



CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY

Office of the Secretary

February 17, 2026

Via this website: <http://www.regulations.gov>

Dr. Mehmet Oz, Administrator
Center for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule CMS-3481-P, [FR Doc No. 2025-23465](#), “Conditions of participation: Sex-rejecting procedures.”

Dear Dr. Oz,

The California Health and Human Services Agency (CalHHS), along with the undersigned departments, submits the following comments for your consideration on the Proposed Rule CMS-3481-P “Conditions of participation: Sex-rejecting procedures.” **CalHHS urges the Centers for Medicare and Medicaid Services (CMS) to withdraw this Proposed Rule that seeks to eliminate access to evidence-based care and jeopardizes public health in California.** The Proposed Rule disregards established research on gender-affirming care and threatens the health and well-being of California’s youth. Multiple peer-reviewed scientific studies demonstrate that gender-affirming care is effective, medically necessary, and improves mental health outcomes. Additionally, the Proposed Rule is discriminatory and unlawful, unnecessarily burdens states’ valuable hospital oversight resources, and its vague and ambiguous language will leave state survey agencies, including the California Department of Public Health (CDPH), with considerable confusion regarding the enforcement of this rule.

I. The Proposed Rule restricts access to scientifically supported care and would harm the health of youth in California.

Proposed Rule CMS-3481-P uses a new and misleading term, “sex-rejecting procedures,” to refer to gender-affirming care, a set of treatments that have been shown to be safe and effective for the treatment of gender dysphoria in adolescents and adults (Coleman et al., 2022). The Proposed Rule requires hospitals to ban gender-affirming care for individuals

under eighteen as a Medicare and Medicaid Condition of Participation. Categorically banning gender-affirming care for individuals under the age of eighteen violates the standard of medical care for treating gender dysphoria.

Gender-affirming care consists of a variety of interventions, both medical and non-medical. Some components of gender-affirming care include psychological support (therapy, counseling, support groups), social support (name changes, pronouns, social transition, resilience building), and medical interventions (hormone therapy, puberty blockers, surgeries in some cases, though very rarely for those under eighteen). According to the American Academy of Pediatrics (AAP), the Endocrine Society, and numerous other medical organizations, gender-affirming care is safe, effective, and medically necessary to improve health outcomes of transgender youth (see [Medical Organization Statements on Medical Necessity of Treatment for Gender Dysphoria](#)).

The standard of care for pediatric gender dysphoria in the United States is shaped by guidelines from major medical organizations (e.g., American Academy of Pediatrics, Endocrine Society, World Professional Association of Transgender Health) and supports gender-affirming care (Coleman et al., 2022). This includes puberty blockers and hormone therapy for some adolescents under carefully monitored clinical protocols and informed parent or guardian consent (Dowshen et al., 2025). These guidelines are based on a body of clinical experience and research indicating that, for many youth, gender-affirming care, both social and medical, is associated with mental health benefits and reduced risk behaviors (APA, 2015; Ehrensaft, 2018; Ehrensaft et al., 2018; Malpas et al., 2018; Olson et al., 2016; Olson-Kennedy et al., 2019; Telfer et al., 2018).

The evidence base for pediatric gender dysphoria treatment includes observational studies, case-control methods, prospective cohort data, and some longitudinal follow-ups showing reduced gender dysphoria and suicidality after gender-affirming treatment (Ehrensaft, 2018; Ehrensaft et al., 2018; Malpas et al., 2018; Mehringer et al., 2021; Olson-Kennedy et al., 2018). Gender-affirming medicine has been critiqued for the lack of randomized control trials (RCTs), in which the researchers assign participants randomly to treatment and control groups. This is because RCTs for gender-affirming care are impractical and unethical in most cases. Where treatments, including gender-affirming care, are known or believed to alleviate the symptoms of a diagnosis (here, gender dysphoria), it is immoral to deny patients those treatments by assigning them to a control group. Additionally, RCTs can suffer from the same biases as observational studies. Frequently, results obtained in a laboratory fail to translate to the world outside the lab.

