-guyatt/>; *see also* SUSAN D. BOULWARE ET AL., BIASED SCIENCE: THE TEXAS AND ALABAMA MEASURES CRIMINALIZING MEDICAL TREATMENT FOR TRANSGENDER CHILDREN AND ADOLESCENTS RELY ON INACCURATE AND MISLEADING SCIENTIFIC CLAIMS 28-29 (2022), <https://files-profile.medicine.yale.edu/documents/98a6e83f-d1ac-4098-b67a-25be370aec2b>.

³⁷ BYRNE, *supra* note 35.

³⁸ Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. ADOLESCENT HEALTH 342 (2025).

involvement in transgender-related research) reached remarkably different conclusions about the evidence for pediatric gender-affirming care, relying on essentially the same studies:

“... the consensus of the evidence supports that the treatments are effective in terms of mental health, psychosocial outcomes, and the induction of body changes consistent with the affirmed gender in pediatric GD [gender dysphoria] patients. The evidence also supports that the treatments are safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer.”³⁹

The findings of the nonpartisan Utah report, and to some extent the findings of a similar report produced for the Louisiana legislature a few years prior,⁴⁰ stand in stark contrast to those of the HHS Review. Both reports acknowledge the known benefits of gender-affirming care, even as they discuss potential risks.⁴¹

b. “Low-Quality Evidence” Does Not Mean Bad Quality Healthcare

In curating its evidence base in compliance with Executive Order 14168, the authors of the HHS report relied upon by CMS employed what is known as the “GRADE” system for evaluating the quality of medical evidence.⁴² The term “quality” in this context has a very specific meaning: “quality of evidence is equivalent to certainty of evidence.”⁴³ Applying the system to research on gender-affirming care, HHS characterized a substantial amount of such research as “low-quality.”⁴⁴

However, even if a substantial portion of the evidence in support of gender-affirming care for minors was properly labeled “low-certainty” or “low quality” evidence, that is not a rational justification for restricting access to these treatments. Patients regularly seek and receive health care interventions supported by “low certainty” evidence, and gender-affirming care for minors is not unique in this regard. In fact, one of the GRADE system’s progenitors, Dr. Gordon Guyatt, led an open letter in August 2025 emphasizing the important distinction between “health care

³⁹ JOANNE LAFLEUR ET AL., UNIV. UTAH COLL. PHARMACY DRUG REGIMEN REV. CTR., GENDER-AFFIRMING MEDICAL TREATMENTS FOR PEDIATRIC PATIENTS WITH GENDER DYSPHORIA 90 (2024), <https://le.utah.gov/AgencyRP/reportingDetail.jsp?rid=636>.

⁴⁰ S. AMANDA DUMAS ET AL., LA. DEP’T HEALTH: BUREAU HEALTH SERVS. FIN. (2023) https://ldh.la.gov/assets/docs/LegisReports/HR158_2022RS_LDHRReport.pdf.

⁴¹ *Id.* at 15-19; *see generally* LAFLEUR ET AL., *supra* note 39.

⁴² *See* Gordon Guyatt, et al., *GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations*, 336 *BMJ* 924 (2008); 90 *Fed. Reg.* 59,465.

⁴³ TREATMENT FOR PEDIATRIC GENDER DYSPHORIA: REVIEW OF EVIDENCE AND BEST PRACTICES, *supra* note 33, at 84.

⁴⁴ *Id.* at 82-88.

based on low-certainty evidence” and bad quality health care, particularly as it applies to gender-affirming care:

“It is profoundly misguided to cast health care based on low-certainty evidence as bad care or as care driven by ideology, and low-certainty evidence as bad science. Many of the interventions we offer are based on low certainty evidence, and enlightened individuals often legitimately and wisely choose such interventions. Thus, forbidding delivery of gender-affirming care and limiting medical management options on the basis of low certainty evidence is a clear violation of the principles of evidence-based shared decision-making and is unconscionable. The appropriate use of our work is in ensuring patients receive needed care and in helping TGD patients and their clinicians in decision making.⁴⁵

In fact, the vast majority of medical interventions for conditions other than gender dysphoria—94% in one large-scale study⁴⁶—are not supported by evidence that would be considered “high-quality” under this system. The lack of “high-quality” evidence is particularly acute in pediatrics; few treatments would be offered to children if high-quality evidence was in fact a prerequisite.⁴⁷

Experts in gender-affirming care therefore contest the characterization of the evidence base for pediatric gender-affirming care – which remains supported by major American medical associations – as being uniquely “low-certainty” or “low-quality” as compared to other treatments.⁴⁸ Policies such as the proposed CoP and other restrictions on gender-affirming care based on this rationale are applying a different standard to gender-affirming care for minors than is applied to the vast majority of medical treatments, including other pediatric treatments.

⁴⁵ Gordon Guyatt, et al., *Systematic Reviews Related to Gender-Affirming Care*, MCMaster UNIV. HEALTH SCI., (Aug. 14, 2025), <https://hei.healthsci.mcmaster.ca/systematic-reviews-related-to-gender-affirming-care/>; Gaffney, *supra* note 36.

⁴⁶ Jeremy Howick et al., *Most Healthcare Interventions Tested in Cochrane Reviews Are Not Effective According to High Quality Evidence: A Systematic Review and Meta-Analysis*, 148 J. CLINICAL EPIDEMIOLOGY 160 (2022).

⁴⁷ Tjitske M. van der Zanden et al., *Off-Label, But On-Evidence? A Review of the Level of Evidence for Pediatric Pharmacotherapy*, 112 CLINICAL PHARMACOLOGY & THERAPEUTICS 1243 (2022).

⁴⁸ Dowshen et al., *supra* note 38; *Clarification of Evidence-Based Gender-Affirming Care H-185.927*, AM. MED. ASSOC. (2024), <https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%20H-185.927%22?uri=%2FAMADoc%2FHOD-185.927.xml>; Alyson Sulaski Wyckoff, *AAP Reaffirms Gender-Affirming Care Policy, Authorizes Systematic Review of Evidence to Guide Update*, AM. ACAD. PEDIATRICS (Aug. 4, 2023), <https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy>. In 2026, The American Medical Association concurred with a new position statement from American Society of Plastic Surgeons recommending that gender-affirming surgery be withheld from minors; the AMA remains supportive of other indicated gender-affirming medical care for minors. Notably, the American Society of Plastic Surgeons statement was developed without consulting the society's own expert Gender Surgery Task Force. AM. SOC'Y PLASTIC SURGEONS, POSITION STATEMENT ON GENDER SURGERY FOR CHILDREN AND ADOLESCENTS (2026), <https://www.plasticsurgery.org/documents/health-policy/positions/2026-gender-surgery-children-adolescents.pdf>; Theresa Gaffney, *Did the AMA Change Its Position on Surgery for Transgender Minors?*, STAT NEWS (Feb. 10, 2026), <https://www.statnews.com/2026/02/10/medical-societies-trans-care-minors-ama-asps/>.

