February 17, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

Re: Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, RIN 0938-AV73

Dear Secretary Kennedy,

The National Health Law Program (NHeLP) writes in opposition to the notice of proposed rulemaking from the Department of Health and Human Services (HHS) titled Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children (hereinafter "Proposed Rule"). For over 55 years, NHeLP has advocated, educated, and litigated to preserve, protect, and expand access to health care for low-income and underserved populations.

If finalized, the Proposed Rule would prohibit Medicaid coverage of a range of medical services, including medications that delay puberty, hormones, and surgery, when they are used to treat gender dysphoria in adolescents. Throughout these comments, we use the term "gender-affirming care" to refer to these services. For the reasons explained below, NHeLP strongly opposes the Proposed Rule. First, the Proposed Rule is contrary to federal law, and HHS has no authority to finalize it. Second, the Proposed Rule is based on improper motives, flawed assumptions, and a misinterpretation of the available evidence and data, and

therefore fails to reflect reasoned decisionmaking. Third, the proposal will cause significant harm, especially to adolescent Medicaid beneficiaries with gender dysphoria, and will impose a significant burden on states to demonstrate compliance. Fourth, there are reasonable, less-restrictive alternatives to address HHS's purported concerns with gender-affirming care for adolescents.

I. The Proposed Rule is Contrary to Law and Exceeds HHS's Statutory Authority.

a. The Proposed Rule is contrary to the provisions of the Medicaid Act governing coverage of prescription drugs.

HHS claims that the Proposed Rule is consistent with 42 U.S.C. § 1396r-8.[1] That is incorrect. The Medicaid Act requires states to adhere to detailed requirements regarding the coverage of prescription drugs.[2] States must cover all FDA-approved prescription drugs offered by manufacturers that have entered into a rebate agreement with the government when the drugs are prescribed for a "medically accepted indication."[3] The statute defines a medically accepted indication as a use that is: 1) FDA-approved; or 2) "supported by one or more citations included or approved for inclusion in any of the compendia" listed.[4] One of the listed compendia is DRUGDEX.[5]

The Proposed Rule would prohibit Medicaid and CHIP coverage of prescription drugs when they are used to treat gender dysphoria in adolescents. But, DRUGDEX *includes* citations supporting the use of a number of prescription drugs when they are used to treat gender dysphoria in adolescents.[6] For example, there are citations in DRUGDEX that support the use of various forms of estrogen and testosterone to treat gender dysphoria in adolescents

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[1] Medicaid Program: Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59441, 59455 (Dec. 19, 2025) [hereinafter "Proposed Rule"].

[2] *See* 42 U.S.C. §§ 1396a(a)(54), 1396r-8, 1396b(i)(10); *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1330 (S.D. Fla. 2006) (describing the "carefully constructed" statutory scheme for coverage of prescription drugs).

[3] 42 U.S.C. § 1396r-8(a), 1396r-8(k)(2), 1396r-8(d)(1)(B); CMS, *CMCS Informational Bulletin* 2 (July 21, 2022), https://www.medicaid.gov/federal-policy-guidance/downloads/cib07212022.pdf (noting that "covered outpatient drugs that are prescribed for a medically accepted indication must be covered" by Medicaid). There are narrow exceptions that *allow*–but do not *require*–states to exclude coverage of particular drugs. *See, e.g.*, 42 U.S.C. § 1396r-8(d)(1)(B)(iv) (allowing states to establish a drug formulary if the requirements of § 1396r-8(d)(4) are met). These narrow exceptions do not affect states' obligation to cover prescription drugs for beneficiaries under age 21 pursuant to the EPSDT provisions. *See* CMS, *CMCS Informational Bulletin* 4 (July 21, 2022) https://www.medicaid.gov/federal-policy-guidance/downloads/cib07212022.pdf (explaining the interaction between § 1396r-8 and the EPSDT mandate).

[4] 42 U.S.C. § 1396r-8(k)(6). HHS recognizes as much in the Proposed Rule. *See* Proposed Rule at 59455.

[5] 42 U.S.C. § 1396r-8(g)(1)(B)(i).

[6] *See, e.g.*, *Dobson v. Sec'y of Health & Hum. Servs.*, 2022 WL 424813 at *7 (11th Cir. 2022) (interpreting the phrase "supported by one or more citations" in § 1396r-8(k)(6) to mean a citation "tend[s] to show or help[s] provide the efficacy and safety of the prescribed off-label use").

and adults.[7] Likewise, a citation supports the use of triptorelin pamoate to suppress puberty in adolescents with gender dysphoria.[8]

Thus, in arguing that the proposed regulation does not run afoul of § 1396r-8 because it allows states to cover the relevant drugs when prescribed for an indication other than gender dysphoria,[9] HHS ignores the plain language of the Medicaid Act. HHS does not have the authority to prohibit coverage of drugs where, as here, Congress has explicitly required that states provide that coverage.

Further, the DRUGDEX entries underscore the arbitrary nature of the Proposed Rule. Take, for example, triptorelin pamoate. The Proposed Rule would not affect coverage of that drug when used to treat central precocious puberty, but it would prohibit coverage of the drug when used to treat gender dysphoria in adolescents. However, the DRUGDEX recommendation for using triptorelin pamoate to treat gender dysphoria is stronger than the recommendation for using the drug to treat central precocious puberty.[10] As another example, the strength of the evidence supporting the use of testosterone enanthate to treat hypogonadism in adolescents is lower than the strength of the evidence supporting its use to treat gender dysphoria.[11] Similarly, the DRUGDEX recommendation for (and the strength of the evidence in support of) using testosterone enanthate to treat delayed puberty in adolescents is the same as the recommendation for using it to treat gender dysphoria.[12] Nevertheless, the Proposed Rule would prohibit coverage of these drugs when used to treat gender dysphoria in adolescents, but allow coverage when used to treat these other conditions. Thus, the Proposed Rule is not only illegal, it runs counter to the scientific evidence, as described further below.

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[7] DRUGDEX, *Testosterone* (accessed Jan. 23, 2026) (attached); DRUGDEX, *Estradiol* (accessed Jan. 29, 2026) (attached). *See* Micromedex, *Recommendation, Evidence and Efficacy Ratings* (accessed Jan. 29, 2026) (attached); Micromedex, *Gender Dysphoria/Gender Incongruence – Gender-Affirming Hormone Therapy Guidelines* (accessed Jan. 29, 2026) (attached).

[8] DRUGDEX, *Triptorelin* (accessed Jan. 29, 2026) (attached).

[9] *See* Proposed Rule at 59455 ("There is no pharmaceutical that is solely indicated for these sex-rejecting procedures; the pharmaceuticals that are used for these procedures are approved for other indications. Thus, these pharmaceuticals will continue to be coverable by Medicaid programs for other indications in accordance with section 1927 of the Act.").

[10] *See* DRUGDEX, *Triptorelin* at 3 (for central precocious puberty, indicating that evidence favors efficacy, giving a recommendation of class IIb and listing the strength of evidence as category B); *id*. at 7 (for gender dysphoria, indicating that the drug is effective, giving a recommendation of class IIa, and listing the strength of evidence as category B); Micromedex, *Recommendation, Evidence and Efficacy Ratings* (accessed Jan. 29, 2026) (attached).

[11] *See* DRUGDEX, *Testosterone* at 16 (for hypogonadism in adolescents, indicating the evidence favors efficacy, giving a recommendation of class IIb, and listing the strength of evidence as category C); *id*. at 33–34 (for gender dysphoria in pediatric patients, indicating the evidence favors efficacy, giving a recommendation of class IIb, and listing the strength of evidence as category B).

[12] *See* DRUGDEX, *Testosterone* at 16 (for delayed puberty in adolescents, indicating the evidence favors efficacy, giving a recommendation of class IIb, and listing the strength of evidence as category B); *id*. at 33–34 (same, for gender dysphoria in pediatric patients).

b. The Proposed Rule is contrary to the EPSDT provisions of the Medicaid Act.

The EPSDT provisions are also implicated. These provisions require each state Medicaid program to cover any service that falls within one of the service categories listed in § 1396d(a) when the service is "necessary…to correct or ameliorate" illnesses or conditions in beneficiaries under age 21, regardless of whether the state covers the service for adults.[13] The services at issue in the Proposed Rule fall within the scope of the service categories listed in § 1396d(a). Surgical services fall under outpatient hospital services, inpatient hospital services, and/or physicians' services.[14] Drugs used to delay puberty and prescription hormones (*e.g.*, estrogen and testosterone) fall under the prescribed drugs category.[15]

HHS seems to contend that the services at issue are never necessary for beneficiaries under age 18 because "they may pose a risk of harm to children, including long-term irreversible harm."[16] As described in detail below, the determination that the services are never medically necessary is contrary to the published scientific research, as well as clinical experience and expert opinion.[17] Because the Medicaid-coverable services are "necessary…to correct or ameliorate" gender dysphoria for many transgender young people, the Proposed Rule clashes with the EPSDT provisions of the Medicaid Act.[18]

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[13] 42 U.S.C. §§ 1396d(r)(5), 1396a(a)(10)(A), 1396d(a)(4)(B); CMS, *EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* 9–10 (2014), https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf; CMS, *Dear State Health Official Letter #24-005, Best Practicers for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements* 6–7 (2024), https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf. Courts have recognized that the EPSDT obligation is "extremely broad." *Katie A., ex rel. Ludin v. L.A. Cnty.*, 481 F. 3d 1150, 1154 (9th Cir. 2007); *see Smith v. Benson*, 703 F. Supp. 2d 1262, 1269-70 (noting that CMS "has made the broad mandate of the EPSDT program abundantly clear").

[14] 42 U.S.C. § 1396d(a)(1), (2)(A), (5)(A). CMS indicates that states "may be using" § 1396d(a)(6) to cover services the Proposed Rule would exclude. Proposed Rule at 59451. It is not clear why that may be the case. Federal regulations make clear that § 1396d(a)(6) refers to "any medical or remedial care or services, *other than physicians' services*, provided by licensed practitioners within the scope of practice as defined under State law." 42 C.F.R. § 440.60 (emphasis added). These services include those provided by chiropractors, professional nurses (with some exceptions), podiatrists, psychologists, optometrists, and Christian Science Practitioners. CMS, *State Medicaid Manual* § 2500.2.

[15] 42 U.S.C. § 1396d(a)(12); *see* 42 U.S.C. § 1396d(r)(5); CMS, *EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents* 9–10 (2014), https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf.

[16] Proposed Rule at 59452.

[17] *See* Section II.b.II below.

[18] HHS suggests that states "may not have considered the full effects of all aspects of a child's needs (including long-term needs) as required under EPSDT," Proposed Rule at 59452, but provides no evidence to support that assertion. Further, even if we assume for the sake of argument that a particular state did not consider the long-term effects of the services in developing its coverage criteria, that would not support excluding coverage of the services nationwide as proposed.

c. 42 C.F.R. § 440.230 does not support the Proposed Rule.

While HHS focuses on 42 C.F.R. § 440.230 as supporting the Proposed Rule, that focus is misplaced for a number of reasons. First, HHS is correct that § 440.230(b) does not give states absolute flexibility to determine the amount, duration, and scope of covered services.[19] But HHS ignores that the regulation sets a floor for states, requiring them to provide services in sufficient amount, duration, and scope.[20] It does not follow that the regulation then somehow permits HHS to cap the amount, duration, or scope of services that states are able to cover. And while suggesting otherwise, HHS does not have unfettered discretion to disapprove a Medicaid state plan amendment.[21]

Second, the regulation does not supersede the statutory EPSDT obligations that attach to the states. As CMS has made clear many times, states cannot impose "a limit on the amount, duration, or scope of services that can never be exceeded" for EPSDT-eligible beneficiaries.[22] Yet, the proposed rule would force states to do just that.

Third, while HHS contends that the Proposed Rule is consistent with § 440.230(c), that is not the case. Under the regulation, states cannot arbitrarily deny or reduce the amount, duration, or scope of services based solely on diagnosis or condition. That is exactly what HHS is seeking to force states to do. The Proposed Rule would provide coverage for surgical procedures, medications to delay puberty, and hormone therapy when necessary to treat conditions other than gender dysphoria and deny coverage for the services when necessary to treat gender dysphoria. While HHS suggests that this differential treatment is justified based on the "risk/benefit profile" of the services when used to treat gender dysphoria, that justification holds no water, as described in detail in Section II below. Indeed, because the Proposed Rule permits "discrimination among individuals with the same medical needs stemming from different medical conditions," it violates the comparability provision of the Medicaid Act.[23]

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[19] Proposed Rule at 59451.
[20] 42 C.F.R. § 440.230(b).
[21] *See* Proposed Rule at 59451; 42 C.F.R. § 430.15 (explaining that determinations as to whether a state plan or state plan amendment meets or continues to meet "the requirements for approval are based on relevant Federal statutes and regulations").
[22] CMS, *Dear State Health Official Letter #24-005, Best Practicers for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements* 20 (2024), https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf; *see id*. at 21 ("Thus, while services available to adults may include limits on the amount, duration, and scope of services that can never be exceeded (i.e., a "hard limit"), states are not permitted to apply these kinds of limits to any service covered under EPSDT…").
[23] *Davis v. Shah*, 821 F.3d 231, 258 (2d Cir. 2016); *see White v. Beal*, 555 F.2d 1146, 1148 (3d Cir. 1977); *Cota v. Maxwell-Jolly*, 688 F.Supp.2d 980, 993 (N.D. Cal. 2010); *Flack v. Wis. Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1019 (W.D. Wis. 2019).

d. 42 U.S.C. § 1396a(a)(19) and 1396a(a)(30) do not provide CMS with legal authority for the Proposed Rule.

