Do No Harm

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February 17, 2026

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 2451-P, CMS-3481-P
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children (CMS-3481-P); Medicaid Program Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children (CMS-2451-P)

Do No Harm, Inc., is a nonprofit organization with over 50,000 members, including physicians, nurses, medical students, patients, and policymakers. Do No Harm is committed to ensuring that the practice of medicine is driven by scientific evidence rather than ideology. In recent years, the practice of biology-denying interventions, euphemistically known as "gender affirming care," has become more common despite the serious harm caused by those medical interventions, and the complete lack of reliable evidence of any benefit for minors. Indeed, Do No Harm has recently released a database demonstrating that nearly 14,000 minors were subjected to biology-denying interventions in the United States between 2019 and 2023. *See Do No Harm Launches First National Database Exposing the Child Trans Industry*, Do No Harm (Oct. 8, 2024), perma.cc/C5U3-7W94. Many others are suing for the injuries caused by these procedures.

Part of Do No Harm's mission is to ensure that the public, courts, and federal agencies have a proper understanding of the dangers of these medical interventions and the lack of evidence supporting them. Do No Harm supports the proposed rules and submits this comment to propose modest changes that will ensure the final rule will fulfill its laudable goals.

I. So-called "gender affirming care" is a medical scandal, and the proposed rules a critical step to protect children from gender ideology.

Among other things, the Department proposes to bar hospitals from performing transgender procedures on minors as a condition of participating in Medicare and Medicaid programs. 90 Fed. Reg. 59463. It also proposes to prohibit the use of Medicaid dollars "to fund sex-rejecting procedures" for minors. 90 Fed. Reg. 59441. Do No Harm fully supports these efforts. "Gender affirming care" is a medical scandal. This purported "treatment" consists of using physical interventions—puberty blockers, cross-sex hormones, and surgeries—to treat gender dysphoria, a psychological condition. These interventions supposedly help "align a child's physical appearance or body with an asserted identity that differs from the child's sex." 90 Fed. Reg. 58449; 90 Fed. Reg. 58470. But such intervention often comes at great cost, including sterilization of healthy children. As a result, young children and adolescents are allowed to make potentially irreversible life-altering decisions—in many cases without sufficient parental consent or engagement. *See Protecting Minors from Gender Ideology*, Do No Harm, perma.cc/EW5A-CWRZ.

The Department is right to be concerned about the "weak evidence and growing international retreat" from the use of puberty blockers, cross-sex hormones, and surgeries to address gender dysphoria in minors. 90 Fed. Reg. 59444. These interventions—promoted by medical specialty societies engaged in political activism—have inflicted serious harms on minors across the country. And to date, no reliable evidence shows that they resolve gender dysphoria.

While proponents of "gender affirming care" often claim that a medical or scientific consensus justifies the use of puberty blockers, cross-sex hormones, or surgeries as a treatment for gender dysphoria in minors, these claims are false. As a Justice of the Supreme Court recently explained, the relevant "medical and regulatory authorities" are "not of one mind" about the "risks and benefits" of these treatments. *United States v. Skrmetti*, 605 U.S. 495, 536 (2025) (Thomas, J., concurring). Clinicians and researchers around the world have publicly questioned providing these sorts of treatments to minors, highlighting the significant risks, including "sterility," "lifelong dependence on medication," and "the anguish of regret." *See* Rittakerttu Kaltiala et al., *Youth Gender Transition Is Pushed Without Evidence*, Wall St. J. (July 13, 2023), perma.cc/P9GM-MHF7.

Just days ago, the American Society of Plastic Surgeons released a position statement recommending surgeons do not perform sex-denying surgical procedures on minors, citing "concerns about potential long-term harms and the irreversible nature of surgical interventions in a developmentally vulnerable population." *Position Statement on Gender Surgery for Children and Adolescents*, ASPS (Feb 3, 2026), perma.cc/KD8B-7GKV. *See*

also Do No Harm Applauds ASPS for Rejecting Sex-Denying Surgeries for Children, Do No Harm (Feb. 3, 2026), perma.cc/X8AE-AXPF.

