ALLIANCE DEFENDING FREEDOM
FOR FAITH. FOR JUSTICE.

April 10, 2025

The Honorable Mehmet Oz, M.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9884-P
P.O. Box 8016
Baltimore, MD 21244-8016
Via regulations.gov

RE: Comment on Notice of Proposed Rulemaking: "Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability," 90 FR 12942 (March 19, 2025), Code CMS-9884-P; RIN 0938-AV61

Dear Administrator Oz,

Alliance Defending Freedom (ADF) supports the proposed rule published by the Centers for Medicare & Medicaid Services (CMS), "Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability," 90 FR 12942 (March 19, 2025) (CMS-9884-P). In particular, ADF supports CMS's proposal to amend 45 CFR § 156.115(d) to provide that issuers of health coverage subject to essential health benefit (EHB) requirements—namely, non-grandfathered individual and small group market health insurance—may not provide coverage for sex-trait modification as an EHB.

ADF is an alliance-building legal organization that advocates for the right of all people to live and speak the truth. Since its launch in 1994, ADF has handled many legal matters involving federal healthcare laws, and has litigated many issues concerning sex-trait modification or "gender transition."

As CMS observed, this rule is supported in part because sex-trait modifications do not qualify to be an EHB since they are not typically included in employer health plans and therefore cannot legally be covered as an EHB. Our comment wishes to answer CMS's request for comment on additional grounds supporting the rule. Namely, because sex-trait modification, or "gender transition," is an experimental and dangerous array of procedures, particularly for children, ADF supports CMS removing it from EHB requirements. Our comment seeks to provide you with some of the latest studies supporting your decision.

"Gender Transition" is Experimental and Dangerous

CMS asked for public comment on whether the use of sex-trait modifications is supported by scientific integrity and are appropriate in health care settings. They are not, and for that reason should not be in the EHBs. CMS's proposal to remove them is supported by science, which shows that sex-trait modification or "gender transition" is experimental at best and is proving to be dangerous, especially to children.

Attached are several sources demonstrating the dangers and lack of clinical benefit of sex-trait modification or "gender transition." We summarize them as follows:

A. Expert report of James M. Cantor, PhD.

Dr. Cantor's expert report, filed as attached from May 2024, demonstrates several facts, including that:

- Medicalized transition of gender remains experimental, lacking causal evidence of mental health improvement;
- As of the date of his report, there were 18 cohort studies of puberty blockers and cross-sex hormones in minors. They provide no reliable evidence of effectiveness for improving mental health relative to mental health treatments that lack medical risk;
- There are severe and in some cases permanent known and potential harms associated with administration of puberty blockers and cross-sex hormones to children and adolescents for "gender transition" purposes;
- Assertions that puberty blockers for "gender transition" act only as a "fully reversible" "pause button" are not supported by scientific evidence;
- Methodological defects limit or negate the evidentiary value of many studies purporting to show the benefits of hormonal interventions for gender dysphoria in minors; and
- Systematic reviews of safety and effectiveness have been conducted by the health care ministries/departments of several governments, and all concluded the evidence on medicalized transition in minors to be of poor quality.

B. Expert report of Stephen B. Levine, M.D.

Dr. Levine's expert report, filed as attached from March 2025, demonstrates the following facts about the threat of "gender transition" to children, including:

- There is no consensus or agreed "standard of care" concerning therapeutic approaches to child or adolescent gender dysphoria;
- Transgender identity is not biologically based;
- Transition and affirmation are psychological and medical interventions, but are experimental and have not been shown to improve mental or physical health outcomes by young adulthood;
- Transition and affirmation do not decrease, and may increase, the risk of suicide;
- Hormonal interventions are experimental procedures that have not been proven safe or effective;
- The guidelines published by the World Professional Association for Transgender Health (WPATH) are unscientific, unreliable, and do not justify the use of hormonal interventions for young people.

C. McMaster University systematic reviews on youth up to 26 years of age.

Notably, Dr. Levine's report discusses three systematic reviews and meta-analyses by a team of evidence-based medicine experts at McMaster University, which are also attached here. The author group includes Dr. Gordon Guyatt, who is widely regarded as a "father" of evidence-based medicine.[1] These were not limited to minors, but concerned mastectomies, puberty blockers, and cross-sex hormones for "gender transitions" of youth below 26 years of age. All three concluded the evidence base is predominantly "very low certainty," meaning there is no reliable evidence that these interventions are beneficial.

D. Expert report of Farr A. Curlin, M.D.

Dr. Curlin's expert report, filed as attached from February 2024, shows that it is doubtful, at best, that minors could give informed consent to "gender transition" procedures.

E. Cass Review Final Report and supporting systematic reviews.

In 2020, the National Health Service of England commissioned a comprehensive review—known as the Cass Review—of its approach to treating young people's gender-related distress. This included a team of methodological experts at the University of York conducting a series of systematic reviews on the available medical evidence, all of which were ultimately published in the peer-reviewed *Archives of Disease in Childhood*. We include here the Cass Review's Final Report and the systematic reviews on puberty blockers and cross-sex hormones.

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[1] *See, e.g.*, https://www.cbc.ca/news/canada/hamilton/einstein-foundation-gordon-guyatt-1.6671974.