c. *International Treatment Protocols Toward Transgender Minors Have Not Changed Substantially as a Result of “Low-Quality Evidence”*

CMS justifies the proposed change to the CoPs by stating that other nations have revised their treatment protocols and reversed practices due to low-quality evidence.⁴⁹ Rather than walking back previous practice, however, based on their assessment that the evidence base is uncertain, these health authorities have imposed limitations that allow gender-affirming medical care to be provided only in research settings and/or recommended that care be provided with caution, on a case-by-case basis.⁵⁰ CMS also acknowledges this fact in the proposed regulation, noting that no European countries entirely banned gender dysphoria treatment for minors.⁵¹

The prevailing international standards of care for treatment of transgender minors (The World Professional Association for Transgender Health (WPATH)’s Standards of Care), which the Administration officially rejected and described as “junk science” in Executive Order 14187,⁵² are in fact already consistent with the recommendation of some European health authorities that medical interventions for minors be considered only on a case-by-case basis. WPATH recommends that healthcare providers conduct a “comprehensive biopsychosocial assessment” to “individualize [their] care”, which may or may not ultimately involve prescribing medical intervention.⁵³ Where countries have restricted access to care to only research settings, they have done so because they assert that the balance of benefits and harms at a population level is uncertain, while recognizing that individual patients may benefit from access to gender-affirming medical interventions.⁵⁴ By contrast, the CoP proposed by CMS would prevent the research necessary to clarify the risk-benefit profile of various gender-affirming medical interventions and to identify the patients most likely to experience benefits or harms. Furthermore, as described below, it would harm those transgender youth who benefit from gender-affirming medical care.

⁴⁹ 90 Fed. Reg. at 59466-67.

⁵⁰ *Id.*; see Isak Gran et al., *Gender-Affirming Healthcare in the Nordic Countries: An Overview*, SCANDINAVIAN J. SURGERY (2025), <https://helda.helsinki.fi/server/api/core/bitstreams/a3f8ef1c-be09-4bc5-a2e1-a2addeb4b0fb/content>; see also NAT’L BD. HEALTH & WELFARE (SOCIALSTYRELSEN), CARE OF CHILDREN AND ADOLESCENTS, <https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330>; Hilary Cass, THE CASS REVIEW (2024), <https://cass.independent-review.uk/home/publications/final-report>. WITH GENDER DYSPHORIA: SUMMARY OF NATIONAL GUIDELINES (2022), <https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330>.

⁵¹ 90 Fed. Reg. at 59466.

⁵² Protecting Children from Chemical and Surgical Mutilation, *supra* note 24.

⁵³ Coleman et al., *supra* note 1, at S50-51.

⁵⁴ NAT’L BD. HEALTH & WELFARE (SOCIALSTYRELSEN), CARE OF CHILDREN AND ADOLESCENTS WITH GENDER DYSPHORIA: SUMMARY OF NATIONAL GUIDELINES (2022), *supra* note 46; Hilary Cass, THE CASS REVIEW (2024), *supra* note 46.

d. The Proposed CoP Does Not Substantiate Alleged Risks of Harms of Gender-Affirming Care for Minors

CMS additionally justifies its proposed CoP with reference to the HHS review’s assertion that “[t]he risks of serious impairment that PMT [pediatric medical transition] involves have not been shown to be justified”⁵⁵ and says that it is concerned about the “considerable” evidence of risks.⁵⁶ However, the HHS Review itself acknowledges that evidence of such harm is “sparse.”⁵⁷ Although the HHS review speculates on a range of potential harms to minors, it presents empirical evidence (i.e., from epidemiologic or experimental studies) for two such risks: that puberty suppression in minors is associated with temporary impairment of bone density development and potentially reversible infertility.⁵⁸ It also presents evidence that cross-sex hormone therapy in adults assigned female at birth is associated with increased cardiovascular risk;⁵⁹ however, it does not evaluate risks for minors receiving cross-sex hormone therapy nor compare the risk among transmasculine adults to the elevated cardiovascular risk that cisgender men experience relative to cisgender women until age 75.⁶⁰ CMS does not provide justification for the assertion that these known risks constitute serious impairment; but more importantly, they do not provide evidence that any known or hypothesized risks exceed those of other pediatric medical treatments.

2. A More Comprehensive Review of Evidence Shows Benefits to Gender-Affirming Care, Including for Youth

A more comprehensive review of the evidence demonstrates that for many transgender people, medical treatments such as puberty blockers, hormone therapy, and, in some cases, surgeries are associated with a decrease in gender dysphoria, anxiety, depression, and suicidality.⁶¹ Lack of access to these treatments is associated with increases in gender dysphoria, anxiety, depression, substance use, self-harm, and suicidality.⁶²

a. Evidence Shows That Gender-Affirming Care Alleviates Gender Dysphoria

Researchers have shown that access to gender-affirming care is associated with relief of gender dysphoria by aligning physical appearance with the individual’s gender identity

⁵⁵ ABBRUZZESE ET AL., *supra* note 33, at 246.

⁵⁶ 90 Fed. Reg. at 59470.

⁵⁷ ABBRUZZESE ET AL., *supra* note 33, at 13.

⁵⁸ *Id.* at 246.

⁵⁹ *Id.* at 126-27.

⁶⁰ Lori Mosca, Elizabeth Barrett-Connor & Nanette Kass Wenger, *Sex/Gender Differences in Cardiovascular Disease Prevention: What a Difference a Decade Makes*, 124 CIRCULATION 2145 (2011).

⁶¹ See Joshua Arrayales & Elana Redfield, Re: Request for Information Regarding Gender-Affirming Care for Minors 5-8 (Sept. 26, 2025) (<https://williamsinstitute.law.ucla.edu/wp-content/uploads/Comment-FTC-Sep-2025.pdf>).

⁶² *Id.* at fn. 80.