Many of the European countries that were early adopters of these treatments have also restricted their use due to efficacy and safety concerns. To date, every systematic review (a comprehensive review of all relevant studies on a subject) has concluded that no reliable evidence shows that gender affirming medical interventions help resolve gender dysphoria in minors. *See* Brief of Do No Harm as Amicus Curiae at 3-16, *United States v. Skrmetti*, No. 23-477; Brief of Do No Harm as Amicus Curiae at 3-8, *Wailes v. Jefferson Co. Pub. Sch.*, No. 25-1341 (10th Cir.). In addition to the Department's own recent comprehensive review, *see* 90 Fed. Reg. 59444, several international institutions—including health authorities in Finland, Sweden, and the United Kingdom—have conducted systematic reviews of the evidence justifying the use of puberty blockers, cross-sex hormones, or surgeries as a treatment for minors with gender dysphoria. Each one has concluded that the evidence supporting such medical intervention is insufficient or nonexistent. *See, e.g.*, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Apr. 2024); Jo Taylor, et al., *Interventions To Suppress Puberty in Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, Archives Disease Childhood 1 (2024), perma.cc/3ZCW-MYHJ; Jo Taylor, et al., *Masculinising and Feminising Hormone Interventions for Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review*, Archives Disease Childhood 1 (2024), perma.cc/Q2JB-EGGM; Jonas F. Ludvigsson, et al., *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and Recommendations for Research*, 112 Acta Paediatrica A 2279, 2280 (2023)); Romina Brignardello-Petersen & Wojtek Wiercioch, *Effects of Gender Affirming Therapies in People with Gender Dysphoria: Evaluation of the Best Available Evidence* 5 (May 16, 2022), perma.cc/BGQ9-P2EH; *Recommendation of the Council for Choices in Health Care in Finland (PALKO/COHERE Finland) Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* at 7-8, Palveluvalikoima Nov. 6, 2020).

On top of that, there is ample reason to question the American medical societies promoting these medical interventions. Political activism is increasingly "common across specialty medical societies." Ian Kingsbury, *Outside Their Lane: Mission Creep in Medical Specialty Societies*, Do No Harm at 5 (Nov. 2024), perma.cc/E4LB-PF58. *See also Wailes* Amicus, supra at 3-8. The World Professional Association for Transgender Health (WPATH), which purports to set the standard of care for treating gender dysphoria, is the worst offender. As the State of Alabama uncovered during litigation over Alabama's restrictions on gender affirming procedures, WPATH crafted its standards of care "to advance political and legal goals"—not medical goals—to the detriment of those it was purporting to help. WPATH failed to "follow the evidence-based medicine it said it followed." *See* Brief for

Alabama as Amicus Curiae at 10, 24, *United States v. Skrmetti*, No. 23-477. Indeed, WPATH members "intentionally chose not to seek a systematic review of the evidence before making treatment recommendations" because, in their own words, an "'evidence-based review'" would "'reveal[ ] little or no evidence'" supporting their claims—an "untenable position in terms of affecting policy or winning lawsuits.'" *Id.* at 7. *See also* Kaltiala, *supra* (doctors noting their "surprise[ ]" at statements by the Endocrine Society that were "not supported by the best available evidence" and suggesting that U.S. medical societies have "exaggerat[ed] the benefits and minimiz[ed] the risks" of gender affirming care).

At bottom, the evidence justifying the use of medical intervention as a treatment for gender dysphoria in minors is completely lacking. Given this lack of evidence, it is entirely appropriate to ban hospitals from performing sex change interventions on minors as a condition for Medicare and Medicaid participation and to bar federal Medicaid dollars from funding sex-rejecting procedures.

II. Proposed changes to 42 C.F.R. Parts 441, 457 and 482.

Do No Harm proposes modest changes to clarify certain portions of the proposed rules and better support the rules' important goals. Do No Harm's suggested revisions are based in part on the proposed Chloe Cole Act—a bill pending before Congress that would protect vulnerable children by prohibiting physicians from prescribing puberty blockers, cross-sex hormones, or "gender affirming" surgeries with the intention of aligning a child's body with a sex other than that child's natal sex. *See* H.R. 5483, 119th Cong. (2025). Do No Harm's proposed revisions will help ensure that the final rule effectively targets dangerous and unproven "gender affirming care" for children while leaving recognized treatments unaffected.