Critics of gender-affirming care point out the limitations in evidence quality in systematic reviews and clinical guidelines. However, it is important to note that these reviews and guidelines do not characterize the data as inadequate to support gender-affirming care interventions as treatment of gender dysphoria. Instead, authors of systematic reviews themselves acknowledge that “clinicians should work with patients to ensure that care reflects the experience, goals, and priorities of those needing care,” and that many commonly offered medical interventions are based on similar quality evidence. It is therefore “a clear violation of the principles of evidence-based shared decision-making” to outlaw an entire set of interventions on this basis. (Guyatt et al., 2025).

The conclusions of the report "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" (HHS Report), published by the United States Department of Health and Human Services and relied on to justify this Proposed Rule, stand in clear conflict with positions held by major professional medical associations, which support access to gender-affirming care based on existing evidence that it can improve psychological outcomes for transgender and gender diverse youth when provided within established clinical frameworks guided by WPATH. In response to the release of the HHS report, the AAP issued a statement rejecting characterizations of gender-affirming care as negligent or driven by political ideology, emphasizing that such claims “misrepresent the consensus of medical science, undermine the professionalism of physicians, and risk harming vulnerable young people and their families” (Walker, 2025). The divergence from prominent major medical associations highlight the report’s willingness to not reflect a unified scientific consensus or standard of care.

If the HHS Report is used to justify clinical guidelines, laws, or regulations, as is the case with the Proposed Rule, its methodological flaws and contested conclusions will have negative public health consequences. Restrictive policies shaped by the report have already begun to limit access to medically necessary, evidence-informed care for transgender youth, leading to worsened mental health outcomes, including anxiety, depression, and suicidality, which are already well documented at higher rates in this population (Bhatt et al., 2022). Although the report emphasizes potential harms of medical interventions for gender dysphoria, it does not account for harms associated with withholding appropriate care, a point raised by clinicians and stakeholders in the field (de Vries et al., 2021; Green et al., 2022).

Research shows:

- Access to gender-affirming care reduces health disparities such as HIV/AIDs, STI infection, suicidality, mental health distress, drug use, and other risk behaviors for transgender and gender diverse populations in the United States (Bhatt et al., 2022).
- Access to gender-affirming care is positively linked with the mental health of transgender youth, lowering their risk of depression and suicide (Bauer et al., 2015; Green et al., 2022).
- Transgender youth who have access to gender-affirming medical care experience improvements in mental health and often show mental health comparable to their cisgender peers (Toomey et al., 2022).
- A study of 104 youths aged 13-20 years old observed 60% lower odds of depression and 73% lower odds of suicidality among youth who had initiated puberty blockers or gender affirming hormones compared with youths who had not (Tordoff et al., 2022).

Not only does banning gender-affirming care for individuals under the age of eighteen neglect scientific research, but it also impedes the relationship between physicians, youth, and their families, and their ability to engage in shared decision-making. This rule, if adopted, will limit the availability of treatment for adolescents experiencing gender dysphoria and put them at risk for long-term complications, including worsening mental health, increased distress, and higher risks of self-harm or suicide (Green et al., 2022).

II. The Proposed Rule relies on misinterpreted evidence and makes conclusions that are not scientifically verified.

The Proposed Rule relies on the HHS Report, as well as the “Independent review of gender identity services for children and young people” by Dr. Hilary Cass (known as the Cass Review) to justify its ban on pediatric gender-affirming care. Both of these reports are based on unsound science and misinterpreted evidence. While the HHS Report purports to be evidence based and peer reviewed, the report’s inadequate transparency, significant concerns about its methodology, lack of author expertise, and misalignment with scientific consensus limit its scientific validity and integrity. The report does not adhere to the rigor expected in systematic academic and medical reviews used to guide clinical practice (Dowshen et al., 2025). The report’s influence on federal policy changes warrants scrutiny due to the serious implications for adolescent health.

The HHS Report uses questionable citation practices. Independent critics and media reports note inclusion of studies published in non-traditional journals and citations of controversial, non-clinical, and/or withdrawn concepts including rapid-onset gender dysphoria (ROGD), raising concerns about evidence selection bias (Manto, 2025). ROGD is

a widely influential but unvalidated research hypothesis. It describes adolescents and young adults who, from their parents' perspective, did not meet the gender dysphoria diagnostic criteria as children but as adolescents "suddenly" claim to be gender dysphoric or transgender, as though "out of the blue," disregarding the commonality of other seemingly sudden changes that may occur in the transition from childhood to adolescence. No psychological, pediatric, or health professional organization, in the United States or abroad—or any established professional organization—recognizes "ROGD" as a diagnosis or mental disorder. Nor does the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) or any other clinical guidelines list ROGD as a diagnosis. The person who coined the phrase "ROGD" has herself acknowledged that "[r]apid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis" (Littman, 2019).