(“appearance congruence”).⁶³ In one longitudinal two-year study of 315 transgender youth, researchers measured significant increases in appearance congruence, positive affect, and life satisfaction after initiating hormone therapy.⁶⁴ At the same time, depression and anxiety significantly decreased.⁶⁵ Appearance congruence was associated with decreased anxiety and depression as well as increased positive affect and life satisfaction.⁶⁶ Starting gender-affirming care early was associated with larger improvements in mental health: participants who started hormone therapy in early puberty had higher levels of appearance congruence, positive affect, and life satisfaction and had lower levels of depression and anxiety compared to participants who started hormone therapy during later puberty.⁶⁷ In another one-year study of transgender youth, researchers found that after one year of hormone therapy, participants experienced significant reductions in body dissatisfaction, parental non-affirmation, and victimization.⁶⁸ Additionally, reductions in anxiety and depression were also found as the youth’s quality of life improved.⁶⁹ Another survey of 109 adolescent transgender patients found that patients with higher levels of appearance congruence were 2.25 times less likely to meet the diagnostic criteria for major depressive disorder compared to patients with lower levels of appearance congruence.⁷⁰

These findings in youth-specific studies mirror the findings from research on transgender people generally. For example, in a randomized trial comparing immediate versus delayed prescription of masculinizing hormone therapy, those who received hormones had significant decreases in gender dysphoria, depression, and suicidality after three months.⁷¹ In a survey of 697 transgender people from Georgia and California, transgender respondents who accessed more of their desired gender-affirming treatments showed lower levels of depression and anxiety compared to respondents who accessed fewer or none of their desired treatments.⁷² Additionally, individuals in that study who received extensive gender-affirming care also reported higher body-gender congruence and satisfaction with their body image compared to individuals who

⁶³ Madeline B. Deutsch, *Overview of Gender-Affirming Treatments and Procedures*, UNIV. CAL. S.F.: TRANSGENDER CARE (June 17, 2016), <https://transcare.ucsf.edu/guidelines/overview> (explaining that hormones and surgeries lead to the development of secondary sex characteristics which allow the individual’s appearance to align with their gender identity).

⁶⁴ Diane Chen et al., *Psychosocial Functioning in Transgender Youth After 2 Years of Hormones*, 388 NEW ENG. J. MED. 240, 243, 244 (2023).

⁶⁵ *Id.* at 244.

⁶⁶ *Id.* at 243.

⁶⁷ *Id.* at 245.

⁶⁸ Priya Chelliah, May Lau & Laura E. Kuper, *Changes in Gender Dysphoria, Interpersonal Minority Stress, and Mental Health Among Transgender Youth After One Year of Hormone Therapy*, 74 J. ADOLESCENT HEALTH 1106, 1109 (2024).

⁶⁹ *Id.*

⁷⁰ Gia Chodzen et al., *Minority Stress Factors Associated With Depression and Anxiety Among Transgender and Gender-Nonconforming Youth*, 64 J. ADOLESCENT HEALTH 467, 468, 470 (2019).

⁷¹ Brendan J. Nolan et al., *Early Access to Testosterone Therapy in Transgender and Gender-Diverse Adults Seeking Masculinization: A Randomized Clinical Trial*, 6 J. AM. MED. ASS’N NETWORK OPEN e2331919 (2023).

⁷² Ashli A. Owen-Smith et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J. SEXUAL MED. 591, 594, 596 (2018).

received less or no gender-affirming treatments.⁷³ Another study of 287 transgender and nonbinary people found that those who reported that their external appearance better reflected their gender identity were less likely to report symptoms of disordered eating.⁷⁴

b. Evidence Shows that Gender-Affirming Care Can Improve Mental Health

In addition to directly treating gender dysphoria, several studies document the benefits that gender-affirming care has on overall mental health.

Many transgender people personally report that their experiences with gender-affirming care are positive and that care has improved their well-being. In the 2022 United States Transgender Survey, 98% of all respondents who were receiving hormone therapy reported that gender-affirming care left them more satisfied with their life and 97% of those who received gender-affirming surgery said the same.⁷⁵ One study using data from the U.S. Transgender Survey found that those who had received gender-affirming hormones or surgery showed a decreased prevalence of suicide attempts within the last year compared to those who wanted but could not access gender-affirming care (5.1% vs. 8.5%).⁷⁶

Because the U.S. Transgender Survey asks respondents when they began receiving gender-affirming care, some studies have used the data to analyze outcomes for respondents who began gender-affirming care at younger ages. Using 2015 data from the U.S. Transgender Survey, one study found that adults who obtained puberty blockers as adolescents were less likely to report suicidal ideation throughout their lifetime compared to adults who had not obtained puberty blockers.⁷⁷ A study using rigorous econometric methods compared the risk of suicide attempts among youth who began hormone therapy earlier versus later, finding that initiation of hormones was associated with a 14% reduction in the risk of subsequent suicide attempts.⁷⁸ Another study which used the same data found that individuals who received gender-affirming care as adolescents showed significant decreases in suicidal ideation, binge drinking,

⁷³ *Id.* at 594.

⁷⁴ Blair Uniacke et al., *Predictors of Eating-Related Psychopathology in Transgender and Gender Nonbinary Individuals*, 42 *EATING BEHAVS.* 101527, 2, 3-4 (2021).

⁷⁵ SANDY E. JAMES ET AL., NAT'L CTR. TRANSGENDER EQUAL., 2022 U.S. TRANS SURVEY EARLY INSIGHTS 18 (2024).

⁷⁶ Jody Herman et al., *Effect of Gender Transition-Related Health Care Utilization on Suicidal Thoughts and Behaviors: Findings from the 2015 U.S. Transgender Survey (2017)* (presented at APHA 2017 Annual Meeting & Expo).

⁷⁷ Jack L. Turban et al. *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145 *PEDIATRICS* e20191725, 4 (2020).

⁷⁸ Travis Campbell et al., *Hormone Therapy, Suicidal Risk, and Transgender Youth in the U.S.* 4-5 (2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4277148.

illicit drug use, and distress compared to people who did not receive gender-affirming care, or did not receive it until they were adults.⁷⁹

Other studies using different data sources have made similar conclusions regarding the positive mental health impacts of gender-affirming care. One study with 104 transgender and nonbinary youth found that those who received gender-affirming care had 60% lower odds of having moderate to severe depression and 73% lower odds of self-harm or suicidal thoughts compared to youth who had not received gender-affirming care.⁸⁰ Youth who did not access gender-affirming care showed a significant increase in moderate to severe depression and self-harm or suicidal thoughts after three months and six months, respectively.⁸¹ Likewise, a recent publication from the Trevor Project following over 1,500 LGBTQ youth longitudinally found that for transgender and nonbinary participants, access to hormones and puberty blockers was independently associated with subsequent reductions in depression.⁸² Furthermore, access to hormones was independently associated with a reduction in suicidal ideation.⁸³ In a cohort study of 342 U.S. adults initiating hormones via telehealth, depression and anxiety were significantly reduced after three months of treatment, with almost one-third of those who initially had depression or anxiety achieving remission.⁸⁴

By improving mental health, access to gender-affirming care may also reduce the use of mental health care. A study of over 32,000 individuals receiving gender-affirming hormone therapy over 12 years in Australia – one of the largest and most rigorous studies ever conducted about the effects of gender-affirming care – found that while mental health care use rose initially (consistent with guidelines recommending mental health assessment and support during gender-affirming care initiation), it declined sharply afterwards and remained lower after five years, including among youth aged 15-24.⁸⁵

⁷⁹ Jack L. Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, 17 PLOS ONE e0261039, 3, 8 (2022) ("In post hoc analyses, access to GAH during adolescence (ages 14–17) was associated with lower odds of past-year suicidal ideation (aOR = 0.7, 95% CI = 0.6–0.9, p = .0007) when compared to accessing GAH during adulthood.").