These reviews all concluded that even though these interventions carry substantial risks there is insufficient evidence that the interventions are beneficial. In response, far from considering them an essential health benefit, the United Kingdom has banned puberty blockers.[2]

CMS Should Encompass All Interventions for Sex-Trait Modification

CMS asked for comment on whether and how it should define "sex-trait modification" in excluding it from EHB.

ADF recommends that CMS specify that by excluding "sex-trait modifications" from EHBs, CMS means what it said in the proposed rule, that is, that sex-trait modification encompasses interventions or procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex, or that attempt to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions.[3] CMS should specify, either in regulatory text or guidance, some of the procedures and interventions commonly used for this purpose, including those procedures CMS mentioned in the proposed rule: puberty blockers, sex hormones, and surgical procedures. But this list should be inclusive, given by way of example, rather than being a closed set. That way, current methods used in this experimental and dangerous treatment will be encompassed, but additional experimental approaches that may develop in the future will also be encompassed.

CMS also appropriately recognized that there are some legitimate uses of certain procedures and interventions that are also misused by applying them in sex-trait modification situations. These include, as CMS noted, puberty blockers for precocious puberty, or therapy subsequent to a traumatic injury. Likewise, mastectomies are done for various therapeutic purposes that have nothing to do with sex-trait modification, such as for cancer treatment. CMS should specify that it is not excluding from EHBs these treatments when *not* done for sex-trait modification or gender transition.

The fundamental difference between using these interventions for sex-trait modification and using them therapeutically is that sex-trait modification, gender transition, and affirmation of "gender identity" are not healthcare. A person's biological characteristics of sex are in a state of either health or unhealth based on whether they are functioning according to their biological purposes. They do not

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[2] *See, e.g.*, https://apnews.com/article/britain-puberty-blockers-banned-indefinitely-8993f4c3251aadd55521fa4ed987fc58.
[3] *See also* https://womenshealth.gov/article/sex-based-definitions.

become unhealthy just because someone declares that he or she has an opposing "gender identity." Ailments such as cancer and precocious puberty involve the malfunction or failure of a biological system, and therefore they are unhealthy. Thus in those situations mastectomies and temporary puberty blockers, respectively, aim to restore proper biological function and health—they advance health and therefore are truly therapeutic. In contrast, removing healthy breasts and interrupting normally-occurring puberty in order to "affirm" one's "gender identity" is the destruction of healthy biological functions. That is not healthcare, it is ideology. And it is experimental and dangerous.

CMS Should Ensure Taxpayer Dollars Do Not Subsidize Sex-Trait Modifications in EHBs

CMS asked for comment on whether it should add program integrity measures to ensure federal subsidies do not continue to fund sex-trait modification in states that choose to continue to require coverage of those items without federal subsidies.

ADF supports the implementation of such program integrity measures. As CMS observed, federal subsidies pay for items and services that are included in EHBs in plans to which those apply. On the other hand, if a state separately mandates coverage for an item outside of EHBs, the state is required to defray the cost of that item included in addition to EHB. 45 CFR § 155.170.

It is essential that CMS apply program integrity requirements in implementing § 155.170 in general, including for the decision to remove sex-trait modifications from EHBs. This will help ensure that taxpayer dollars are preserved for the statutory purposes of the EHB requirements. Taxpayer dollars should not subsidize an experimental and dangerous procedure implementing radical gender ideology.

CMS should ensure that states mandating sex-trait modification in EHB benchmark plans despite the finalization of this rule give a clear accounting to show they are fully defraying the costs of their state mandate. Otherwise states will use state law to violate CMS's decision to exclude these items from EHBs, and will indirectly or directly be requiring federal taxpayer subsidies for interventions that are both wasteful and harmful.

The Rule Is Legally Sound and Should Go Into Effect As Soon As Possible

This rule is legally supported—indeed it is legally required—notwithstanding some court decisions against recent executive orders. As noted above, this rule is

based on the independent reason that sex-trait modifications do not qualify to be an EHB because they are not typically included in employer health plans and therefore cannot legally be covered as EHB.

As noted above, the scientific record provides additional reasons to exclude sex-trait modifications from EHBs, which is another independent reason for this rule. Science shows that these interventions are experimental, dangerous, and fail to be supported by evidence showing a clear clinical benefit. For this reason, CMS was right to observe that some stakeholders do not believe that sex-trait modification interventions fit into any of the 10 categories of EHB and, therefore, do not fit within the EHB framework even if some employers cover such services. ADF agrees with those stakeholders. As discussed above, sex-trait modification is anti-health rather than being the restoration or protection of health. Consequently, sex-trait modification is not properly considered to fall into any of the EHB categories.

CMS should reaffirm in the final rule that its decision to exclude sex-trait modification from EHBs is *not* being made pursuant to executive orders, but pursuant to these independent reasons. And this is true notwithstanding the agency's acknowledgment that those orders exist, and that those orders discuss a similar topic, such as the kinds of procedures that CMS is encompassing in its exclusion of sex-trait modification. The fact that the topics overlap does not make this rule an implementation of those orders, because this rule is supported by independent statutory authority and reasoned decision-making. CMS should make that clear in the final rule to reduce its litigation risk.

CMS should also make the effective date of this rule no later than plan year 2026. Waiting longer than that perpetuates the illegality of including sex-trait modification in EHBs, the harm that gender transition causes adults and children, and the improper use of federal taxpayer dollars.

Respectfully Submitted,

Matthew S. Bowman

Director of Regulatory Practice
Alliance Defending Freedom