We strongly agree that states have a legal duty to ensure that payments for Medicaid and CHIP Services for children are consistent with quality of care and that care and services are provided in the best interests of beneficiaries.[24] The Proposed Rule would not help states fulfill these duties; rather, it would hamper their ability to do so.

According to HHS, 42 U.S.C. § 1396a(a)(19) supports its promulgation of the Proposed Rule. This provision "is intended to protect the administration of the Medicaid program and the interests of Medicaid recipients with respect to their health care" and ensure that the administration of the program "inures to the benefit of the Medicaid population or the Medicaid program as a whole."[25] This provision also requires that Medicaid services be provided "in a manner consistent with simplicity of administration."[26]

Courts have interpreted § 1396a(a)(19) to require HHS to ensure that states cover medically necessary care in their state Medicaid programs. These courts have made clear that a policy that eliminates coverage of an entire category of services is not in the best interests of beneficiaries.[27] Thus, this provision does not permit HHS to withhold payments for gender-affirming care to youth; on the contrary, it compels HHS to ensure Medicaid coverage of the services at issue when they are necessary to treat gender dysphoria in a beneficiary, including a beneficiary under age 18.

HHS has historically used § 1396a(a)(19) as the basis for regulations aimed at improving the operation of state Medicaid programs. Only once before has HHS used this provision to justify a regulation eliminating federal Medicaid funding for a particular service: provider-preventable conditions.[28] That situation was factually quite distinct from HHS's present proposal to eliminate federal Medicaid funding for all gender-affirming care for youth. First, the provider-preventable condition prohibition emanated from a specific statutory requirement instructing HHS to stop federal Medicaid payments for certain provider-preventable conditions and health care-acquired conditions.[29]

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[24] Proposed Rule at 59450.
[25] *Pharm. Rsch. & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 57, 72 (D.D.C. 2003), *aff'd* 362 F.3d 817 (D.C. Cir. 2004).
[26] 42 U.S.C. § 1396a(a)(19).
[27] *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 665 (2003) (a policy that "severely curtailed Medicaid recipients' access to prescription drugs" is not in beneficiaries' best interests); *see also Stewart v. Azar*, 366 F. Supp. 3d 125, 152 (D.D.C. 2019) (a "program [that] threatened the entirety of beneficiaries' Medicaid coverage — or even an aspect of their coverage, like that for prescription drugs" is unlikely to be in the best interests of beneficiaries).
[28] Medicaid Programs: Payment Adjustment for Provider Preventable Conditions Including Health Care Acquired Conditions, 76 Fed. Reg. 32816 (June 6, 2011) (codified at 42 C.F.R. § 447.26).
[29] 42 U.S.C. § 1396b–1; *see also* CMS, *Dear State Medicaid Director Letter, SMDL #08-004* at 3 (July 31, 2008), https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/smd073108.pdf (discussing a state's ability, prior to the enactment of the statutory prohibition on payment, to deny payment for provider-preventable conditions as not medically necessary).

Second, the prohibition on funding provider-preventable conditions did not prohibit beneficiaries from receiving services–it merely created a financial incentive to encourage providers to avoid serious clinical errors.[30] Specifically, the funding prohibition implemented in 42 C.F.R. § 447.26 requires states to withhold or adjust payments to a provider for the portion of any service or treatment that is attributable to that provider's error (*e.g.*, a surgery accidentally performed on the wrong body part).[31] The regulation makes clear that the state reductions or adjustments in payments cannot "prevent access to services for Medicaid beneficiaries."[32] Thus, the limitation is carefully crafted to prevent Medicaid from funding care that would have been unnecessary but for provider error, without restricting access to care for beneficiaries. In contrast, the proposal here would institute a blunt prohibition on payments for broad categories of services any time they are used to treat gender dysphoria for a person under age 18. The proposal fails to account for the impact on access to necessary care for Medicaid beneficiaries, including for those youth who need the services at issue to treat a condition other than gender dysphoria.

HHS also cites as authority for its proposal § 1396a(a)(30) of the Medicaid Act.[33] This provision is designed to ensure that states "consider the relevant factors of equal access, efficiency, economy, and quality of care…when setting [Medicaid] reimbursement rates."[34] In the Proposed Rule, HHS isolates the phrase "quality of care" and claims that it allows it to prohibit federal Medicaid funding for the services at issue. Specifically, HHS states: "Given the potential risks and lack of clear benefits associated with sex-rejecting procedures, we believe that covering them with Federal Medicaid…funding would be, for Medicaid beneficiaries, inconsistent…with quality of care."[35] But the plain language of § 1396a(a)(30) does not permit HHS to simply declare entire categories of services "inconsistent with quality of care" based on its own desired outcomes. Rather, it instructs HHS to oversee state Medicaid programs' rate-setting to ensure that Medicaid reimbursement rates are both efficient and economical, but not so low as to prevent

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[30] 42 C.F.R. § 447.26.
[31] *Id*. This includes situations previously identified in the Medicare program for which Medicare will not pay, and any other services identified in a state's Medicaid plan based on "a review of medical literature by qualified professionals, to be reasonably preventable through the application of procedures supported by evidence-based guidelines" that have negative consequences for beneficiaries and can be audited. *Id.* § 447.26(b).
[32] *Id.* § 447.26(c)(5).
[33] The provision requires a state's Medicaid plan to "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan…as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A).
[34] *Ark. Med. Soc'y, Inc. v. Reynolds*, 6 F.3d 519, 530 (8th Cir. 1993); *see also Orthopaedic Hosp. v. Belshe*, 103 F. 3d 1491, 1497 (9th Cir. 1997) ("Since the payments themselves must also be consistent with quality of care, the Department must consider the costs of providing quality care.").
[35] Proposed Rule at 59450.

beneficiaries from accessing quality health care services when medically necessary.[36] Thus, prior HHS rulemaking has relied on § 1396a(a)(30) to support rules related to state Medicaid rate-setting,[37] increasing access to covered services,[38] and avoiding duplicate payments for covered services.[39] HHS's reliance on § 1396a(a)(30) to support the Proposed Rule is misplaced.

Even if § 1396a(a)(30) could be understood to allow HHS to prohibit states from covering services it deems to be inconsistent with quality of care, HHS has not demonstrated that the services at issue here are inconsistent with quality of care. Elsewhere, HHS has defined the term "quality of care" to mean:

> The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. High quality care means that providers follow current best medical evidence and prioritize decisions that are consistent with peoples' values, needs, and preferences for a positive patient experience.[40]

The idea that gender-affirming care is associated with undue risks and lacks "clear benefits" is false, as explained in detail in Section II below. But even if it were true, the fact that a medical service has potential risks and its benefits are not clear does not mean that the service is inconsistent with "quality of care." As explained in more detail below, gender-affirming care has been shown to improve health outcomes and is consistent with current professional knowledge. In addition, the existing standards of care instruct providers to administer these services in accordance with the best medical evidence and to prioritize the values, needs, and preferences of young people with gender dysphoria in consultation with their parents and guardians as appropriate. The services at issue are consistent with quality of care.

Further, despite HHS's claims, the 1978 federal regulations prohibiting coverage of sterilization services for beneficiaries under age 21 do not support the Proposed Rule.[41] At the outset, it is important to note that the sterilization regulations do not prohibit coverage of gender-affirming care. As described below, many of the services excluded from coverage by the Proposed Rule do not result in permanent infertility. And, to the extent that a service

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[36] *Orthopaedic Hosp.*, 103 F. 3d at 1497.
[37] *See, e.g.,* Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 71142 (2020); Medicaid Program: Reassignment of Medicaid Provider Claims, 84 Fed. Reg. 19718 (2018); Medicaid Program; Optional State Plan Case Management Services, 72 Fed. Reg. 68077 (2007).
[38] *See, e.g.*, Medicaid Program: Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality, 85 Fed. Reg. 72754 (2018); Medicaid Program: Methods for Assuring Access to Covered Medicaid Services, 80 Fed. Reg. 67576 (2011).
[39] *See, e.g.*, Medicaid Program: Face-to-Face Requirements for Home Health Services, 81 Fed. Reg. 5530 (2011).
[40] CMS, *Key Concepts: Quality of Care* (Feb. 27, 2025), https://www.cms.gov/priorities/innovation/key-concepts/quality-care.
[41] *See* Proposed Rule at 59454 (citing 42 C.F.R. § 441.253).

does result in sterilization, it does not fall within the sterilization regulations because it is not provided "for the purpose of rendering an individual permanently incapable of reproducing."[42] Rather, it is provided for the purpose of treating gender dysphoria.[43]

There are a number of reasons why the sterilization regulations are not analogous to the Proposed Rule. First, when adopting the sterilization regulations in 1978, HHS relied on a different source of legal authority–42 U.S.C. § 1396d(a)(4)(C). That provision, which defines family planning services and supplies, does not apply to services provided to treat gender dysphoria. Second, the policy considerations here are quite different from those that informed the 1978 regulations. Unlike sterilization services, many of the services HHS is seeking to exclude are not "permanent and irreversible."[44] In addition, unlike in the sterilization context, there is no evidence that among individuals who receive gender-affirming care, adolescents have a higher rate of regret than adults.[45] To the contrary, the available scientific evidence shows that very few adolescents who receive gender-affirming care experience regret.[46]

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[42] 42 C.F.R. § 441.251 (defining sterilization); *see id*. § 441.255(a).
[43] *Cf*. Provision of Sterilization in Federally Assisted Programs of the Public Health Service, 43 Fed. Reg. 52146, 52149 (Nov. 8, 1978) (explaining that the definition "does not cover medical procedures which, while they may have the effect of producing sterility, have an entirely different purpose" because in those circumstances, "there is no reasonable alternative to the procedure"); Federal Financial Participation in State Claims for Sterilizations, 43 Fed. Reg. 52171 (Nov. 8, 1978) (indicating that the preamble published with the amendments to the Public Health Service regulations explains the new Medicaid regulations).
[44] 43 Fed. Reg. 52147.
[45] *See* 43 Fed. Reg. 52151, 52152 (pointing to research finding a higher rate of regret among younger women as compared to older women who receive sterilization services).
[46] *See, e.g.*, Kristina R. Olsen et al., *Levels of Satisfaction and Regret With Gender-Affirming Medical Care in Adolescence*, 178 JAMA PEDIATRICS 1354 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11581734/; Luca Crabtree et al., *A More Nuanced Story: Pediatric Gender-Affirming Healthcare is Associated With Satisfaction and Confidence* 75 J. ADOLESCENT HEALTH 772 (2023) (attached); A. Tang et al., *Gender-Affirming Mastectomy Trends and Surgical Outcomes in Adolescents*, 88 ANNALS PLASTIC SURGERY S325 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9555285 (finding 0.95% regret rate). Research on gender-affirming surgeries (which are rare for adolescents) demonstrate levels of regret that are far lower than those for other reconstructive surgeries. *Compare* Valeria P. Bustos et al., *Regret after Gender-affirmation Surgery: A Systematic Review and Meta-analysis of Prevalence*, 19 PLASTIC & RECONSTRUCTIVE SURGERY GLOBAL OPEN e3477 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8099405/ (finding a 1% regret rate) *and* Thomas Ren et al., *Prevalence of Regret in Gender-Affirming Surgery: A Systematic Review,* 92 ANNALS OF PLASTIC SURGERY 597 (2024), https://pubmed.ncbi.nlm.nih.gov/38685500/ (finding a 1.94% regret rate) *and S.K. Narayan et al., Guiding the Conversation – Types of Regret After Gender-Affirming Surgery and Their Associated Etiologies*, 9 ANNALS TRANSLATIONAL MED. 605 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8105823/ (finding a regret rate of 0.2% to 0.3%), *with* P.I. Borgen et al., *Patient Regrets After Bilaterial Prophylactic Mastectomy*, 5 ANNALS SURGICAL ONCOLOGY 603 (1998) (attached) (finding a 5% regret rate among women who underwent bilateral prophylactic mastectomy) *and* T. Zhong et al., *Decision Regret Following Breast Reconstruction: The Role of Self-Efficacy and Satisfaction with Information in the Preoperative Period*, 132 PLASTIC & RECONSTRUCTIVE SURGERY 724e-734e (2013), https://pubmed.ncbi.nlm.nih.gov/24165624/ (finding a 40% regret rate among women who underwent breast reconstruction).

Further, HHS promulgated the sterilization regulations in response to "tragic examples of sterilization abuse" in federal programs.[47] Indeed, the country has a long and disturbing history of forcing or coercing low-income women, women of color, immigrant women, and women with disabilities to undergo sterilization, often without their knowledge.[48] Here, however, there is no evidence to suggest that adolescents enrolled in Medicaid have been forced or coerced into receiving gender-affirming care. (It is difficult to imagine what could ever motivate a state or a provider to attempt to force or coerce adolescents to receive gender-affirming care.) In fact, the WPATH Standards of Care recommend a thorough informed consent/assent process prior to providing medical interventions for adolescents.[49]

Finally, in adopting the sterilization regulations, HHS noted that other "temporary methods of birth control which have no side effects and a high degree of effectiveness are generally available" to individuals under age 21.[50] In contrast, there are no equally effective, alternative services available to treat adolescents with gender dysphoria. While HHS contends that psychotherapy alone is effective, no evidence supports that contention, as described in detail in Section II below. In sum, HHS's 1978 rationale for restricting coverage of sterilization services does not support the funding exclusion in the Proposed Rule.

e. The Proposed Rule is contrary to the Children's Health Insurance Program (CHIP) statute.