⁸⁰ Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5 J. AM. MED. ASS'N NETWORK OPEN e220978, 6 (2022).

⁸¹ *Id.*

⁸² RONITA NATH ET AL., TREVOR PROJECT, PROJECT SPARK INTERIM REPORT: A LONGITUDINAL STUDY OF RISK AND PROTECTIVE FACTORS IN LGBTQ+ YOUTH MENTAL HEALTH (2023-2025) 37 (2025), https://storage.googleapis.com/trevor-web-public/2025/10/b2829ba6-tp_2025_longitudinalreport.pdf.

⁸³ *Id.* at 39.

⁸⁴ Jae Downing Corman et al., *Mental Health Changes in US Transgender Adults Beginning Hormone Therapy Via Telehealth: Longitudinal Cohort Study*, 27 J. MED. INTERNET RSCH. e64017 (2025).

⁸⁵ Karinna Saxby et al., *Mental Health Treatment Among Transgender and Gender Diverse People Following Gender Affirming Hormone Therapy: Evidence from Whole-of-Population Australian Administrative Data*, ECLINICALMEDICINE 103765 (2026).

3. CMS Fails to Consider the Potential Harms to Transgender Minors if the CoP is Implemented

Although CMS hypothesizes the potential for harms to transgender minors if they are able to receive care in its justification for the proposed CoP, it does not sufficiently examine the risks to transgender minors if they cannot obtain gender-affirming care, or are forced to discontinue gender-affirming care.⁸⁶ Evidence suggests that denial of access to treatments that are shown to improve wellbeing, and increased stress and worry that accompany those denials, would constitute substantial harms that should be factored into CMS's determination as to whether to enact this proposed CoP.

a. Denial of Gender Affirming Care Affects a Substantial Number of Transgender Minors

There are 2.8 million transgender people aged 13 and older in the U.S.⁸⁷ Approximately 3.3% of 13-to-17-year-olds in the US identify as transgender, representing 724,000 youth.⁸⁸ Williams Institute scholars estimate that approximately half of transgender youth in the U.S. aged 13-17 (360,800) live in a state where they can currently access gender-affirming care when prescribed; that is, they live in states without a state-level prohibition.⁸⁹ Of those, the majority (285,300) live in a state where access to such care is protected by a "shield" law,⁹⁰ and many live in states where Medicaid laws or policies cover gender-affirming care.⁹¹

The number of transgender minors who access the types of treatments that would be prohibited by the proposed CoP is difficult to estimate, but it is likely low compared to the overall number of transgender youth in this age group. Because of the individualized nature of treatment for gender dysphoria and typical application of conservative evaluation criteria, puberty blockers, hormone therapy, or surgeries are not part of treatment for most transgender adolescents.⁹² Additionally, as CMS tacitly acknowledges, the state-level restrictions affecting half of transgender youth aged 13-to-17 in the U.S. likely result in fewer youth being able to access them.⁹³ Research using billing records has consistently found that the overall utilization of these gender-affirming treatments among minors is low relative to the number of transgender

⁸⁶ 90 Fed. Reg. at 59475.

⁸⁷ HERMAN & FLORES, *supra* note 2.

⁸⁸ *Id.*

⁸⁹ JOSHUA ARRAYALES & ELANA REDFIELD, WILLIAMS INST., THE IMPACT OF 2025 ANTI-TRANSGENDER LEGISLATION ON YOUTH 8 (2026), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/2025-Anti-Trans-Legislation-Jan-2026.pdf>.

⁹⁰ *Id.* at 29-30. "Shield" laws protect providers, families and patients from out-of-state laws attempting to regulate gender-affirming care.

⁹¹ *Medicaid Coverage of Transgender-Related Healthcare*, MOVEMENT ADVANCEMENT PROJECT, <https://www.lgbtmap.org/equality-maps/medicaid> (last visited Feb. 12, 2026).

⁹² Coleman et al., *supra* note 1, at S50; 90 Fed. Reg. at 59465, 59472.

⁹³ 90 Fed. Reg. at 59472.

youth in that age group.⁹⁴ Accordingly, CMS’s estimate that 9,851 transgender individuals under the age of 18 could lose access to these treatments as a result of as a result of the CoP is not unreasonable.⁹⁵ Even though individual utilization of these treatments is low when considering the entire population of transgender youth, the denial of potentially effective treatments for gender dysphoria to nearly 10,000 individuals is still a substantial consideration.

Additionally, the use of these same treatments for conditions other than gender dysphoria, at any age including infancy, does not violate CMS’s proposed rule.⁹⁶ CMS proposes to permit intersex individuals to undergo the same procedures it is trying to prohibit transgender youth from obtaining.⁹⁷ Unlike gender-affirming medical interventions for transgender youth, these treatments are typically performed on intersex minors without their assent, with consequent risk of harm.⁹⁸ Therefore, professional associations and international human rights standards recommend deferring non-medically-necessary “normalizing” procedures until intersex minors can actively participate in the informed consent process.⁹⁹

b. Lack of Access to Gender-Affirming Care May Directly Undermine the Well-Being of Transgender Minors Who Need It

As described above, studies show that both transgender youth and adults have better mental health outcomes when they have access to care, including reduced gender dysphoria, lower anxiety, depression, and suicidality, and increased gender concordance and feeling of wellbeing. The same research also supports the inverse: transgender youth and adults have worse outcomes when they lack access.

Of particular concern is the risk of suicidality. Studies have found high rates of suicidal ideation among transgender youth. Among the transgender people who responded to the 2015 United States Transgender Survey and who had attempted suicide, 34% made their first attempt at age 13 or younger, and 39% had made their first attempt between the ages of 14 and 17.¹⁰⁰ In a 2019 study by the Centers for Disease Control and Prevention, researchers found that, within the

⁹⁴ *Id.*; Landon D. Hughes et al., *Gender-Affirming Medications Among Transgender Adolescents in the U.S., 2018-2022*, 179 J. AM. MED. ASS’N PEDIATRICS 342 (2025); Dannie Dai et al., *Prevalence of Gender-Affirming Surgical Procedures Among Minors and Adults in the US*, 7 J. AM. MED. ASS’N NETWORK OPEN e2418814 (2024); *see also* 90 Fed. Reg. at 59472; HERMAN & FLORES, *supra* note 2.