Major medical organizations such as the American Psychiatric Association (APA) have also explicitly criticized the HHS report for lacking transparency, noting that it "fails to clearly articulate how the studies it reviewed were selected, what criteria governed inclusion or exclusion, or how their quality was assessed," and therefore, its conclusions cannot be accepted "at face value" ([see, APA Peer Review](#)). Observers have also noted that many of the report's authors are public critics of gender-affirming care who lack clinical research and treatment delivery experience in transgender youth and adults, which limits their ability to weigh clinical evidence effectively (Gaffney & Merelli, 2025).

In addition to the HHS Report, the Cass Review fails to meet standards for scientific rigor and does not support the ideological position of the Federal administration. Researchers found that the Cass Review:

- Does not follow established standards for evaluating evidence and evidence quality.
- Fails to contextualize the evidence for gender-affirming care with the evidence base for other areas of pediatric medicine.
- Misinterprets and misrepresents its own data.
- Levies unsupported assertions about gender identity, gender dysphoria, standard practices, and the safety of gender-affirming medical treatments and repeats claims that have been disproved by sound evidence.
- Has serious methodological flaws, including the omission of key findings in the extant body of literature.

Researchers found that the Review's relationship with and use of the York systematic reviews violates standard processes that lead to clinical recommendations in evidence-based medicine (McDeavitt et al, 2025, p.4). Reliance on the Cass Review as scientific evidence is inappropriate, and it should not form the basis of health policy or regulations.

In fact, the Cass Review makes statements that are consistent with the models of gender-affirming medical care described by WPATH and the Endocrine Society. The Cass Review does not recommend a ban on gender-affirming medical care.

The Proposed Rule's divergence from prominent major medical associations' roles, conclusions, and guidance demonstrates a disregard for the unified scientific consensus and standard of care for gender diverse youth.

III. The Proposed Rule interferes with states' sovereign authority to protect public health and define healthcare safety and quality standards.

Furthermore, states have traditionally regulated the delivery of healthcare as part of their sovereign authority to protect the health of the states' population, and historically, Conditions of Participation have respected this authority. In fact, no prior Condition of Participation has been used to ban a specific medical treatment, reflecting CMS's understanding that defining professional norms and disciplining facilities and practitioners is a state responsibility.

Considering this traditional state authority, existing California law requires health plans and insurers to cover medically necessary gender-affirming care and prohibits discrimination based on an individual's transgender status. By banning gender-affirming care for individuals under the age of eighteen as a federal Condition of Participation, this Proposed Rule attempts to supplant state-defined healthcare safety and quality standards and intrudes upon states' sovereign authority to regulate the delivery of healthcare. Specifically, hospitals failing to provide medically necessary gender-affirming care would violate California hospital licensure requirements prohibiting discrimination. California defines "gender-affirming health care" for minors as medically necessary care (Welf. & Inst. Code, § 16010.2), reflecting the generally recognized standard of care for pediatric gender dysphoria, which as discussed above, is supported by extensive scientific research. Moreover, California hospital licensing regulations expressly prohibit discrimination in the treatment of patients "based on sex" (Cal. Code Regs., tit. 22, § 70715), and California law defines "sex" to include gender, gender identity, and gender expression (Gov. Code, § 12926). Hospitals that deny medically necessary gender-affirming care for minors may violate this California licensing regulation (Cal. Code Regs., tit. 22, § 70715) by discriminating against patients based on gender identity rather than providing legally recognized, medically necessary care (Welf. & Inst. Code, § 16010.2) that represents the prevailing clinical standard of care and is supported by extensive scientific research. Hospitals invoking the Proposed Rule's exceptions and providing to cisgender individuals the very same treatments the rule bans for transgender individuals may constitute gender identity discrimination under California law.

Additionally, hospital licensing statutes reinforce the need to prevent gender-identity discrimination. Hospitals must inform patients in writing of their right to be free from gender identity and expression discrimination (Health & Saf. Code, § 1262.6, subd. (a)(5)). Consequently, California hospitals may be forced into an impossible position: comply with state healthcare facility licensing and state gender-affirming care requirements to provide medically necessary gender-affirming care or follow this federal ban—either choice jeopardizes licensure or federal funding.