HHS contends that the Proposed Rule would implement requirements in 42 U.S.C. §§ 1397aa(a) and 1397gg(e).[51] That is incorrect. Section 1397aa(a) sets forth the purpose of the CHIP statute: "to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children."[52] HHS misconstrues the provision in several respects. First, HHS wrongly suggests that the term "effective" refers to the effectiveness of particular services or treatments.[53] Rather, it requires that initiation and expansion of coverage be effective and

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[47] 43 Fed. Reg. 52146.
[48] *See, e.g.*, *Relf v. Weinberger*, 372 F. Supp. 1196, 1199 (D.D.C. 1974) (finding that "an indefinite number of poor people have been improperly coerced into accepting a sterilization operation under the threat that various federally supported welfare benefits would be withdrawn unless they submitted to irreversible sterilization"), *vacated as moot*, 565 F.2d 722 (D.C. Cir. 1977); Alexandra Minna Stern, *Sterilized in the Name of Public Health: Race, Immigration, and Reproductive Control in Modern California*, 95 AM. J. PUB. HEALTH 1128 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449330/ (describing the history of forced or coerced sterilization in the 1960s and 1970s); Sally J. Torpy, *Native American Women and Coerced Sterilization: On the Trail of Tears in the 1970s*, 24 AM. INDIAN CULTURE & RSCH. 1 (2000), https://escholarship.org/uc/item/2254n09g.
[49] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, *Version 8*, 23 INT. J. TRANS. HEALTH SUP. 1, S48-51, S61-62 (2022), https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644.
[50] 43 Fed. Reg. 52153.
[51] Proposed Rule at 59442, 59453.
[52] 42 U.S.C. § 1397aa(a).
[53] *See, e.g.*, Proposed Rule at 59450.

efficient.[54] In other words, the administration of the program must be effective and efficient. Existing CHIP regulations implement this interpretation of the statute, not the newly improvised interpretation in the in the Proposed Rule. Subpart D of 42 C.F.R. part 457 sets forth the state plan requirements for coverage and benefits, and that subpart does not purport to interpret or implement § 1397aa(a).[55]

Second, HHS suggests that the Proposed Rule would ensure that CHIP is coordinated with "Medicaid, the FEHB Program, and EHBs."[56] Again, § 1397aa(a) concerns the administration of the CHIP program. It does not indicate that states must align the scope of benefits provided in the various sources of health coverage for children.[57] Indeed, there is no question that Congress designed these programs to provide different benefits.[58] (What is more, HHS is wrong to suggest that plans required to cover EHBs are prohibited from covering gender-affirming care outside the scope of EHBs.)

As for § 1397gg(e), HHS is correct that it "applies numerous provisions in Medicaid in the same manner to title XXI."[59] That is irrelevant to the Proposed Rule. As noted above, Congress made clear that the two programs (Medicaid and CHIP) need not provide equivalent benefits. In addition, § 1397gg(e) does not include the two Medicaid Act provisions–§§ 1396a(a)(19) and 1396a(a)(30)–that HHS contends allow it to exclude gender-affirming care from Medicaid. (And, as described above, that contention is false.) In short, these novel interpretations of the CHIP statute cannot support the Proposed Rule, and adoption of such an interpretation would trigger the major questions doctrine.[60]

Further, these novel interpretations are directly contrary to 42 U.S.C. § 1397cc. That provision explicitly gives states that implement a separate CHIP program the choice to provide coverage that consists of: 1) benchmark coverage; 2) benchmark equivalent

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[54] *See* 42 U.S.C. § 1397jj(a) (defining child health assistance as "payment for part or all of the cost of health benefits coverage for targeted low-income children that includes any of the following" listed services).
[55] *See* 42 C.F.R. § 457.401. *Compare id*. §§ 457.500 (listing § 2101(a) [§ 1397aa(a)] as a statutory basis for subpart E, which sets forth the state plan requirements for enrollee financial responsibilities), 457.700 (listing § 2101(a) as a statutory basis for subpart G, regarding strategic planning, reporting, and evaluation requirements), 457.900 (listing § 2101(a) as a statutory basis for subpart I, regarding program integrity requirements).
[56] Proposed Rule at 59453.
[57] Additional provisions of the CHIP statute make clear what kind of coordination Congress envisioned. *See, e.g.*, 42 U.S.C. § 1397bb(a)(3) (requiring coordination with state efforts to increase creditable health coverage for children), 1397bb(b)(3) (requiring coordination with other health coverage programs in screening for eligibility), 1397bb(c) (requiring coordination of CHIP administration with other public and private health insurance programs); 42 C.F.R. § 457.80.
[58] *See, e.g.*, 42 U.S.C. § 1397aa(a) (allowing states to provide coverage to CHIP-eligible children through Medicaid, coverage that meets the requirements of § 1397cc, or a combination of the two options).
[59] Proposed Rule at 59453.
[60] *See, e.g.*, *West Virginia v. EPA*, 597 U.S. 697, 724 (2022) (finding when an agency claims "a newfound power in the vague language of an ancillary provision of the Act…there is every reason to hesitate before concluding that Congress meant to confer" the authority the agency claims" (cleaned up)).

coverage; 3) in three specified states, benefits provided in an existing comprehensive state-based program; or 4) Secretary-approved coverage.[61]

If a state chooses benchmark coverage, it provides coverage that is at least equivalent to the benefits in: 1) the standard Blue-Cross/Blue Shield preferred provider plan offered to federal employees; 2) the plan generally available to state employees; or 3) the largest HMO plan in the state.[62] Given the text of the statute, it is clear that if *any* of the benchmark plans cover gender-affirming care for adolescents under age 19, states have the authority to cover that care for CHIP enrollees. In a number of states, the plan generally available to state employees covers gender-affirming care for young people.[63] Further, the statute does not limit states to the specific benefits covered in one of the benchmark plans. Rather, it requires states to provide coverage that "is at least equivalent to" the benefits in a benchmark plan.[64] Thus, Congress gave states the flexibility to cover specific services or treatments for CHIP beneficiaries, regardless of whether the selected benchmark plan covers the services or treatments, so long as the coverage is equivalent in total.

Similarly, with the benchmark-equivalent coverage option, Congress explicitly gave states the flexibility to design a benefits package for CHIP, subject to certain minimum criteria. Congress set a floor for states with respect to the categories of services that must be covered and the minimum actuarial value of the coverage (in total and for certain optional categories of services included in the relevant benchmark plan).[65] The statute makes clear that states must or are permitted to cover the categories of services that include the services at issue in the Proposed Rule. Inpatient and outpatient hospital services and physicians' surgical and medical services are mandatory, and prescription drugs, clinic services, and other services recognized by state law are optional.[66] Further, nothing in the statute constrains state flexibility to determine the scope of those services, so long as the actuarial requirements are met.

Finally, even assuming for the sake of argument that the Secretary has the authority to exclude gender-affirming care from Secretary-approved coverage, that would not affect the other three coverage options available to states.[67] Under the statute, a state that is currently offering Secretary-approved coverage has the flexibility to switch to benchmark or

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[61] 42 U.S.C. § 1397cc(a); *see* 42 C.F.R. § 457.410(a) (noting state choice).
[62] 42 U.S.C. § 1397cc(b); *see* 42 C.F.R. § 457.420.
[63] *See* Movement Advancement Project, *Healthcare Laws and Policies, State Employee Benefits Coverage for Transgender-Related Care* (2024), https://www.lgbtmap.org/img/maps/citations-healthcare-state-employees.pdf; *see also e.g.*, Anthem Blue Cross, *Select HMO Basic Plan for CalPERS, Combined Evidence of Coverage and Disclosure Form* 38-39 (eff. Jan. 1, 2026), https://www.anthem.com/content/dam/digital/docs/microsites/calpers/select-hmo/select-hmo-eoc-latest.pdf.
[64] 42 U.S.C. § 1397cc(a)(1); *see* 42 C.F.R. § 457.420 (describing benchmark coverage as coverage that is "substantially equal to the health benefits coverage" in one of the benchmark options).
[65] 42 U.S.C. § 1397cc(a)(2), (c); *see* 42 C.F.R. § 457.430.
[66] 42 U.S.C. § 1397cc(a)(2), (c), 1397jj; *see* 42 C.F.R. §§ 457.430, 457.402.
[67] *See* Proposed Rule at 59453 (noting the majority of separate CHIP programs provide Secretary-approved coverage); 42 U.S.C. § 1397cc(a)(1)–(3).

benchmark-equivalent coverage. And, if it chooses to do so, the state has the option to cover gender-affirming care for youth, as described above.

f. The Proposed Rule runs afoul of federal non-discrimination protections.

HHS asserts that the Proposed Rule does not constitute sex discrimination in violation of section 1557 of the ACA or the Equal Protection clause. Not so.

While HHS claims that the decision in *United States v. Skrmetti*, 605 U.S. 495 (2025) means that the Proposed Rule does not constitute impermissible sex discrimination under the Equal Protection clause, that is not correct.[68] First, the Proposed Rule discriminates based on transgender status and sex, making it subject to heightened scrutiny. Second, in *Skrmetti*, the court reaffirmed that even if "a law's classifications are neither covertly nor overtly based on sex," it is still subject to heightened review if "it was motivated by an invidious discriminatory purpose."[69] Here, as described in Section II.b below, *all* of the evidence indicates that the Proposed Rule was motivated by an invidious discriminatory purpose. None of HHS's justifications for the Proposed Rule are sufficient to withstand heightened scrutiny, as described in detail in Section II below.

As for section 1557, HHS again relies on *Skrmetti*. But that decision does not even involve section 1557. The standard for evaluating sex discrimination under section 1557 is not the same as the standard in constitutional cases.[70] Rather than look to *Skrmetti*, the better course is to use the standard set forth by the Court in *Bostock,* a case interpreting Title VII.[71] Section 1557 incorporates Title IX, and courts have repeatedly held that a statutory analysis of sex discrimination under Title IX and Title VII is the same.[72] Under *Bostock,* where sex is a "but for" cause of harm, there is sex discrimination.[73] Because the Proposed Rule here would prohibit Medicaid funding for the services at issue based on the sex of the person seeking the service, and the person's sex is the "but for" cause of the funding prohibition, the proposal violates section 1557.[74]

The Proposed Rule cites only one district court case to support its assertion that the proposal does not constitute sex discrimination: *Tennessee v. Kennedy*, No. 1:24CV161-LG-BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025). But at least one other district court

[68] Proposed Rule at. 59449, 59451.
[69] *Skrmetti*, 605 U.S. at 516. The Court did not determine whether Tennessee's law was pretextual because the plaintiffs in *Skrmetti* did not make that argument. *See id.* at 519.
[70] *See Walker v. Kennedy*, 790 F. Supp. 3d 138, 147 (E.D.N.Y. 2025) (holding that "*Skrmetti* did not resolve the debate" as to the scope of 1557's sex discrimination provision).
[71] *Bostock v. Clayton Cnty.*, 590 U.S. 644 (2020).
[72] *See, e.g., AC v. Metro. Sch. Dist. of Martinsville*, 75 F. 4th 760, 769 (7th Cir. 2023); *Grabowski v. Ariz. Bd. of Regents*, 69 F. 4th 1110, 1116 (9th Cir. 2023); *Vengalattore v. Cornell Univ.*, 36 F. 4th 87, 103 (2d Cir. 2022).
[73] *Bostock,* 590 U.S. at 656.
[74] *See L.B. v. Premera Blue Cross*, 795 F. Supp. 3d 1311, 1315 (W.D. Wash. 2025); *see also Am. Ass'n of Physicians for Hum. Rts., Inc. v. Nat'l Insts. of Health*, 795 F. Supp. 3d 678, 695 (D. Md. 2025) (violation of § 1557 to terminate grants that "relate to LGBTQI+ health").

has reached the opposite conclusion after *Skrmetti,* finding that section 1557's prohibition on sex discrimination makes it unlawful to prohibit coverage of medical services to treat gender dysphoria, when those services are covered to treat other conditions.[75] The *L.B. v. Premara Blue Cross* case's reasoning is compelling; it demonstrates that the kind of funding ban HHS is attempting to implement in this proposal would violate section 1557.

II. The Proposed Rule Does Not Reflect Reasoned Decisionmaking.

a. *An increase in the number of adolescents with gender dysphoria does not justify prohibiting Medicaid and CHIP coverage of gender-affirming care.*

HHS points to the increase in the number of adolescents who have been diagnosed with gender dysphoria.[76] But, HHS does not (and cannot) explain how this could support prohibiting Medicaid and CHIP coverage of services to treat gender dysphoria.

To the extent that HHS is asserting that adolescents are being misdiagnosed with gender dysphoria, there is no evidence to support that assertion. The HHS "review of evidence" that the Proposed Rule relies on (discussed in detail below) states that gender dysphoria is "overdiagnosed."[77] Specifically, HHS postulates that a "rise in mental health awareness campaigns aimed at reducing stigma and increasing understanding" may account for an increase in gender dysphoria diagnoses.[78] As support, the HHS Review cites only one study. That study merely calls for research to test the hypothesis that "mental health awareness efforts [are] contributing to the rise in reported mental health problems."[79] It does not conclude that greater awareness is causing a rise in diagnoses, much less that the diagnoses are incorrect.