⁹⁵ 90 Fed. Reg. at 59472.

⁹⁶ 90 Fed. Reg. 59477-78.

⁹⁷ *Id.* at 59471.

⁹⁸ Sara A. Mar et al., *Intersex Exceptions in US Laws Restricting Medical Care for Transgender Minors*, MEDRXIV (2025), <https://www.medrxiv.org/content/10.1101/2025.04.22.25326142v1.full>.

⁹⁹ *Genital Surgeries in Intersex Children*, AM. ACAD. FAM. PHYSICIANS (Oct. 2023), <https://www.aafp.org/about/policies/all/genital-surgeries.html>; U.N. HUM. RTS. COUNCIL, 55/14 COMBATING DISCRIMINATION, VIOLENCE, AND HARMFUL PRACTICES AGAINST INTERSEX PERSONS (2024), <https://docs.un.org/en/A/HRC/RES/55/14>.

¹⁰⁰ SANDY E. JAMES ET AL., NAT’L CTR. TRANSGENDER EQUAL., THE REPORT OF THE 2015 U.S. TRANSGENDER SURVEY 115 (2017), <https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf>.

last 12 months, 43.9% of transgender students considered attempting suicide, and 16.5% attempted it.¹⁰¹ Accordingly, evidence suggests that policies that reduce the risks of suicidality better serve the needs of transgender youth.

c. Denial of Access to Gender-Affirming Care May Increase Stress Among Transgender Minors

For those who require medical treatment for their gender dysphoria, the denial of access can lead to increased stress. This is sometimes described as “minority stress” and is a type of stress experienced by minority populations, such as transgender people, when exposed to stressful conditions that are unique to that population.¹⁰² For example, while losing a job is a stressor for many, losing a job due to gender identity discrimination is a minority stressor experienced by transgender people.¹⁰³ The Institute of Medicine has recognized the minority stress model as a key perspective for understanding the health of LGBT populations.¹⁰⁴ Research has shown that minority stress is associated with negative health outcomes in transgender people, including increased depression, anxiety, and suicidality risk.

Denial of healthcare is recognized as a form of major discrimination that contributes to poor health in minority populations;¹⁰⁵ thus, being denied gender-affirming care may contribute to minority stress. Indeed, using data from the 2015 United States Transgender Survey, scholars from the Williams Institute found that transgender people who were denied care by a provider in the past year were more likely to report suicidal thoughts (68.2% vs. 47.2%) and suicide attempts (18.8% vs. 6.8%) within the past 12 months.¹⁰⁶ Using the same data, a different study found that healthcare discrimination related to gender identity was associated with higher odds of misusing prescription drugs.¹⁰⁷ Additionally, lack of access to gender-affirming care increases the

¹⁰¹ Michelle M. Johns et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students – 19 States and Large Urban School Districts, 2017*, 68 MORBIDITY & MORTALITY WKLY. REP. 67 (2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6803a3-H.pdf>. However, the survey did not include any questions about gender-affirming care, so a direct relationship cannot be studied.

¹⁰² David M. Frost & Ilan H. Meyer, *Minority Stress Theory: Application, Critique, and Continued Relevance*, 51 CURRENT OP. PSYCH. 101579, 1; see also Walter Bockting et al., *Adult Development and Quality of Life of Transgender and Gender Nonconforming People*, 23 CURRENT OP. ENDOCRINOLOGY, DIABETES & OBESITY 188 (2016).

¹⁰³ Meyer & Frost, *supra* note 102.

¹⁰⁴ INST. MED., THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING 20 (2011), <https://www.ncbi.nlm.nih.gov/books/NBK64806/>.

¹⁰⁵ Ayden I. Scheim & Greta R. Bauer, *The Intersectional Discrimination Index: Development and Validation of Measures of Self-Reported Enacted and Anticipated Discrimination for Intercategorical Analysis*, 226 SOC. SCI. & MED. 225 (2019).

¹⁰⁶ JODY L. HERMAN, TAYLOR N.T. BROWN & ANN P. HAAS, WILLIAMS INST. SUICIDE THOUGHTS AND ATTEMPTS AMONG TRANSGENDER ADULTS: FINDINGS FROM THE 2015 U.S. TRANSGENDER SURVEY 24 (2019), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Suicidality-Transgender-Sep-2019.pdf>.

¹⁰⁷ Jeremy D. Kidd et al., *Prevalence and Minority-Stress Correlates of Past 12-Month Prescription Drug Misuse in a National Sample of Transgender and Gender Nonbinary Adults: Results from the U.S. Transgender Survey*, 219 DRUG & ALCOHOL DEPENDENCE 108474, 2, 4 (2021).

likelihood that a transgender person will be perceived as transgender by others (due to discordance between their social gender presentation and sex characteristics), which can increase exposure to further stigma and discrimination.¹⁰⁸ Research has found that individuals who were earlier in their transition process or who had not started hormone therapy perceived that others would react negatively toward them more frequently.¹⁰⁹

As most state-level bans on gender-affirming care for minors were implemented in 2023 or later, evidence for potential population-level mental health effects of such bans is still accumulating. However, research has confirmed that laws and policies limiting access to gender-affirming care have caused transgender people across the United States to worry.¹¹⁰ As a result of the 2024 election outcome, 73% of transgender people surveyed were concerned that the quality of their healthcare would worsen.¹¹¹ In a 2024 survey from the Trevor project, 61% of transgender and nonbinary youth respondents currently receiving hormones reported being somewhat or very concerned about losing access to their care.¹¹²

The worry and anxiety transgender people experience around the potential loss of gender-affirming care can result in adverse impacts on both mental and physical health. For example, in a 2023 study of 113 transgender youth and adults examining how news about gender-affirming care legislation was impacting them, researchers found a significant relationship between news consumption and persistent and unwanted thoughts regarding recent legislation.¹¹³ Researchers also found a significant relationship between news consumption and physical health.¹¹⁴ Perceived support for the legislation by people in one's social networks was also associated with increases in rumination and physical health symptoms.¹¹⁵ Respondents were invited to share

¹⁰⁸ Lisa R. Miller & Eric Joy Denise, *The Social Costs of Gender Nonconformity for Transgender Adults: Implications for Discrimination and Health*, 30 Socio. F. 809 (2015); Jaclyn M. White Hughto, Sari L. Reisner & John E. Pachankis, *Transgender Stigma and Health: A Critical Review of Stigma Determinants, Mechanisms, and Interventions*, 147 SOC. SCI. & MED. 222, 225, 228 (2015).