IV. The Proposed Rule is contrary to federal law.

The Proposed Rule violates several aspects of federal law. The Proposed Rule violates the Patient Protection and Affordable Care Act (ACA) which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in health programs and activities receiving federal funding, (42 U.S.C. § 18116.), as well as the Americans with Disabilities Act of 1990 (ADA) (42 U.S.C. § 12101, et. seq.), which bars discrimination based on mental disability. The Proposed Rule's exceptions attempt to discriminate between physical and mental disabilities, allowing treatment for one but not the other. In doing so, the Proposed Rule impermissibly discriminates against individuals with gender dysphoria based on their mental condition. Congress has expressly found "physical or mental disabilities in no way diminish a person's right to fully participate in all aspects of society." And Title III of the ADA prohibits discrimination on the basis of mental disability in public accommodations, such as hospitals. (ADA Title III—public accommodations, see 42 U.S.C. §§ 12181–12189.)

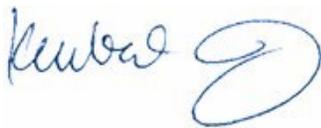
Moreover, the Supreme Court has long recognized the importance of protecting a parent's interest in the care, custody, and control of their children. (*Troxel v. Granville* (2000) 530 U.S. 57; see *Lehr v. Robertson* (1983) 463 U.S. 248, 257–58; *Santosky v. Kramer* (1982) 455 U.S. 745, 753; *Lassiter v. Dep't of Soc. Servs.* (1981) 452 U.S. 18, 27–28; *Stanley v. Illinois* (1972) 405 U.S. 645, 651; *Prince v. Massachusetts* (1944) 321 U.S. 158, 166; *Pierce v. Soc'y of Sisters* (1925) 268 U.S. 510, 534–35.) A parent's interest in "the care, custody, and control of their children," encompasses the right to make "medical decisions for their children," (*Wallis v. Spencer* (9th Cir. 2000) 202 F.3d 1126, 1141.) This liberty interest is not only rooted in a parent's right to raise one's children but also in "the traditional presumption that the parents act in the best interests of their child," *Parham v. J. R.*, (1979) 442 U.S. 584, 605.) Here, the rule arbitrarily rejects science, and there is no legitimate federal interest in preventing medically necessary treatment that both the parent and the state authorize. Thus, the Proposed Rule plainly violates the Due Process Clause. (*Meyer v. Nebraska* (1923) 262 U.S. 390.)

V. The Proposed Rule uses vague and ambiguous terminology that will leave state survey agencies unable to enforce the rule and burden states' valuable hospital oversight resources.

Finally, the Proposed Rule uses terms that are vague and ambiguous, leaving state survey agencies, like CDPH, struggling to decipher a clear standard to implement and enforce. Examples of inadequately defined terms include “biological function/s,” “sex-based traits,” and “disorder of sexual development.” Additionally, this proposed rule fails to describe any means to determine an individual’s biological sex, a foundational fact necessary to determine whether a “sex-rejecting procedure” occurred. These unclear terms and lack of implementation details render CDPH without a clear standard to enforce and thus would waste important resources trying to determine the means, methods, and intent to enforce this vague and ambiguous Proposed Rule—resources that could have been used to investigate and enforce life-threatening patient safety and quality issues. Any attempts at enforcement would almost certainly subject CDPH to legal interpretation battles and litigation challenges further burdening scarce CDPH resources.

In summary, the Proposed Rule disregards evidence-based research, threatens the health and well-being of California’s youth, is discriminatory and contrary to law, lacks clarity, wastes states’ valuable hospital oversight resources, and places hospitals in a no-win compliance situation. To avoid these negative health impacts and serious enforcement challenges, CDPH requests that the Proposed Rule CMS-3481-P be withdrawn and regulation of gender dysphoria treatment remain within the traditional sovereignty of the states.

Sincerely,



Kim Johnson
Secretary
California Health and Human Services Agency



Michelle Baass
Director
Department of Health Care Services

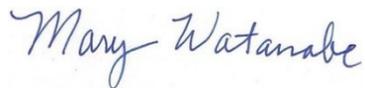
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