In addition, the HHS Review asserts that "[l]oosening the diagnostic criteria for a condition will likely increase overdiagnosis and the risk of iatrogenic harm," before discussing the change from "Gender Identity Disorder" to "Gender Dysphoria" in the DSM.[80] HHS has no

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[75] *L.B.*, 795 F. Supp. 3d at 1315. Several pre-*Skrmetti* cases have similarly held that policies that limit coverage of gender-affirming care constitute sex discrimination under section 1557. *See, e.g., PFLAG, Inc. v. Trump*, 766 F. Supp. 3d 535, 569 (D. Md. 2025), *appeal docketed,* No. 25-1279 (4th Cir. Mar. 25, 2025); *Dekker v. Weida*, 679 F. Supp. 3d 1271, 1298 (N.D. Fla. 2023), *appeal docketed,* No. 23-12159 (11th Cir. Jun. 27, 2023); *Flack v. Wis. Dept. of Health Servs*., 395 F. Supp. 3d 1001, 1015 (W.D. Wis. 2019); *Boyden v. Conlin,* 341 F. Supp. 3d 979, 997 (W.D. Wis. 2018); *Tovar v. Essential Health*, 342 F. Supp. 3d 947, 953 (D. Minn. 2018); *see also, e.g., Doe v. Snyder*, 28 F. 4th 103, 114 (9th Cir. 2022) (remanding to District Court to apply *Bostock* in its section 1557 analysis).

[76] Proposed Rule at 59443.

[77] HHS, *Treatment of Pediatric Gender Dysphoria: Review of Evidence and Best Practices* 249, 250 (2025), https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf [hereinafter "HHS Review"].

[78] HHS Review at 250.

[79] Lucy Foulkes & Jack L. Andrews, *Are Mental Health Awareness Efforts Contributing to the Rise in Reported Mental Health Problems? A Call to Test the Prevalence Inflation Hypothesis*, 69 NEW IDEAS PSYCH. 1 (2023), https://www.sciencedirect.com/science/article/pii/S0732118X2300003X.

[80] HHS Review at 251.

basis for claiming that looser diagnostic criteria are likely to result in overdiagnosis and harm. More critically, in the case of gender dysphoria, the diagnostic criteria have been tightened, not loosened. As HHS acknowledges, the medical community previously used the diagnoses of Gender Identity Disorder and "Transsexualism," which focused on the incongruence between an individual's birth sex and their true gender. Given the breadth of the diagnostic criteria, nearly *all* transgender and gender non-conforming people qualified for a diagnosis.[81] The current diagnosis, gender dysphoria, was adopted in 2013.[82] It focuses on the "clinically significant distress or impairment" a person experiences as a result of the incongruence between their birth sex and true gender, not just the incongruence itself.[83] In other words, the move from Gender Identity Disorder to a gender dysphoria diagnosis narrowed the universe of individuals who qualify for a diagnosis. By HHS's logic, that change will likely reduce overdiagnosis and the risk of harm.

Further, even with the rise in the number of adolescents diagnosed with gender dysphoria, medical interventions to treat gender dysphoria remain extremely rare among adolescents. A recent analysis found that fewer than 0.1% of U.S. adolescents with private insurance received medication to delay puberty or gender-affirming hormones between 2018 and 2022.[84] Utilization rates are likely even lower among Medicaid beneficiaries.[85] Another recent study found that a miniscule percentage of insured minors received gender-affirming surgery in 2019: 0.002% of minors ages 15 to 17 and 0.0001% of minors ages 13 to 14.[86] Almost all of the procedures were chest-related.[87] HHS points to a study that found a recent increase in gender-affirming surgery,[88] but ignores the authors' conclusion that gender-affirming surgery is "relatively uncommon" in patients under 18, with fewer than 1200 patients in this age group undergoing surgery in any given year.[89] In addition, HHS ignores the authors' statement linking the increase in surgery to the documented benefits of the treatment.[90]

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[81] *See* Brief of GLBTQ Legal Advocates & Defenders et al. as Amici Curiae in Support of Plaintiff-Appellants at 10-12, *Williams v. Kincaid*, 45 F.4th 759 (4th Cir. 2022) (No. 21-2030), https://glad-org-wpom.nyc3.cdn.digitaloceanspaces.com/wp-content/uploads/2021/12/20211208-Williams-v-Kincaid-amicus.pdf (discussing evolution of scientific and medical classification of GID and GD).
[82] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition (DSM-V)* 453 (2013).
[83] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition Text Revision (DSM-5-TR)* (2022).
[84] Landon D. Hughes et al., *Gender-Affirming Medications Among Transgender Adolescents in the U.S., 2018–2022,* 179 JAMA PEDIATRICS 342 (2025) https://jamanetwork.com/journals/jamapediatrics/fullarticle/2828427.
[85] *Id.*
[86] *See* Dannie Dai et al., *Prevalence of Gender-Affirming Surgical Procedures Among Minors and Adults in the US*, 7 JAMA NETWORK OPEN 6 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11211955/.
[87] *Id*. Further, the study found that the vast majority of breast reductions in 2019 were performed on non-transgender males.
[88] Proposed Rule at 59443 (citing Jason D. Wright et al., *National Estimates of Gender-Affirming Surgery in the US*, 6 JAMA NETWORK OPEN e2330348 (2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707).
[89] Wright et al., *National Estimates of Gender-Affirming Surgery in the US*.
[90] *See id*.

Taken together, these data indicate that an increase in gender dysphoria diagnoses does not justify prohibiting federal Medicaid and CHIP funding for gender-affirming care in minors.

b. The HHS Review, on which the Proposed Rule relies, is not a valid scientific assessment of the evidence.

Throughout the Proposed Rule, HHS uses its own Review–initially released in May 2025 and finalized in November 2025–to justify prohibiting Medicaid and CHIP coverage of gender-affirming care for youth. HHS claims that its Review takes an "evidence-based medicine approach" to evaluating these services and is "methodologically rigorous."[91] However, that is not accurate. Major medical associations, as well as expert clinicians and researchers, have denounced the HHS Review as a politically- and ideologically-driven document that mischaracterizes gender-affirming care and distorts the scientific evidence.[92]

1. The HHS Review is not an unbiased scientific document, but rather a document designed to further the administration's political agenda.

Events leading up to the initial release of the HHS Review show that it was drafted to reach a predetermined outcome. Soon after he assumed office, President Trump issued two Executive Orders targeting transgender individuals generally and gender-affirming care specifically. The first EO (14168): declared it "the policy of the United States to recognize two sexes, male and female;" defined "gender ideology" as "permitting the false claim that males can identify as and thus become women and vice versa;" and directed federal agencies to "end the Federal funding of gender ideology" and prohibit the use of federal funding to "promote gender ideology."[93]

In the second EO (14187), President Trump declared it "the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called 'transition' of a child from

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[91] Proposed Rule at 59444.

[92] *See, e.g.*, Nadia Dowshen et al., *A Critical Scientific Appraisal of the Health and Human Services Report on Pediatric Gender Dysphoria*, 77 J. ADOLESCENT HEALTH 3 (2025) (attached); G. Nic Rider et al., *Scientific Integrity and Pediatric Gender Healthcare: Disputing the HHS Review,* SEXUALITY RSCH. & SOC. POL'Y (2025) (attached); Letter from Am. Psychiatric Ass'n to U.S. Dep't of Health & Hum. Servs. (updated Sept. 26, 2025) (in HHS Review, Supplement at 7); Am. Acad. of Pediatrics, *News Release, AMA and AAP Joint Statement on Evidence-Based Health Care* (Nov. 19, 2015), https://www.aap.org/en/news-room/news-releases/aap/2025/ama-and-aap-joint-statement-on-evidence-based-health-care/; Am. Acad. of Pediatrics, *News Release: AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria* (May 1, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-hhs-report-treatment-for-pediatric-gender-dysphoria/; Am. Psych. Ass'n, *APA Statement on Access to Treatment for Transgender, Gender Diverse, and Nonbinary People* (May 1, 2025), https://updates.apaservices.org/statement-on-access-to-treatment-for-transgender-gender-diverse-and-nonbinary-people.

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

one sex to another."[94] Referring to gender-affirming care with the derisive and inaccurate term "chemical and surgical mutilation," he ordered federal agencies to defund medical institutions that provide the care and to exclude coverage of the care in TRICARE, the Federal Employee Health Benefits program, and the Postal Service Health Benefits program.[95] The EO specifically ordered the HHS Secretary to "take all appropriate actions to end" gender-affirming care for youth and to publish a review of the literature on gender-affirming care, which would end reliance on the "junk science" reflected in the WPATH Standards of Care.[96] A week after issuing the EO, the White House stated that "[i]t's already having its intended effect–preventing children from being maimed and sterilized by adults perpetuating a radical, false claim that they can somehow change a child's sex." The online post listed hospitals that had taken action "to downsize or eliminate their so-called 'gender-affirming care' programs."[97]

There is no question that HHS understood its directive. In fact, months before the HHS Review was even completed, CMS sent an alert to hospitals that reflected the Review's eventual conclusions–there is a "lack of medical evidence in support of" gender-affirming care, and the care is "dangerous" and "harmful."[98] The following month, CMS sent a similar letter to state Medicaid directors, warning that gender-affirming care "lack[s] reliable evidence of long-term benefits for minors, and…[is] now known to cause long-term and irreparable harm."[99] In addition, HHS issued a proposed rule (later finalized) prohibiting most insurers in the individual and small-group market from covering gender-affirming care, which the rule called "sex-trait modification procedures," as an Essential Health Benefit (EHB).[100]

HHS's choice of authors for its Review confirms that its conclusions were predetermined. Many of the authors are outspoken critics of gender-affirming care and are affiliated with anti-LGTBQ+ groups.[101] For example, several of the authors have ties to organizations like the Society for Evidence Based Gender Medicine (SEGM), Alliance Defending Freedom,

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[94] Exec. Order No. 14187, Protecting Children from Chemical and Surgical Mutilation, 90 Fed. Reg. 8771 (Feb. 3, 2025).
[95] *Id*. at 8772.
[96] *Id*. at 8771.
[97] The White House, *President Trump is Delivering on His Commitment to Protect Our Kids* (Feb. 3, 2025), https://www.whitehouse.gov/articles/2025/02/president-trump-is-delivering-on-his-commitment-to-protect-our-kids.
[98] Letter from CMS to Hospital Providers and Other Covered Entities (Mar. 5, 2025), https://www.cms.gov/files/document/QSSAM-25-02-Hospitals.pdf.
[99] CMS, *Dear State Medicaid Director Letter* (April 11, 2025), https://www.cms.gov/files/document/letter-stm.pdf.
[100] Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 Fed. Reg. 12942 (Mar. 19, 2025) (proposed rule); 90 Fed. Reg. 27074 (June 25, 2025) (final rule).
[101] Theresa Gaffney & Annalisa Merelli, *HHS names authors and releases peer review comments for gender dysphoria report*, STATNEWS (Nov. 19, 2025), https://www.statnews.com/2025/11/19/hhs-gender-affirming-care-report-authors-named/; S. Baum, *Trump's Anti-Trans Report Authors Revealed: Hate Groups and Billionaire-Funded Anti-Trans Activists*, ERIN IN THE MORNING (2025), https://www.erininthemorning.com/p/trumps-anti-trans-report-authors.

and the American College of Pediatricians, all of which have been designated as hate groups by the Southern Poverty Law Center.[102] In addition, many of the authors have little or no experience providing care to youth with gender dysphoria, and none of them have conducted clinical research on youth with gender dysphoria, as described below.

Indeed, several of the authors of these studies are not even medical researchers or clinicians: Evgenia Abbruzzese is the co-founder of SEGM. She holds a bachelor's degree and previously worked in insurance analytics.[103] Leor Sapir holds a PhD in political science and works as a fellow at the Manhattan Institute for Policy Research, a conservative think tank.[104] He is a vocal critic of gender-affirming care.[105] Alex Byrne is a professor of philosophy who specializes in the philosophy of mind, metaphysics and epistemology.[106] Since 2018, Professor Byrne has written extensively to critique the concept of gender identity, deny the existence of transgender people, and question the effectiveness of gender-affirming care. His 2023 book, *Trouble with Gender: Sex Facts, Gender Fictions*, was rejected by Oxford University Press because peer reviewers felt it did not cover its subject in "a sufficiently serious and respectful way."[107] Moti Gorin is an associate professor of philosophy who specializes in bioethics and moral and political philosophy.[108] Professor Gorin has written extensively to question the effectiveness of gender-affirming care for youth.[109]

Moreover, the authors who are health care providers do not appear to have any relevant experience and hold unscientific, fringe views about transgender people and gender

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[102] *Group Dynamics and Division of Labor within the Anti-LGBTQ+ Pseudoscience Network*, Southern Poverty Law Center (Dec. 13, 2023), https://www.splcenter.org/resources/reports/defining-pseudoscience-network/; *American College of Pediatrics, Extremist Files*, Southern Poverty Law Center, https://www.splcenter.org/resources/extremist-files/american-college-pediatricians/ (last accessed Feb. 15, 2026); *Alliance Defending Freedom, Extremist Files*, Southern Poverty Law Center, https://www.splcenter.org/resources/extremist-files/alliance-defending-freedom/ (last accessed Feb. 15, 2026).

[103] HHS Review at 17.

[104] *Manhattan Inst., Leo Sapir*, https://manhattan.institute/person/leor-sapir (last visited Feb. 8, 2026).

[105] *See, e.g.,* Leor Sapir, *Gender Medicine on the Ropes,* CITY J., Winter 2025, https://www.city-journal.org/article/gender-medicine-trans-movement-donald-trump-election (referring, for example, to "girls" who "had their breasts amputated for 'gender transition' purposes" and advocating for the Trump administration to appoint "individuals with experience combating transgender activism").