¹⁰⁹ Brian A. Rood et al., *Expecting Rejection: Understanding the Minority Stress Experiences of Transgender and Gender-Nonconforming Individuals*, 1 TRANSGENER HEALTH 151, 158 (2016).

¹¹⁰ See Megan S. Pacey et al., *The Perceived Health Implications of Policies and Rhetoric Targeting Transgender and Gender Diverse Youth: A Community-Based Qualitative Study*, 8 TRANSGENER HEALTH 100 (2023); George B. Cunningham, Nicholas M. Watanabe & Erin Buzuvis, *Anti-Transgender Rights Legislation and Internet Searches Pertaining to Depression and Suicide*, 17 PLOS ONE e0279420 (2022); Roberto L. Abreu et al., *Impact of Gender-Affirming Care Bans on Transgender and Gender Diverse Youth: Parental Figures' Perspective*, 36 J. FAM. PSYCH. 643 (2022).

¹¹¹ ABBIE E. GOLDBERG & BRAD SEARS, WILLIAMS INST., THE IMPACT OF ANTI-TRANSGENDER POLICY AND PUBLIC OPINION ON TRAVEL AND RELOCATION 12 (2025), <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Moving-May-2025.pdf>.

¹¹² RONITA NATH ET AL., TREVOR PROJECT, 2024 U.S. NATIONAL SURVEY ON THE MENTAL HEALTH OF LGBTQ+ YOUNG PEOPLE 10 (2024), https://www.thetrevorproject.org/survey-2024/assets/static/TTP_2024_National_Survey.pdf.

¹¹³ Lindsay Y. Dhanani & Rebecca R. Totton, *Have You Heard the News? The Effects of Exposure to News About Recent Transgender Legislation on Transgender Youth and Young Adults*, 20 SEXUALITY RSCH. & SOC. POL'Y 1345, 1349 (2023).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

their personal descriptions of their experiences with gender-affirming care. One respondent shared, “I would kill myself without gender affirming care, it’s the only thing worth living for: the potential that some day I might be able to be myself.”¹¹⁶ Similarly, a quasi-experimental study found that passage of state laws restricting transgender rights in 2019-2020 was associated with an increase in depression and suicide-related internet searches.¹¹⁷

These effects have also been reported by providers of gender-affirming care. A 2025 study by Williams Institute scholars surveyed gender-affirming care providers in states that had not enacted gender-affirming care restrictions with the goal of assessing how restrictions in other states were impacting their practice.¹¹⁸ Nearly three-quarters of providers (72%) said their youth clients were increasingly worried about their ability to continue care, and 42% said their youth clients had concerns about the privacy and security of their medical information related to gender-affirming care.¹¹⁹ Increasing restrictive legislation in other states caused 81% of gender-affirming care providers to report an increase in stress, 77% reported increases in anxiety symptoms, and 53% reported increases in depressive symptoms.¹²⁰

d. Psychotherapy Is Not a Sufficient Substitute for Existing Treatment Protocols

CMS proposes that transgender minors who may lose access to puberty blockers, hormones or other treatments as a result of the proposed CoP “may choose new forms of treatment such as psychotherapy.”¹²¹ However, the HHS Review acknowledges there is “no evidence on the effect of psychotherapy on [gender dysphoria] itself.”¹²² Moreover, psychotherapy may not be a viable option for many who are not already able to access it. Research shows that within states that have more restrictive legislation for transgender people also have lower rates of mental health providers that serve transgender adolescents.¹²³ If these regulations are enacted, because of the influx of patients who will need mental health services, transgender youth who already lack access to mental health services are likely to struggle even more as transgender youth across the country compete for services that can help address their specific needs.

¹¹⁶ *Id.*

¹¹⁷ Cunningham, Watanabe & Buzuvis, *supra* note 110, at 10-11.

¹¹⁸ GOLDBERG & REDFIELD, *supra* note 2.

¹¹⁹ *Id.* at 17.

¹²⁰ *Id.* at 22.

¹²¹ 90 Fed. Reg. at 59475.

¹²² ABBRUZZESE ET AL., *supra* note 33, at 94.

¹²³ Nathan L. Hollinsaid, Maggi A. Price & Mark L. Hatzenbuehler, *Transgender-Specific Adolescent Mental Health Provider Availability is Substantially Lower in States with More Restrictive Policies*, 53 J. CLINICAL CHILD & ADOLESCENT PSYCH. 828, 833 (2024).

4. CMS Fails to Consider the Collateral Consequences of the Proposed CoP

Narrowly, compliance with the proposed CoP could lead to direct denial of treatments for the 9,851 transgender individuals CMS estimates may have benefitted from accessing those treatments via hospitals. However, aspects of the new CoP could affect any of the 360,800 transgender youth aged 13-to-17 living in a state where they are currently permitted to access the care. Broadly speaking, compliance by hospitals with the proposed CoP could also have the collateral consequence of making gender-affirming care inaccessible or poorer in quality for any of the 2.1 million transgender adults living in the U.S., if hospitals are unable to sustain the staffing, training, and resources to sustain specialization.

Conversely, CMS should not underestimate the potential impact of disruption to general medical care in the U.S as a result of attempts to enforce this rule against hospitals it suspects of noncompliance. There are over 6,000 hospitals in the U.S., which rely heavily on Medicaid and Medicare to provide services to millions of patients.¹²⁴ For example, the American Hospital Association found that more than 34 million people were admitted to hospitals in its 2023 survey.¹²⁵ An analysis by KFF found that in 2023, Medicaid accounted for 19% of all funding for hospitals, and Medicare made up 25%.¹²⁶ Even minor disruptions to service as a result of this CoP could have broad reaching effects for all patients who rely on hospitals for medical care.

This risk is particularly acute for children's hospitals. The Children's Hospital Association estimates that children's hospitals provide care for 50% of all children in the U.S., and 50% of patients in children's hospitals rely on Medicaid.¹²⁷ The Administration has already targeted children's hospitals in its efforts to prevent transgender youth from accessing gender-affirming treatments.¹²⁸ Efforts to exclude these providers from key sources of federal funding altogether could have devastating consequences.

¹²⁴ *Fast Facts on U.S. Hospitals, 2026*, AM. HOSPITAL ASS'N (Feb. 2026), <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹²⁵ *Id.*

¹²⁶ Scott Hulver et al., *5 Key Facts About Medicaid and Hospitals*, KAISER FAM. FOUND. (Mar. 5, 2025), <https://www.kff.org/medicaid/5-key-facts-about-medicaid-and-hospitals/>.