A. Clear and precise definitions are critical. They are especially critical in a rule of this scope, where coverage determinations and compliance obligations turn directly on the meaning of the terms "female," "male," and "sex." Ambiguity or imprecision in such definitions risks inconsistent application and unintended effects beyond the rule's objectives. The Chloe Cole Act, for example, precisely defines these terms by fleshing out how the reproductive system functions and framing the definition in the past, present, and future tense. Accordingly, in proposed §441.801, Do No Harm suggests using the following definitions of "female," "male," and "sex" from the Chloe Cole Act.

> ***Female* is a person who naturally has, had, will have, or would have but for a congenital anomaly or intentional or unintentional disruption, the reproductive system that produces, transports, and utilizes the large gamete (ova) for fertilization.**

***Male* is a person who naturally has, had, will have, or would have but for a congenital anomaly or intentional or unintentional disruption, the reproductive system that produces, transports, and utilizes the small gamete (sperm) for fertilization.**

***Sex* means a person's immutable biological classification, determined at the moment of conception, as either male or female.**

B. Do No Harm is concerned that there are a wide range of procedures that operate to feminize or masculinize an individual even if they do not specifically "destro[y] primary or secondary sex-based traits"—the proposed definitional language of "sex-rejecting procedure" proposed in 42 C.F.R. §441.801(2). Take, for example, body contouring. Entities performing procedures like these on children should not be rewarded with federal funding.

To better cover feminization or masculinization procedures that do not specifically "destro[y] primary or secondary sex-based traits," Do No Harm suggests modifying proposed §441.801(2) as follows:

"intentionally changing a child's body, including the child's external appearance or biological functions, when the change is purposed to align the child's body with the opposite sex."

In the alternative, Do No Harm proposes the following revisions to the current proposed language of §441.801(1)-(2).

Sex-rejecting procedure means, except as specified in paragraph (3) of this definition, any pharmaceutical or surgical intervention that attempts to align a child's physical appearance or body with an asserted identity that differs from the child's sex by either of the following:

(1) Intentionally **delaying, halting,** disrupting or suppressing the normal development of natural biological functions, including primary or secondary traits **when such actions are purposed to align a child's body with the opposite sex**; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary traits such as the sexual and reproductive organs, **when such actions are purposed to align the child's body with the opposite sex.**

To be sufficiently precise, each of the above definitions in Part II.B depends on HHS adopting Do No Harm's proposed definitions of "male," "female," and "sex" in Part II.A.

C. Precocious puberty is a well-recognized pediatric endocrine condition in which abnormally early pubertal development can cause irreversible physical changes, compromised adult height, and significant psychosocial harm if left untreated. *See* Endocrine Society, *Precocious Puberty*, Endocrine.org, tinyurl.com/47w5mu56. Puberty-suppressing medications, most commonly long-acting gonadotropin-releasing hormone (GnRH) analogs, are the standard therapy for central precocious puberty and are used to pause pubertal progression until an age-appropriate time without altering a child's underlying sex characteristics or reproductive anatomy. *See* Erica A. Eugster, *Treatment of Central Precocious Puberty*, 3 J. Endocrine Soc'y 965 (2019), tinyurl.com/yux2jesa. Thus, any final rule restricting Medicaid coverage for "gender affirming" interventions should expressly clarify that such restrictions do not apply to the medically indicated use of puberty-suppressing medications for the treatment of precocious puberty. Doing so will avoid unintended harm to children who rely on this standard form of care. Do No Harm thus suggests the language of proposed §441.801(3) be revised as follows:

> (3) For purposes of this definition, the term sex-rejecting procedure does not include procedures undertaken—
>
> (i) To treat a child with a medically verifiable disorder of sexual development; or
>
> (ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or
>
> (iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s)**; or**
>
> **(iv) For purposes of treating precocious puberty.**

* * *

With respect to each of the above definitional provisions, Do No Harm also recommends using the same definitions in both 42 C.F.R. Part 441 and 42 C.F.R. Part 482 to ensure continuity between the final rules.

If you have any questions or require further information, please feel free to contact me at kurt@donoharmmedicine.org. Thank you for your attention to this important matter.

Sincerely,

Kurt Miceli, M.D.

Chief Medical Officer
Do No Harm