[106] *Mass. Inst. Tech., Faculty Profiles: Alex Byrne*, https://philosophy.mit.edu/byrne (last visited Feb. 8, 2026).

[107] Alex Byrne, *Philosophy's No-Go Zone*, QUILLETTE (Apr. 17, 2023), https://quillette.com/2023/04/17/philosophys-no-go-zone.

[108] *Colo. State Univ., Moti Gorin*, https://www.libarts.colostate.edu/people/mgorin (last visited Feb. 8, 2025).

[109] *See e.g.,* Moti Gorin, *What Is the Aim of Pediatric "Gender-Affirming" Care?,* 57 HASTINGS CTR. REP. 35 (2024), https://onlinelibrary.wiley.com/doi/10.1002/hast.1583; Moti Gorin, *The Cure for Politicized Pediatric Gender Care*, HASTINGS BIOETHICS FORUM (Nov. 17, 2022), https://www.thehastingscenter.org/pediatric-gender-care-the-cure-for-politicized-medicine-is-evidence-based-medicine.

dysphoria. Kristopher Kaliebe is a child and adolescent psychiatrist.[110] Dr. Kaliebe: (1) has never conducted any original, peer-reviewed research about gender identity, transgender people, or gender dysphoria;[111] 2) has not published any literature, let alone scientific, peer-reviewed literature, on gender dysphoria or transgender people;[112] (3) has never treated a patient for gender dysphoria;[113] (4) lacks any training or experience on the development of clinical practice guidelines;[114] and (5) has suggested that cognitive behavioral therapy or yoga could be effective treatments for gender dysphoria, though these approaches are wholly unsupported by any clinical literature.[115]

Michael Laidlaw is an adult endocrinologist in private practice.[116] Dr. Laidlaw: (1) has never conducted any original, peer-reviewed research about gender identity, transgender people, or gender dysphoria;[117] (2) has not published any scientific, peer-reviewed literature on gender dysphoria or transgender people;[118] (3) has never diagnosed a patient with gender dysphoria;[119] and (4) has only treated one patient with gender dysphoria (nearly two decades ago, prior to the existence of the DSM-V's gender dysphoria diagnosis).[120] Dr. Laidlaw has acknowledged that his "opposition to gender-affirming care for the treatment of gender dysphoria in youth and adults is contrary to the vast majority of medical associations' recommendations."[121] Indeed, he opposes affirmation of a transgender person's identity in any circumstances.[122]

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[110] *Univ. S. Fla., Kristopher Kaliebe, MD*, https://health.usf.edu/medicine/psychiatry/faculty/kkaliebe (last visited Feb. 8, 2026).
[111] *Dekker v. Marstiller,* No: 4:22cv325, Kaliebe Dep. 43:17–44:1 (Mar. 20, 2023) (excerpts attached).
[112] *Id.* at 25:5–14.
[113] *Id.* at 33:18–21 ("So you wouldn't be providing treatment for the dysphoria at Silver Clinic? A. I think we would not be directly addressing gender dysphoria in psychotherapy."); *id.* at 33:15–16 ("A…I don't know that we would say we were giving therapy for gender dysphoria"); *id.* at 138:24–139:1 ("Q. You do not provide medical treatment for gender dysphoria; is that right? A. Medicines, correct.").
[114] *Id.* at 101:3–10.
[115] *Id.* at 152:7–22 (cognitive behavioral therapy), 164:21–165:9, 166:5–11 (yoga).
[116] DrLaidlaw.com, About, http://www.drlaidlaw.com/about.html (last visited Feb. 8, 2026). Dr. Laidlaw has testified that fewer than 5% of his patients are under 18. *Dekker v. Marstiller,* No: 4:22cv325, Prelim. Injunction Hearing Tr. 8:14-16 (Oct. 12, 2022) (excerpts attached).
[117] *Dekker v. Marstiller,* No. No: 4:22cv325, Prelim. Injunction Hearing Tr. 10:15-11:13 (Oct. 12, 2022); *C.P. v. Blue Cross*, No. 3:20-cv-06145-RJB, Laidlaw Dep. 29:23-30:6 (Sep. 2, 2022) (excerpts attached).
[118] *C.P. v. Blue Cross*, No. 3:20-cv-06145-RJB, Laidlaw Dep. 42:10-42:22 (Sep. 2, 2022). Dr. Laidlaw's only publications relating to gender dysphoria in a peer-reviewed journal are letters to the editor not based on any original research or scientific study; he cannot confirm these were subjected to peer-review. *Id.* at 31:14-39:23; *Dekker v. Marstiller,* No. No: 4:22cv325, Prelim. Injunction Hearing Tr. 9:21–11:18; Ex. 5 (Oct. 12, 2022).
[119] *Dekker v. Marstiller,* No. No: 4:22cv325, Prelim. Injunction Hearing Tr. 11:19–11:21 (Oct. 12, 2022); *C.P. v. Blue Cross*, No. 3:20-cv-06145-RJB, Laidlaw Dep. 45:21–46:3 (Sep. 2, 2022).
[120] *Dekker v. Marstiller,* No. No: 4:22cv325, Prelim. Injunction Hearing Tr. 11:22–12:16 (Oct. 12, 2022); *C.P. v. Blue Cross*, No. 3:20-cv-06145-RJB, Laidlaw Dep. 43:11–43:17 (Sep. 2, 2022).
[121] *Dekker v. Marstiller,* No. No: 4:22cv325, Prelim. Injunction Hearing Tr. 25:22–26:1 (Oct. 12, 2022).
[122] *Id*. at 87:15–87:21, 39:22–40:19.

Further, events following the initial release of the HHS Review in May 2025 underscore that the Review (along with the Proposed Rule) is part of a coordinated political campaign to end the provision of gender-affirming care for youth. In April 2025, the Attorney General issued a memo condemning the "radical ideological agenda…that teaches children to deny biological reality" and describing gender-affirming care as "the barbaric practice of surgically and chemically maiming and sterilizing children."[123] Pursuant to EO 14187, the Attorney General directed the DOJ to pursue criminal and civil enforcement actions against practitioners, hospitals, and clinics that provide gender-affirming care to youth, as well as drug manufacturers and distributers that promote off-label use of medications "to facilitate a child's so-called 'gender transition.'"[124] In June 2025, the Assistant Attorney General issued a memo indicating that the Civil Division of the DOJ "will use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities consistent with these directives.[125] The DOJ issued civil subpoenas to more than 20 hospitals and providers, with the Attorney General claiming that they "mutilated children in the service of a warped ideology."[126] In addition, the Federal Trade Commission began investigating "unfair or deceptive trade practices in 'gender-affirming care' for minors."[127] The White House then issued a news release boasting that President Trump delivered on his campaign promise to end "child sexual mutilation" and listing hospitals that stopped providing gender-affirming care to youth.[128]

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[123] Memo from the Off. of the Attorney General to Select Component Heads (April 22, 2025), https://www.justice.gov/ag/media/1402396/dl.
[124] *Id*. at 3–4.
[125] Memo from Brett A. Shumate, Assistant Attorney General, to All Civil Division Employees 2–3 (June 11, 2025), https://www.justice.gov/civil/media/1404046/dl?inline.
[126] U.S. Dep't of Justice, *Press Release, 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. The subpoenas challenged in court have been quashed or set aside, with judges finding that the government did not have a proper purpose in issuing them. *See, e.g.*, *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-mc-00041-JHC, 2025 WL 3562151 *12 (W.D. Wash. Sept. 3, 2025) (finding "the DOJ requested documents as part of an effort to end gender-related care for minors"); *In Re: Administrative Subpoena No. 25-1431-019,* 800 F. Supp. 3d 229, 239 (D. Mass. 2025) ("It is abundantly clear that the true purpose of issuing the subpoena is to interfere with the Commonwealth of Massachusetts' right to protect GAC within its borders, to harass and intimidate BCH to stop providing such care, and to dissuade patients from seeking such care."); *In re: 2025 UPMC Subpoena*, No. 2:25-mc-01069-CB, 2025 WL 3724705 (W.D. Pa. Dec. 24, 2025) (noting that no federal reported decision has ruled for the government and joining the other courts in finding that the subpoena "carries more than a whiff of ill-intent"); *In re Child.'s Nat'l Hosp.*, No. 1:25-cv-03780-JRR, 2026 WL 160792 (D. Md. Jan. 21, 2026); *In re Dep't of Justice Administrative Subpoena No. .25-1431-030*, No. 25-mc-00063-SKC-CYC, 2026 WL 33398 (D. Colo. Jan. 5, 2026) (finding that the government was using "the FDCA as a smokescreen for its true objective of pressuring pediatric hospitals into ending gender-affirming care through commencing vague, suspicionless 'investigations'").
[127] FTC, *News Release: FTC Requests Public Comment Regarding 'Gender-Affirming Care' for Minors* (July 28, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/07/ftc-requests-public-comment-regarding-gender-affirming-care-minors (noting the FTC held a "workshop" on the issue on July 9, 2025).
[128] The White House, *President Trump Promised to End Child Sexual Mutilation – and He Delivered* (July 25, 2025), https://www.whitehouse.gov/articles/2025/07/president-trump-promised-to-end-child-sexual-mutilation-and-he-delivered/.

Finally, when HHS released the Proposed Rule, it took several companion actions: 1) issuing a notice of proposed rulemaking that would prohibit hospitals from providing gender-affirming care ("sex-rejecting procedures") to minors as a condition of participation in Medicare and Medicaid;[129] and 2) declaring that "sex-rejecting procedures "fail[] to meet professional recognized standards of care," meaning individuals and entities that provide the care can be excluded from participation in federal health programs.[130] HHS then (via posts on X) referred many hospitals and several federally qualified health center (FQHCs) to the HHS Office of Inspector General to be investigated for "performing sex-mutilating and sex-rejecting procedures for minors." [131]

The use of the term "sex-rejecting procedures" in the Proposed Rule is further evidence of HHS's biased view of the services. As with the other labels that the administration has adopted for gender-affirming care, the term "sex-rejecting procedures" has no basis in science, medicine, or law.

Again, this effort to end gender-affirming care for youth has occurred alongside a broader effort to erase transgender people–from schools, sports teams, the military, and their communities.[132] The evidence is clear that the outcome of the HHS Review was predetermined.

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[129] CMS, *Press Release, HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children* (Dec. 18, 2025) https://www.cms.gov/newsroom/press-releases/hhs-acts-bar-hospitals-performing-sex-rejecting-procedures-children; Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59463 (Dec. 19, 2025).

[130] CMS, *Press Release, HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children* (Dec. 18, 2025) (noting also that FDA sent warning notices to manufacturers and retailers of chest-binders for "illegal marketing…to children"); HHS, the Sec'y of Health & Hum. Servs., *Declaration of the Secretary of the Department of Health and Human Services Re: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures* (Dec. 18, 2025), https://www.hhs.gov/sites/default/files/declaration-pediatric-sex-rejecting-procedures.pdf. *See also* Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 90 Fed. Reg. 59478 (Dec. 19, 2025).

[131] HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Feb. 3, 2026), https://x.com/HHSGCMikeStuart/status/2018828343144010025 (stating that hospitals "are continuing to perform heinous and horrific acts of intentional permanent harm to minors…We will not stop until every single child is protected from the destruction of the integrity of God's chosen human body"); HHS General Counsel Mike Stuart (@HHSGCMikeStuart), X (Feb. 11, 2026), https://x.com/HHSGCMikeStuart/status/2021649628639240524.

[132] *See, e.g.*, Exec. Order 14,190, Ending Radical Indoctrination in K-12 Schools, 90 Fed. Reg. 8853 (Feb. 3, 2025); Exec. Order No. 14,201, Keeping Men Out of Women's Sports, 90 Fed. Reg. 9279 (Feb. 11, 2025); Exec. Order No. 14183, 90 Fed. Reg. 8757 (Feb. 3, 2025); Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 90 Fed. Reg. 59478 (Dec. 19, 2025).

2. The HHS Review lacks scientific rigor and misrepresents the evidence regarding the risks and benefits of gender-affirming care.

The HHS Review purports to undertake a "methodologically rigorous assessment" of the evidence through an umbrella review of systematic reviews.[133] However, it falls short of accepted scientific standards in several respects, as experts have explained in detail.[134]

For one, the HHS Review ignores problems with systematic reviews included in its umbrella review. For example, HHS does not disclose that three of the systematic reviews were commissioned by SEGM, a designated anti-LGBT hate group with an express agenda to "support the development of non-invasive [i.e., non-pharmaceutical or surgical] approaches for the care of young people with gender dysphoria."[135] In addition, HHS does not acknowledge that several of the authors of those systematic reviews revealed that they have a financial conflict of interest: receiving financial compensation from SEGM for other related work.[136] As another example, HHS does not acknowledge that several of the other systematic reviews have been heavily criticized by researchers.[137]

Relatedly, the HHS Review improperly dismisses a comprehensive appraisal of the evidence by the University of Utah on the basis that HHS determined it to have a high risk of bias, while crediting other systematic reviews that HHS also determined to have a high

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[133] HHS Review at 13.