¹²⁷ *5 Eye-Opening Data Points About Children's Hospitals*, CHILDREN'S HOSPITAL ASS'N (Aug. 19, 2025), <https://www.childrenshospitals.org/news/cha-blog/2025/08/5-data-points-about-childrens-hospitals>.

¹²⁸ Press Release, U.S. Dep't of Just.: Off. of Pub. Affs., Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children (July 9, 2025) (<https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical>); Ana B. Ibarra, *Feds Drop Effort to Get Trans Patients' Records from LA Children's Hospital*, CALMATTERS (Jan. 24, 2026), <https://calmatters.org/health/2026/01/childrens-hospital-transgender-patients-california/>.

C. A Comprehensive Review of Evidence Does Not Support the Proposed CoP

Here, CMS has proposed to exclude hospitals from participation in Medicaid, Medicare, and CHIP programs if they provide gender-affirming treatments to minors. CMS relies on a base of evidence that was curated in response to the political directive and by researchers with well-documented animus toward the provision of gender-affirming care, and that applies standards of quality, safety, and efficacy to gender-affirming care that inexplicably diverge from those routinely applied to nearly every other type of health care. Most notably, the evidence cited by CMS excludes or gives little weight to a substantial body of social science research regarding the health benefits of gender-affirming care and completely fails to address evidence of the harms to transgender youth who may no longer be able to access gender-affirming care as a result of the proposed CoP. Finally, CMS also fails to consider the effects that enforcement of this CoP could have on any and all patients who rely on hospitals for medical care. Accordingly, the proposed CoP is inconsistent with fundamental principles of objective, evidence-based policymaking.

II. The Proposed CoP Is Inconsistent with Principles of Federalism

The Administrative Procedure Act requires courts to find agency action unlawful when they are “contrary to constitutional right, power, privilege, or immunity,” or “in excess of statutory jurisdiction, authority, or limitations...”¹²⁹ Pursuant to the Supreme Court decision in *Loper Bright v. Raimondo* (2023), agency interpretations of statutory authority are no longer afforded deference when their actions are subject to judicial review.¹³⁰

As federal-state programs authorized under the Spending Clause of the U.S. Constitution, Medicaid, Medicare, and CHIP must comport with the basic principles of federalism.¹³¹ Most centrally, the federal government may not compel recipients of federal grants to agree to coercive policies as a condition of receiving federal funding.¹³² One traditional expression of

¹²⁹ 5 U.S.C. § 706(2)(B); 5 U.S.C. § 706(2)(C).

¹³⁰ *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024).

¹³¹ “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.” U.S. CONST. amend. I.; Bryan L. Adkins et al., *Federalism-Based Limitations on Congressional Power: An Overview*, CONG. (Jan. 31, 2023), <https://www.congress.gov/crs-product/R45323>; Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 10, 1999); Robin Rudowitz et al., *Medicaid 101*, KAISER FAM. FOUND. (Oct. 8, 2025), <https://www.kff.org/medicaid/health-policy-101-medicaid/?entry=table-of-contents-introduction>.

¹³² *NFIB v. Sebelius*, 567 U.S. 519, 577-78 (2012) (“Congress may use its spending power to create incentives for States to act in accordance with federal policies. But when “pressure turns into compulsion,”...the legislation runs contrary to our system of federalism.” [internal citations omitted] *citing* *South Dakota v. Dole*, 483 U.S. 203, 211 (1987)); *Barnes v. Gorman*, 536 U.S. 181, 185 (2002) (in resolving a case about remedies for federal nondiscrimination violations, “the legitimacy of Congress’ power to legislate under the spending power . . . rests on whether the [recipient of federal funds] voluntarily and knowingly accepts the terms of the ‘contract.’ ... Accordingly, if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously[.]” *citing* *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 17 (1981)); *see also* Victoria L. Killion, *Funding Conditions: Constitutional Limits on Congress’s Spending Power*, CONG. (July 1, 2021), <https://www.congress.gov/crs-product/R46827>.

federalism is the reservation of the power to regulate medicine to the states.¹³³ For example, in the provision of the laws governing the Medicare program entitled “[p]rohibition against any federal interference,” Congress made clear that the federal government is prohibited from “exercise[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided.”¹³⁴ The Supreme Court’s 2025 decision in *U.S. v. Skrmetti*, which held that Tennessee may regulate gender-affirming care, suggests that supervision and control over these treatments is properly vested in state legislatures.¹³⁵

Under the current Administration’s interpretation of federal law, states are not required to provide Medicaid coverage for hormonal or surgical interventions for the treatment of gender dysphoria.¹³⁶ As a result, many states have decided for themselves to as to whether to provide Medicaid coverage for gender dysphoria treatment.¹³⁷ As of the end of 2025, 17 states had laws

¹³³ See, e.g., *Linder v. United States*, 268 U.S. 5, 18 (1925) (“direct control of medical practice in the states is beyond the power of the federal government”); *Whalen v. Roe*, 429 U.S. 589, 597-98 (1977) (states have broad police powers to regulate the administration of drugs by health professionals); *Gonzales v. Oregon*, 546 U.S. 243, 274 (“[The Controlled Substances Act]” does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct.”); see also *Conant v. Walters*, 309 F.3d 629, 639 (2002) (“principles of federalism that have left states as the primary regulators of professional conduct.”).

¹³⁴ 42 U.S.C. § 1395.

¹³⁵ *U.S. 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[.]’” citing *Gonzalez v. Carhart*, 550 U.S. 124 (2007)) (“The fact the line might have been drawn differently at some points is a matter for legislative, rather than judicial, consideration[.]”” citing *Railroad Retirement Bd. v. Fritz*, 449 U.S. 166 (1980)) [internal citations omitted].

¹³⁶ *Mandatory & Optional Medicaid Benefits*, MEDICAID, <https://www.medicaid.gov/medicaid/benefits/mandatory-optional-medicaid-benefits> (last visited Jan. 26, 2026). Federal policy on coverage for gender-affirming care has a complex history. Regulations were issued in 2016 that would have required coverage for gender-affirming care. 42 C.F.R. 92.206 (2018); 42 C.F.R. 92.207 (2018); 42 CFR § 440.262 (2018); 42 CFR § 438.206 (2018); 42 CFR § 438.3 (2018). However, those rules were challenged in court. *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (Tex. N.D. Ct. 2016). The subsequent administration issued a rule removing coverage for gender-affirming care. *Nondiscrimination in Health and Health Education Programs or Activities*, 85 Fed. Reg. 37160 (June 19, 2020). This rule was itself challenged and a court issued a nationwide injunction preventing the implementation of the rule. See *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D. N.Y. 2020); *Whitman-Walker v. Department of Health and Human Services*, 485 F. Supp. 3d (D.C. 2020). Another rule then reinstated the protections of the 2016 rule. *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37522 (May 6, 2024). These regulations were ultimately vacated by a court. *Tennessee v. Kennedy*, 2025 U.S. Dist. LEXIS 207870 (Miss. S.D. Ct. 2025). See also *Elana Redfield et al., Re: Notice of Proposed Rulemaking: Nondiscrimination in Health Programs and Activities* (RIN 0945-AA17).