[134] *See, e.g.*, Dowshen et al., at 343; Rider et al., at 3; Letter from Am. Psychiatric Ass'n to U.S. Dep't of Health & Hum. Servs. (updated Sept. 26, 2025) (in HHS Review, Supplement at 7–10). While HHS responded to the contentions of these experts in the supplement to the HHS Review, its responses are rebuttals without merit. For example. HHS's response to APA's claim that the HHS review lacked methodological rigor goes through the selection process for the systematic reviews included in the HHS Review, but fails to respond the critical questions of how the quality of the systematic reviews was assessed and the inclusion/exclusion of various systematic reviews. Similarly, HHS dismisses Dowshen et al.'s contention that a significant percentage of the sources included in the HHS Review were not peer-reviewed by simply pointing out that the focus on "the ratio…is misguided" and non-peer-reviewed articles are only discussed when "appropriate." However, HHS makes no effort to explain how the department determines whether discussion of a particular source is appropriate.

[135] *What does SEGM do?* , https://segm.org/about_us; *see also Group Dynamics and Division of Labor within the Anti-LGBTQ+ Pseudoscience Network*, Southern Poverty Law Center (2023), https://www.splcenter.org/resources/reports/defining-pseudoscience-network.

[136] *See* Anna Miroshnychenko et al., *Puberty blockers for gender dysphoria in youth: A systematic review and meta-analysis*, 110 ARCHIVES DISEASE CHILDHOOD 429 (2025), https://adc.bmj.com/content/110/6/429.long (funding and competing interests disclosures); Anna Miroshnychenko et al., *Gender affirming hormone therapy for individuals with gender dysphoria aged <26 years: a systematic review and meta-analysis*, 110 ARCHIVES DISEASE CHILDHOOD 437 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12105977/ (funding and competing interests disclosures); Anna Miroshnychenko et al., *Mastectomy for Individuals with Gender Dysphoria Younger Than 26 Years: A Systematic Review and Meta-Analysis*, 155 PLASTIC & RECONSTRUCTIVE SURGERY 915 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC12105977/ (disclosures).

[137] For discussion on the criticism of the systematic reviews associated with the Cass Review (Taylor et al., Hall et al., Heathcote et al., and Hewitt et al.) and the Ludvigsson et al. review out of Sweden, see Section II.c below.

risk of bias.[138] Critically, after examining the evidence on the use of medications to suppress puberty and hormones to treat adolescents with gender dysphoria, the University of Utah report concluded that "the consensus of the evidence supports that the treatments" are effective and safe.[139] The authors noted that "policies to prevent access to and use of [gender-affirming hormones] for treatment of [gender dysphoria] in pediatric patients cannot be justified based on the quantity or quality of medical science findings or concerns about potential regret in the future, and that high-quality guidelines are available to guide qualified providers in treating pediatric patients who meet diagnostic criteria."[140]

In addition, the HHS Review uses different standards to draw conclusions about the risks versus the benefits of gender-affirming care. On the risks side, the Review repeatedly highlights risks of harms it refers to as "irreversible," with a particular emphasis on infertility.[141] As an initial matter, it is incorrect to suggest that all of the services at issue are irreversible or cause permanent infertility.[142] In addition, the discussion of the risks in the HHS Review: 1) does not acknowledge that many risks can be mitigated;[143] and 2) ignores

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[138] *Compare* HHS Review, Appendix 4 at 21–26 (discussion of Utah), *with id*. at 12 (noting 7 other SRs included in the umbrella review had a high risk of bias).

[139] Joanne LaFleur et al., Univ. of Utah Coll. of Pharmacy, L.S. Skaggs Pharmacy Inst., *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria* 90 (2024), https://www.researchgate.net/publication/400035577_Gender-affirming_medical_treatments_for_pediatric_patients_with_gender_dysphoria.

[140] *Id*. at 91.

[141] According to the Proposed Rule, the HHS Review "highlights evidence pointing to the significant risks associated with the use of" gender-affirming care, "including irreversible harms such as infertility." Proposed Rule at 59444.

[142] Medications to delay puberty (GnRHa) are fully reversible and do not cause infertility. *See, e.g.*, Frederica Guaraldi et al., *Management of Endocrine Disease: Long-term outcomes of the treatment of central precocious puberty*, 174 EUR. J. ENDOCRINOLOGY R79–R87 (2016) (attached); Laetitia Martinerie et al., *Fertility of Women Treated during Childhood with Triptorelin (Depot Formulation) for Central Precocious Puberty: the PREFER Study*, 26 HORMONE RSCH. PAEDIATRICS 529 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8686727/. Hormone therapy (e.g., estrogen or testosterone) is a partially reversible intervention, and while it has the potential to affect fertility, research indicates that it does not result in permanent sterilization in every patient. *See, e.g.*, I. Yaish, *Functional ovarian reserve in transgender men receiving testosterone therapy: evidence for preserved anti-Mullerian hormone and antral follicle count under prolonged treatment*, 18 HUM. REPRODUCTION 2752 (2021) (attached); Iris de Nie et al., *Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women*, 4 CELL REPORTS MED. (2023), https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(22)00422-0#%20; A.D. Light et al., *Transgender men who experienced pregnancy after female-to-male gender transitioning*, 124 OBSTETRICS & GYNECOLOGY 1120 (2014), https://escholarship.org/uc/item/3dz427qw. Further, HHS ignores that the existing standards of care recommend that providers counsel transgender adolescents on the potential for reduced fertility and options for fertility preservation before initiating GnRHa or hormone therapy. *See* Coleman et al., at S57 (2022).

[143] For example, HHS highlights the risk that medications to delay puberty can reduce bone density accrual but ignores the research indicating that the risk can be mitigated by screening for, and treating, vitamin D deficiency if necessary and by limiting the number of years that an adolescent remains on GnRHa. *See, e.g.*, Stephen M. Rosenthal, *Approach to the patient: transgender youth: endocrine considerations*, 99 J. CLIN. ENDOCRINOLOGY. & METABOLISM 4379 (2014) (attached). Further, the HHS Review notes that using GnRHa followed by hormone therapy could result in permanent infertility. *See* HHS Review at 119. That ignores that fertility preservation can occur before hormone therapy is initiated. *See, e.g.*, Caitlin E. Martin et al., *Successful oocyte*

the health risks associated with withholding the care from adolescents.[144] More to the point, the "evidence" of harms that HHS refers to is not grounded in the published literature. As HHS acknowledges in its Review (and the Proposed Rule), the systematic reviews found "limited evidence regarding the harms."[145] Indeed, one of the systematic reviews found that "these interventions have not shown the serious risks of harm that would suggest the need for policies to restrict the interventions."[146] In an effort to skirt that finding, HHS devotes an entire chapter to the "biological plausibility of harms," even pointing to an internet post from a so-called whistleblower as evidence of harms.[147] But, that approach–ignoring the systematic reviews and the individual studies in favor of mere plausibility (and a second-hand, anecdotal report)–is hard to square with what HHS characterizes as its "evidence-based medicine approach," which it describes as "stressing the examination of evidence from clinical research."[148]

More critically, it is hard to square with HHS's approach to evaluating the benefits of gender-affirming care. While leaning on what it admits is "limited evidence" of harms, the

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cryopreservation using letrozole as an adjunct to stimulation in a transgender adolescent after GnRH agonist suppression, 116 FERTILITY & STERILITY P5222 (2021), https://www.fertstert.org/article/S0015-0282(21)00143-6/fulltext.

[144] *See* Letter from Am. Psychiatric Ass'n to U.S. Dep't of Health & Hum. Servs. (updated Sept. 26, 2025) (in HHS Review, Supplement at 7-10); Tim C. van de Grift, *Waiting for transgender care and its effects on health and equality: a mixed-methods population study in the Netherlands*, 73 ECLINICAL MED. 1 (2024), https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(24)00236-0/fulltext (finding waiting long periods for gender-affirming care was associated with negative effects on physical and psychosocial health); Margaret L. Lawson et al., *Pathways to Care for Adolescents Attending a First Hormone Appointment at Canadian Gender Affirming Medical Clinics: A Cross-Sectional Analysis From the Trans Youth CAN! Study*, 74 J. ADOLESCENT HEALTH 140 (2024), https://www.jahonline.org/article/S1054-139X(23)00387-7/fulltext (finding, among adolescents under age 16 at an initial appointment for pubertal suppression or hormones, longer waiting times from referral to initial appointment were associated with suicidal ideation among); Jack L. Turban et al., *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults*, 17 PLOS ONE e0261039 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8754307/ [hereinafter "Turban et al., *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults*"] (finding that individuals who accessed gender-affirming hormones during adolescence had better mental health outcomes than those who accessed gender-affirming hormones during adulthood); *See* Hane Htut Maung, *Gender Affirming Hormone Treatment for Trans Adolescents: A Four Principles Analysis*, 21 J. BIOETHICAL INQUIRY 345 (2024), https://link.springer.com/article/10.1007/s11673-023-10313-z#Sec4 (concluding that the provision of gender-affirming hormone treatment to trans adolescents is "ethically required" in part because "research indicates that the potential risks of providing access to [gender-affirming hormone treatment] are greatly outweighed by the considerable harms of restricting access to [gender-affirming hormone treatment]").

[145] Proposed Rule at 59444; *see* Dowshen et al., at 343 (pointing to the unsubstantiated claims of harms).

[146] Alex R. Dopp et al., RAND, *Interventions for Gender Dysphoria and Related Health Problems in Transgender and Gender-Expansive Youth* 35 (2024), https://www.rand.org/pubs/research_reports/RRA3223-1.html.

[147] HHS Review at 113–133, 134–36; Proposed Rule at 59444.

[148] HHS Review at 26 (indicating that evidence-based medicine "de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale…and stresses the examination of evidence from clinical research").

HHS Review dismisses the large body of evidence in the published literature demonstrating the benefits of gender-affirming care on the basis that the quality of the evidence is "very low."[149] In this way, the Review misrepresents the state of the scientific evidence.[150] In the body of the HHS Review, the authors are not even willing to acknowledge what the systematic reviews and the individual studies (forming the basis of their umbrella review) actually find regarding benefits: gender-affirming care is associated with a range of positive health effects for adolescents.[151] Similarly, the HHS Review dismisses benefits found in

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[149] Proposed Rule at 59444.

[150] *See, e.g.*, Dowshen et al., at 343; Rider et al., at 2 (explaining that the report does not evaluate how quality of evidence determinations are made and their limitations).

[151] For systematic reviews included in the HHS Review, see, e.g., Dopp et al.,(puberty suppression, hormones, and surgery associated with reductions in reported gender dysphoria); Denise Chew et al., *Hormonal treatment in young people with gender dysphoria: A systematic review*, 141 PEDIATRICS e20173742 at 14 (2018) (attached) (puberty suppression "associated with significant improvements in multiple psychological measures, including global functioning, depression, and overall behavioral and/or emotional problems"); G.G.F. Ramos et al., *Systematic review: Puberty suppression with GnRH analogues in adolescents with gender incongruity*, 44 J. ENDOCRINOLOGICAL INVESTIGATION 1151 (2021) (attached) (properly timed puberty suppression can improve psychological functioning); Lynn Rew et al., *Review: Puberty blockers for transgender and gender diverse youth: A critical review of the literature*, 26 CHILD & ADOLESCENT MENTAL HEALTH 3 (2021) (attached) (puberty suppression associated with improved psychological health).
For individual studies included in one or more of the systematic reviews included in the Review, see, e.g., Annelou L.C. de Vries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. SEXUAL MED. 2276 (2011) (attached) (adolescents who received puberty suppressing medications demonstrated decrease in behavioral and emotional problems and depressive symptoms and improvement in general functioning); Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12 J. SEXUAL MED. 2206 (2015) (attached) (finding youth who received puberty suppression and psychological support experienced greater improvement in psychosocial functioning than youth who received psychological support alone); Anna I.R. van der Miesen et al., *Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared with Cisgender General Population Peers*, 66 J. ADOLESCENT HEALTH 699, 703 (2020) (attached) (transgender adolescents receiving puberty suppressing treatment had less emotional and behavior problems than transgender adolescents just referred for gender-affirming care and "similar rates of mental health problems as their nonclinical cisgender peers on internalizing problems…and self-harm/suicidality"); Jack L. Turban et al. *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145 PEDIATRICS e20191725 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7073269/ (among transgender adults, those who received pubertal suppression in adolescence had lower odds of lifetime suicidal ideation compared with those who wanted pubertal suppression in adolescence but did not receive it); Christal Achille et al., *Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results*, 8 INTERNAT'L J. PEDIATRIC ENDOCRINOLOGY 1 (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7191719/ (gender-affirming endocrine intervention associated with decreased depression and suicidal ideation and improved quality of life); Annelou L.C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS 696, 702 (2014) (attached) (adolescents who received pubertal suppression, followed by hormone therapy and surgery, had improved psychological functioning over time, "resulting in rates of clinical problems that are indistinguishable from general population samples…and quality of life, satisfaction with life, and subjective happiness comparable to same-age peers"); Laura E. Kuper et al., *Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy*, 145 PEDIATRICS e20193006 (2020) (attached) (adolescents who received GnRHa and/or hormones reported large improvements in body satisfaction and modest improvements in mental health functioning one year after treatment); Inga Becker-Hebly et al.,

several studies published after the systematic reviews because they would not "change the conclusions, especially those pertaining to benefits."[152] And, the Review certainly did not include individual or clinician reports of positive outcomes, as it did with respect to harms. What is more, in using the low quality of the evidence regarding benefits to conclude that

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Psychosocial health in adolescents and young adults with gender dysphoria before and after gender-affirming medical interventions: A descriptive study from the Hamburg Gender Identity Service, 30 EUROPEAN CHILD & ADOLESCENT PSYCHIATRY 1755, 1763 (2021) (attached) (adolescents who received puberty suppression and hormones had "psychosocial health scores that were improved (closer to the norm)" compared to their scores before treatment and the scores of adolescents who received no treatment or only puberty suppression); Connor Grannis et al., *Testosterone treatment, internalizing symptoms, and body image dissatisfaction in transgender boys*, 132 PSYCHONEUROENDOCRINOLOGY e105358 (2021) (attached) (transgender youth receiving testosterone had lower anxiety, depression, and suicidality compared to similar transgender youth not receiving testosterone, which could be due in part to improvements in body image dissatisfaction associated with testosterone use); Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7 CLINICAL PRACTICE IN PEDIATRIC PSYCH. 302 (2019) (attached) (levels of suicidality decreased and levels of general well-being increased after receiving gender-affirming hormones); Diane Chen, et al., *Psychosocial Functioning in Transgender Youth after 2 Years of Hormones*, 388 NEW ENG. J. MED. 2023 240 (2023), https://www.nejm.org/doi/full/10.1056/NEJMoa2206297 (depression and anxiety decreased, while positive affect and life satisfaction increased over two years of treatment with gender-affirming hormones; increased appearance congruence "is a candidate mechanism" for these psychosocial improvements); Priya Chelliah et al., *Changes in Gender Dysphoria, Interpersonal Minority Stress, and Mental Health Among Transgender Youth After One Year of Hormone Therapy*, 74 J. ADOLESCENT HEALTH 1106 (2024) (attached) (large improvements in body dissatisfaction one year after beginning gender-affirming medical treatment, with greater improvements associated with fewer symptoms of depression and better psychosocial functioning); Elizabeth R. Boskey et al., *Prospective Evaluation of Psychosocial Changes After Chest Reconstruction in Transmasculine and Non-Binary Youth*, 73 J. Adolescent Health 503 (2023) (attached) (gender-affirming chest reconstruction associated with improved gender and appearance congruence and reduced chest dysphoria); Mona Ascha et al., *Top Surgery and Chest Dysphoria Among Transmasculine and Nonbinary Adolescents and Young Adults*, 176 JAMA PEDIATRICS 1115 (2022) (attached) (top surgery associated with improvements in chest dysphoria, gender congruence, and body image); Jamie E. Mehringer et al. (2021). *Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth*, 147 PEDIATRICS e2020013300 (2021) (attached) (youth who underwent masculinizing chest surgery reported resolution of chest dysphoria and improved quality of life and functioning); Ron Skorochod et al., *Age-related Outcomes of Chest Masculinization Surgery: A Single-surgeon Retrospective Cohort Study*, 11 PLASTIC & RECONSTRUCTIVE SURGERY GLOBAL OPEN e4799 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC9945241 (patients ages 18 and under had lower rates of complication and revision surgery and higher satisfaction rankings than older counterparts). *See also* Rachita Sood et al., *Association of Chest Dysphoria With Anxiety and Depression in Transmasculine and Nonbinary Adolescents Seeking Gender-Affirming Care*, 69 J. ADOLESCENT HEALTH 1135 (2021) (attached) (greater levels of chest dysphoria associated with greater gender dysphoria, lower appearance congruence, and higher anxiety and depression symptoms, lending "preliminary support to the notion that treating chest dysphoria may improve anxiety and depression symptoms").

[152] *See* HHS Review at 97; Natalie M. Wittlin et al., *Mental health during medical transition in a US and Canadian sample of early socially transitioned transgender youth*, 76 J. ADOLESCENT HEALTH 228 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC11738661 (youth who access puberty suppression followed by hormones had levels of anxiety and depressive symptoms similar to cisgender youth); Johanna Olson-Kennedy et al., *Emotional health of transgender youth 24 months after initiating gender affirming hormone therapy*, 77 J. ADOLESCENT HEALTH 41 (2025) (attached) (hormone therapy associated with significant improvement in appearance congruence and several emotional health domains).

gender-affirming care has an unfavorable risk/benefit profile and to strongly imply that the care should not be provided and should be regulated, the Review misunderstands the meaning of evidence-based medicine.[153]

Dr. Gordon Guyatt is a physician and researcher who coined the term "evidence-based medicine" and co-authored three of the systematic reviews included in HHS's umbrella review.[154] Dr. Guyatt, along with some of his co-authors on the systematic reviews, released a statement about their significance in August 2025:

> 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.[155]

Not only does the HHS Review mischaracterize the significance of the quality of the evidence, it ignores that the quality of the evidence supporting gender-affirming care is equivalent to the quality of the evidence supporting many other services in pediatric medicine.[156] There are significant limitations to clinical research in pediatrics across the board. This kind of research is made difficult by smaller patient populations, serious ethical considerations, heightened safety and regulatory requirements, and lower funding.[157] Thus, there is often limited research and data to inform the specific risks and benefits associated with clinical interventions for children and youth.

More specifically, HHS ignores that the quality of the evidence in support of gender-affirming care for adolescents is on par with the quality of the evidence in support of using the *same services* to treat other conditions. For example, as described in detail in Section I.a, DRUGDEX–a drug compendium on which Medicare and Medicaid coverage is based–reaches that conclusion for a number of medications that are routinely used to treat gender dysphoria in adolescents, including by suppressing puberty. The HHS Review's attempts to distinguish the use of these medications to treat other conditions are not reasonable. For

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[153] HHS Review at 134–36.
[154] *Id*. at 25.
[155] Gordon Guyatt et al., McMaster Univ., Faculty of Health Sciences, Dep't of Health Rsch. Methods, Evidence, and Impact, *Systematic review related to gender-affirming care* (Aug.14, 2025) (attached).
[156] *See, e.g.*, Armand H. Matheny Antommaria et al., *Quality of Evidence and Strength of Recommendations in American Academy of Pediatrics' Guidelines*, 155 PEDIATRICS e2024067836 (2025) (attached) (finding that 47.5% of AAP's recommendations are based on Level B evidence, 27.1% on Level C evidence, 6.4% on Level D evidence, and 8.5% on Level X evidence).
[157] *See, e.g.,* Esther M Speer et al., *The State and Future of Pediatric Research*, 24 SOC'Y PEDIATRIC. RSCH. 1 (2023), https://pubmed.ncbi.nlm.nih.gov/36694026/; Inst. on Med., *The Ethical Conduct of Clinical Research Involving Children* (Marilyn J. Field & Richard E. Berman, Eds., 2004), https://www.nationalacademies.org/read/10958/chapter/1#xiii.

example, medications to delay puberty (GnRHa) have been used for decades to treat children with central precocious puberty (CPP). Research shows that the medications are safe, and the same risks that HHS points to exist whether they are prescribed to treat CPP or to treat gender dysphoria.[158] While HHS argues that the risks are higher when GnRHa are used to treat gender dysphoria, the evidence does not support that claim.[159] Indeed, HHS's attempts to distinguish CPP simply reveal its belief that gender dysphoria is not a true medical condition that deserves medical treatment.[160]

Ultimately, the HHS Review's conclusion that the "risk/benefit" profile of gender-affirming care is "unfavorable" does not reflect the scientific evidence.[161] The evidence certainly does not show that the risks of gender-affirming care outweigh the benefits for every single young person. To the contrary, taken as a whole, the evidence–including the existing standards of care discussed in Section II.b.4 below–demonstrates that the care is a safe and effective intervention for many adolescents with gender dysphoria.

3. The scientific evidence does not support the HHS Review's conclusion that psychotherapy alone is effective to treat gender dysphoria.

The Proposed Rule promotes psychotherapy as the "first line treatment" for gender dysphoria.[162] This is entirely consistent with the WPATH Standards of Care (SOC-8) and Endocrine Society guidelines. The SOC-8 chapter on adolescent care specifically recommends that "health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored."[163] Similarly, the SOC-8 chapter on care for children "recommend[s] health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition."[164] Further, the SOC-8 chapter on mental health recommends that mental health practitioners

> working with transgender people should use active listening as a method to encourage exploration in individuals who are uncertain about their gender identity.

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[158] *See*, *e.g.*, Marissa J Kilberg & Maria G Vogiatzi, *Approach to the Patient: Central Precocious Puberty*, 108 J. CLINICAL ENDOCRINOLOGY & METABOLISM 2115, 2119 (2023), https://academic.oup.com/jcem/article/108/8/2115/7076933; D. Mul & I. Hughes, *The use of GnRH agonists in precocious puberty,* EUROPEAN J. ENDOCRINOLOGY S3 (2008) (attached).
[159] For example, while HHS makes much of the effect of GnRHa on bone density, *see* HHS Review at 117-18, research demonstrates that using GnRHa to treat gender dysphoria is safe with respect to changes in bone density. *See, e.g.*, LaFleur et al., at 90; Maria Anna Theodora Catharina van der Loos et al., *Bone Mineral Density in Transgender Adolescents Treated with Puberty Suppression and Subsequent Gender-Affirming Hormones*, 117 JAMA PEDIATRICS 1332 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10616766.
[160] *See* HHS Review, Supplement at 106 (distinguishing CPP on the basis that gender dysphoria is not a physical pathology and cannot be diagnosed based on "objective tests").
[161] Proposed Rule at 59444; HHS Review at 79–80, 135, 220, 231.
[162] Proposed Rule at 59449.
[163] Coleman et al., at S48.
[164] *Id.* at S69.

> Rather than impose their own narratives or preconceptions, [mental health professional]s should assist their clients in determining their own paths.[165]

Similarly, the Endocrine Society guidelines state:

> Because of the psychological vulnerability of many individuals with [gender dysphoria]/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, a [mental health professional] who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing [gender dysphoria]/gender incongruence in children and adolescents is often extremely complex.[166]

In short, the existing standards of care already incorporate psychotherapy as a first line treatment.

Yet, the Proposed Rule goes further, ending funding for gender-affirming care and thus, making psychotherapy the *only* available treatment for gender dysphoria for youth in Medicaid and CHIP. While the Proposed Rule relies on the HHS Review to support the proposition that psychotherapy alone is an effective treatment for gender dysphoria, the evidence does not support that claim. Indeed, the HHS Review acknowledges that its "overview [of systematic reviews] found no evidence on the effect of psychotherapy on [gender dysphoria] itself."[167] If the authors were consistent in their evaluation of the evidence supporting gender-affirming care and the evidence supporting psychotherapy alone, that finding would have ended the inquiry. Instead, the HHS Review concludes that psychotherapy "may effectively resolve [gender dysphoria] noninvasively" based on three individual clinical studies and two non-clinical articles. What is more, those sources provide no support for the HHS Review's conclusion.

As for the research papers cited, one is a longitudinal study finding that, while psychological support alone was associated with a modest improvement in functioning among youth with gender dysphoria, youth who received both puberty blockers and psychological support experienced an even greater improvement in functioning.[168] Another

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[165] *Id*. at S171. *See also id.* at S175 ("Psychological interventions, including psychotherapy, offer effective tools and provide context for the individual, such as exploring gender identity and its expression, enhancing self-acceptance and hope, and improving resilience in hostile and disabling environments. Psychotherapy is an established alternative therapeutic approach for addressing mental health symptoms that may be revealed during the initial assessment or later during the follow-up for gender-affirming medical interventions.") (citations omitted).

[166] Wylie C.Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY &. METABOLISM 3869, 3876 (2017), https://academic.oup.com/jcem/article/102/11/3869/4157558?login=false.

[167] HHS Review at 56.

[168] Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12 J. SEXUAL MED. 2206 (2015) (attached).

is a case review by two clinicians describing their experience working with 12 "young people who presented…with gender dysphoria (GD) emerging in adolescence, and who, during the course of assessment, ceased wishing to pursue medical (hormonal) interventions and/or who arrived at a different understanding of their embodied distress."[169] The authors advocate for the psychosocial assessment of young people pursuing gender-affirming medical care "to be properly located in a developmental framework which takes seriously the inescapable in between-ness of adolescence and joins with young people and their families to broaden the narratives available to them, to make sense of gender-based distress."[170] They certainly do not suggest that psychotherapy alone is sufficient treatment for all adolescents with gender dysphoria. The third study is a prospective follow-up study (reviewing data from the 1990s before a gender dysphoria diagnosis existed) comparing outcomes between a small number of adolescents who received gender-affirming hormone treatment and surgery, and an even smaller number who received no intervention. That study concluded that the group that received treatment (hormones and surgery) no longer had symptoms of dysphoria and showed good psychological functioning without any regret, while the "nontreated group showed some improvement, but they also showed a more dysfunctional psychological profile."[171] The study does not even speak to the benefits of psychotherapy as a treatment for gender dysphoria in adolescents.

As noted above, the other two cited articles are not clinical studies at all: one is a piece by a U.K. practitioner setting out his visions for a "Gender Exploratory Model" of psychotherapy for young people with gender dysphoria, and another is a 1984 opinion piece that appears to encourage the use of psychotherapy in the treatment of adults who have doubts concerning their gender identity or medical interventions, or who need additional support while undergoing medical transition.[172] In short, none of the articles cited stand for the proposition that psychotherapy alone is an effective treatment for gender dysphoria.