¹³⁷ Several federal and state courts have found exclusions of coverage for gender dysphoria treatments under state insurance plans run afoul of the U.S. Constitution. For court cases that found insurance exclusions for gender-affirming care likely violate the Equal Protection Clause of the U.S. Constitution, see *Doe v. Austin*, 755 F. Supp. 3d 51 (Me. Dist. Ct. 2024); *Flack v. Wis. Dep’t of Health Services*, 328 F. Supp. 3d 931 (Wis. W.D. Ct. 2018); *Dekker v. Weida*, 679 F. Supp. 3d 1271 (Fla. N.D. Ct. 2023). One court has found that Executive Order 14187, issued by the Trump administration directing federal agencies to take measures to eliminate federal funding for institutions providing gender-affirming care for minors, cannot be reconciled with the provisions of the Affordable Care Act which protect against sex discrimination. *PFLAG, Inc. v. Trump*, 766 F. Supp. 3d 535 (Md. Dist. Ct. 2025); *PFLAG, Inc. v. Trump*, 769 F. Supp. 3d 405 (Md. Dist. Ct. 2025). However, this is not a settled or clear area of law. Subsequent to its decision in *U.S. v. Skrmetti*, in which the Court upheld Tennessee’s ban on gender-affirming care for minors as a lawful exercise of its power to regular medical treatments under the Equal Protection Clause, the

or policies that explicitly prohibited coverage of medical interventions for gender dysphoria for minors.¹³⁸ At the same time, 26 states and D.C. have policies requiring coverage for gender-affirming care in their Medicaid programs, and several states have statutes requiring such coverage.¹³⁹ Additionally, courts in several states—such as Montana and Iowa—have found that failure to provide Medicaid coverage for gender dysphoria treatment runs afoul of their state constitutions or laws.¹⁴⁰

The currently proposed CoP breaks from the tradition of previous CoPs.¹⁴¹ For example, existing Conditions of Participation for hospitals include requirements such as notifying patients of their rights, having plans in case of emergencies, maintaining standards to assess quality, ensuring staff meet licensing requirements, ensuring proper recordkeeping, and ensuring the safe storage of prescription drugs.¹⁴² None of these conditions limit or ban certain forms of healthcare like CMS proposes to do with gender-affirming care.

Accordingly, the imposition of the proposed CoP on all hospitals participating in Medicaid and Medicare is inconsistent with federalism in two ways: because the CoP may pressure hospitals to the point of compulsion to stop providing care in violation of their own best practices, standards of care, or the laws of the states they are located within,¹⁴³ and may also usurp the power traditionally reserved to the states to regulate the practice of medicine.

Court then remanded several cases for reconsideration, including two cases challenging state insurance plan restrictions. *Folwell v. Kadel*, 145 S. Ct. 2838 (2025) (vacating and remanding to the 4th Circuit Court of Appeals in light of *Skrmetti*); *Kadel v. Folwell*, 2025 U.S. App. LEXIS 25141 (4th Cir. 2025) (vacating and remanding to the district court in light of *Skrmetti*; *Crouch v. Anderson*, 2025 U.S. LEXIS 2596 (2025). At the same time, since *Skrmetti* only weighed in on whether restrictions on medical treatment for gender dysphoria violated the Equal Protection Clause of the U.S. Constitution, courts are still determining the applicability of other nondiscrimination protections. For example, several courts have found that Medicaid exclusions for transgender-related healthcare violate the statutory language of the Affordable Care Act, including the Ninth Circuit in a decision issued after *Skrmetti*. See *Pritchard v. Blue Cross Blue Shield of Ill.*, 159 F.4th 646 (9th Cir. 2025); *L.B. v. Premera Blue Cross*, 781 F. Supp. 3d 1128 (Wash. W.D. Ct. 2025); *Dekker v. Weida*, 679 F. Supp. 3d 1271 (Fla. N.D. Ct. 2023).

¹³⁸ ARRAYALES & REDFIELD, *supra* note 89, at 10-11.

¹³⁹ *Medicaid Coverage for Transgender-Related Health Care*, MOVEMENT ADVANCEMENT PROJECT (Jan. 1, 2026), <https://www.lgbtmap.org/equality-maps/medicaid>.

¹⁴⁰ *Iowa* (*Vasquez v. Iowa Dep't of Human Services*, 2021 Iowa Dist. LEXIS 83); *Montana* (*Cross v. State* (DV-23-541) (Mont. May 13, 2025), <https://lambdalegal.org/wp-content/uploads/2025/05/279-Order-Re-Cross-Motions-for-Summary-Judgment.pdf>).

¹⁴¹ See Michael G. H. McGeary, *Medicare Conditions of Participation and Accreditation for Hospitals* in INST. MED., *MEDICARE: A STRATEGY FOR QUALITY ASSURANCE, VOLUME II: SOURCES AND METHODS* (Kathleen N. Lohr, ed., 1990).

¹⁴² 42 C.F.R. § 482.13 (2019) (patient notification of rights); 42 C.F.R. § 482.15 (2019) (emergency preparedness); 42 C.F.R. § 482.21 (2024) (quality assessment and performance improvement program); 42 C.F.R. § 482.22 (2019) (medical staff); 42 C.F.R. § 482.24 (2020) (medical record services); 42 C.F.R. § 482.25 (2012) (pharmaceutical services).

¹⁴³ See *S.D. v. Dole*, 483 U.S. 203, 211 (1987), *citing* *Steward Machine Co. v. Davis*, 301 U.S. 548, 590 (1987); Dave Muoio, *California AG Sues Rady Children's Health Over Halted Gender-Affirming Care Services*, FIERCE HEALTHCARE (Feb. 4, 2026, 12:00 PM), <https://www.fiercehealthcare.com/providers/california-ag-sues-rady-childrens-health-over-halted-gender-affirming-care-services>.

III. Conclusion

For the above stated reasons, we believe CMS should not adopt its proposed rule and should instead reconsider the evidence base for the proposed CoP, and that the proposed CoP could violate key principles of federalism by infringing on the power of the states to regulate medical care.

Thank you for your consideration of this submission.

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