To promote psychotherapy as a risk-free alternative to gender-affirming care, HHS attempts to distance itself from any recommendation in favor of "conversion therapy," and instead touts the supposed benefits of "exploratory therapy," which it describes as "a process of shared decision making in which the therapist…guides the patient in exploration

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[169] Anna Churcher Clarke & Anastassis Spiliadis, *'Taking the Lid Off the Box': The Value of Extended Clinical Assessment for Adolescents Presenting with Gender Identity Difficulties*, 24 CLINICAL CHILD PSYCHOL. & PSYCHIATRY 338, 338 (2019) (attached).
[170] *Id.* at 349.
[171] Yolanda L. Smith et al., *Adolescents with Gender Identity Disorder Who Were Accepted or Rejected for Sex Reassignment Surgery*, 40 J. AM. ACAD. CHILD & ADOLESCENT PSYCH. 472 (2001) (attached).
[172] HHS Review at 260 (citing Anastassis Spiliadis, NHS Found., *Towards a Gender Exploratory Model* (2019); P. T. Cohen-Kettenis & B. Kuiper, *Transseksualiteit en Psychotherapie*, 10 TIJDSCHRIFT VOOR PSYCHOTHERAPIE 153 (1984)). Notably, the Cohen-Kettenis and Kuiper article appears to be available only in hard copy, in Dutch, in limited archives in the Netherlands. We relied on an abstract available in English to understand its conclusions.

of their material but does not input their own beliefs or ideas."[173] HHS implicitly acknowledges the harms associated with conversion therapy, which are well-documented and significant.[174] Yet, even to the extent that "exploratory therapy" is distinguishable, the HHS Review does not offer any evidence to demonstrate that provided alone, it is an effective treatment for gender dysphoria.

HHS attempts to skirt that lack of evidence by pointing to evidence indicating that psychotherapy is effective for treating conditions other than gender dysphoria in adolescents.[175] HHS provides no basis for this speculation, and research makes clear that even though some mental health conditions have similar profiles, they need different interventions and treatments.[176] Again, the HHS Review takes an inconsistent approach to evaluating psychotherapy and gender-affirming care. In the context of gender-affirming care, the Review emphasizes that a particular treatment (*e.g.*, medications to delay puberty) does not have the same risk/benefit profile when used to treat conditions other than gender dysphoria.[177] When it comes to psychotherapy, HHS abandons that line of reasoning, claiming that if the evidence shows that psychotherapy is an effective (and not

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[173] HHS Review at 260 (quoting Joanne Sinai & Peter Sim, *Psychodynamic Psychotherapy for Gender Dysphoria is not Conversion Therapy*, 33 J. CAN. ACAD. CHILD ADOLESC. PSYCH. (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11201722/.

[174] *See, e.g.*, Terryann C. Clark et al., *The Health and Well-Being of Transgender High School Students: Results from the New Zealand Adolescent Health Survey (Youth '12)* 55 J. ADOLESCENT HEALTH 93 (2014) (attached); Jenifer K. Mcguire et al., *School Climate for Transgender Youth: A Mixed Method Investigation of Student Experiences and School Responses*, 39 J. YOUTH & ADOLESCENCE 1175 (2010) (attached); Stephen T. Russell et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behavior Among Transgender Youth*, 63 J. ADOLESCENT HEALTH 503 (2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6165713/; Lisa Simons et al., *Parental Support and Mental Health Among Transgender Adolescents*, 53 J. ADOLESCENT HEALTH 791 (2013), https://pmc.ncbi.nlm.nih.gov/articles/PMC3838484/; Jack J. Turban et al., *Psychological Attempts to Change a Person's Gender Identity From Transgender to Cisgender: Estimated Prevalence Across US States, 2015*, 109 AM. J. PUB. HEALTH 1452 (2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC6727306/; Erin C. Wilson et al., *The Impact of Discrimination on the Mental Health of Trans*female Youth and the Protective Effect of Parental Support*, 20 AIDS & BEHAVIOR 2203 (2016), https://pmc.ncbi.nlm.nih.gov/articles/PMC5025345/.

[175] HHS Review at 268–69 (2025). HHS provides a long list of reasons that it suggests may explain the limited evidence of benefit of psychotherapy in treating gender dysphoria, but ultimately HHS is merely speculating about these reasons. *See id.* at 265–68.

[176] For example, phototherapy has been shown to be highly effective at treating seasonal depressive disorder, but to have limited effectiveness in treating major depressive disorder, despite the similarity between the two conditions. *Compare* Chiung-Jane Wu et al., *Light Therapy in Seasonal Affective Disorder: A Systematic Review and Meta-Analysis of Randomized Controlled and Crossover Trials,* J. AFFECTIVE DISORDERS. REPS. (2026), https://www.sciencedirect.com/science/article/pii/S2666915325001519?via%3Dihub *with* Andrei Lomnasan et al., *The Use of Phototherapy for the Treatment of Non-Seasonal Depression: A Systematic Review of Efficacy and Safety,* 14 J. CLINICAL MED. 1756 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC11900944/.

[177] *See, e.g,* HHS Review at 117 (purporting to distinguish the use of GnRHa to treat central precocious puberty and to treat gender dysphoria).

harmful) treatment for some health conditions, it is probably effective for treating gender dysphoria, despite no evidence to support that conclusion.[178]

In addition, the HHS Review ignores that one of the systematic reviews refutes its claim. That study determined that adolescents with gender dysphoria who only received treatment for co-occurring mental health conditions "consistently did not benefit" from that treatment.[179] However, "they did appear to benefit from [transgender and gender expansive]-affirming interventions." In fact, "in almost all cases involving treatment targeting mental health problems, patients showed continued symptoms throughout treatment—whereas receipt of [transgender and gender expansive]-affirming interventions led to notable improvements."[180]

In sum, the existing scientific evidence does not support the HHS Review's conclusion that psychotherapy alone is an effective or appropriate treatment for every young person with gender dysphoria.

4. Contrary to the HHS Review's conclusion, the WPATH Standards of Care and Endocrine Society Guidelines are reliable.

The Proposed Rule relies on the HHS Review to conclude that the WPATH SOC-8 and Endocrine Society guidelines "are very low quality and should not be implemented."[181] This conclusion is based in part on two articles associated with the Cass Review.[182] But nothing in those articles, and no other evidence, supports the idea that the WPATH and Endocrine Society recommendations are completely unreliable.

Both guidelines are explicit in recognizing where there are limits to the available data and calibrate their recommendations accordingly.[183] However, the fact that the evidence-base

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[178] *See, e.g, id*. at 263 ("The effectiveness of psychotherapy for a wide range of mental health problems, including those that often present with [gender dysphoria], suggests it may also be beneficial for [gender dysphoria] specifically."); *id.* at 268–69 ("When direct evidence for the role of psychotherapy in children and adolescents with [gender dysphoria] is lacking, the best available evidence can be obtained from the robust evidence supporting treatment effectiveness for children and adolescents with similar types of psychological distress.").

[179] Alex R. Dopp et al., at 28.

[180] *Id*.

[181] Proposed Rule at 59446 (citing HHS Review at 141).

[182] *See* Jo Taylor et al., *Clinical Guidelines for Children and Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review of Guideline Quality (Part 1)*, 109 ARCHIVES DISEASE. CHILDHOOD (SUPP. 2) S65 (2024), https://adc.bmj.com/content/109/Suppl_2/s65.long [hereinafter "Taylor et al., *Clinical Guidelines Part 1*"]; Jo Taylor et al., *Clinical Guidelines for Children and Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review of Guideline Quality (Part 2)*, 109 ARCHIVES DISEASE CHILDHOOD (SUPP. 2) S73 (2024), https://adc.bmj.com/content/109/Suppl_2/s73.long [hereinafter "Taylor et al., *Clinical Guidelines Part 2*"]. For further discussion of the Cass Review, see Section II.c below.

[183] *See, e.g.,* Coleman et al.*,* at S45–46 ("A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments…over time."); *id.* at S47 ("[A]lthough the existing samples reported on relatively small groups of youth (e.g., n = 22-101 per study) and the time to follow-up varied across

for these guidelines is low certainty does not mean that their recommendations are incorrect or have no value.[184] In fact, the evidence-base for the WPATH and Endocrine Society guidelines is comparable to that of other widely used clinical practice guidelines, especially in pediatrics.[185] For example, the Endocrine Society has developed two other guidelines for pediatric populations: guidelines on pediatric obesity and congenital adrenal hyperplasia.[186] Taken together, those guidelines contain 84 recommendations; none are based on high quality evidence, 24 (29%) are based on moderate quality, and 49 (58%) are based on low or very low quality.[187] Forty-three (51%) recommendations are graded as strong and 30 (36%) as weak; the remaining 11 recommendations (13%) are ungraded good practice statements.[188]

Moreover, the suggestion that the WPATH and Endocrine Society guidelines lack complete independence also does not render them unreliable. In the first place, Taylor et al. found that the Endocrine Society guidelines ranked high in terms of editorial independence.[189] While it ranked the SOC-8 lower, its score still placed SOC-8 in the top half of the guidelines reviewed.[190] Again, low scores for editorial independence are common among clinical practice guidelines.[191] Thus, while Taylor et al. are undoubtedly correct that the WPATH and Endocrine Society guidelines are imperfect, their critiques do not render the guidelines useless.[192] Notably, neither of the examinations of the WPATH and Endocrine

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studies (6 months–7 years), this emerging evidence base indicates a general improvement in the lives of transgender adolescents who, following careful assessment, receive medically necessary gender-affirming medical treatment."); *see also* Hembree et al.

[184] *See, e.g.,* Philip Sedgwick, *Understanding Why "Absence of Evidence is Not Evidence of Absence,"* 349 BMJ g4751 (2014).

[185] *See, e.g.,* Carolina Martinez-Castaldi et al., *Child Versus Adult Research: The Gap in High-Quality Study Design*, 122 PEDIATRICS 52 (2008) (attached); Jeremy Howick et al., *Most Healthcare Interventions Tested in Cochrane Reviews Are Not Effective According to High Quality Evidence*, 148 J. CLINICAL EPIDEMIOLOGY 160 (2022) (attached).

[186] Phyllis W Speiser et al., *Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline,* 103 J. CLINICAL ENDOCRINOLOGY & METABOLISM 4043 (2018), https://academic.oup.com/jcem/article-lookup/doi/10.1210/jc.2018-01865; Dennis M. Styne et al. *Pediatric Obesity Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 709 (2017), https://academic.oup.com/jcem/article/102/3/709/2965084.

[187] Speiser et al.; Styne et al.

[188] Speiser et al.; Styne et al.

[189] Taylor et al., *Clinical Guidelines Part 1* at S69.

[190] *Id.*

[191] *See, e.g.,* Pablo Alonso-Coello et al., *The Quality of Clinical Practice Guidelines Over the Last Two Decades*, 19 QUALITY & SAFETY HEALTH CARE e58 (2010) (attached) (in review of 20 years of clinical practice guidelines, finding mean scores for "editorial independence" were low).

[192] HHS overstates Taylor et al.'s conclusions about the guidelines, claiming that "all the guidelines, with the exception of two (from Sweden and Finland), were found to be untrustworthy due to serious deviations from the methodological standards for trustworthy guideline development." HHS Review at 141. But Taylor et al. never characterize the guidelines as "untrustworthy." Rather, Taylor et al. caution clinicians to be cognizant of the WPATH and Endocrine Society guidelines' limitations and recommend that [f]uture guidelines should adhere to standards for guideline development and provide greater transparency about how recommendations are developed and links between evidence and recommendations." Taylor et al., *Clinical Guidelines Part 1* at S71.

Society guidelines that used HHS's preferred methodology (AGREE II) concluded that those guidelines were unreliable or should not be used by clinicians.[193]

Regarding the WPATH guidelines, the HHS Review alleges they were tainted by conflicts of interest and legal and political considerations.[194] These claims are spurious. HHS cherry picks and mischaracterizes examples to make its case. The evidence as a whole does not demonstrate that the creation of SOC-8 marked a "clear departure from the principles of unbiased, evidence-driven clinical guideline development," as HHS contends.[195]

WPATH appropriately managed conflicts of interest and bias. In developing clinical practice guidelines, there is an inherent tension between the interest in engaging clinical experts to develop guidelines, and the interest in maintaining independence. As the World Health Organization points out:

> All individuals and organizations involved in developing a [clinical practice] guideline have secondary interests, which in most cases are legitimate and appropriate in their own right. Such interests include, for example, a technical expert's desire to publish or obtain funding for his or her research, or a stakeholder's desire to advocate for a disease or condition.[196]

HHS identifies a few instances of secondary interests that it suggests created conflicts of interest so great as to call the validity of SOC-8 into question. But none of these instances show that SOC-8 is so permeated by conflicts of interest as to be wholly biased or unreliable.

For example, the HHS Review suggests that SOC-8 authors who served as paid experts in cases concerning gender-affirming medical care for young people had a financial conflict of interest.[197] But the sources HHS relies on only recommend that paid expert work should be disclosed, not that it should prevent a person from developing a clinical practice guideline.[198] Further, HHS seems unbothered by the fact that several authors of its own Review served as paid experts in some of the very same cases. The HHS Review also criticizes WPATH (and the Endocrine Society) for "Panel Stacking" the authors of SOC-8. It cites only one source about the dangers of "Panel Stacking," a commentary that describes expert consensus statements, rather than evidence-based clinical practice guidelines such

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[193] *See id*.; Sarah Dahlen et al., *International Clinical Practice Guidelines for Gender Minority/Trans People,* 11 BMJ OPEN e048943 (2021), https://bmjopen.bmj.com/content/11/4/e048943 (reviewing the WPATH SOC-7); *see also* Taylor et al., *Clinical Guidelines Part 2*.
[194] HHS Review at 182; *see* Proposed Rule at 59445.
[195] HHS Review at 181; *see* Proposed Rule at 59445.
[196] World Health Org., *Handbook for Guideline Development* 57 (2d Ed. 2014), https://iris.who.int/server/api/core/bitstreams/809b813f-fcfe-451e-b242-d914d580c111/content.
[197] *See* HHS Review at 169.
[198] *See* Inst. on Med., *Clinical Practice Guidelines We Can Trust* 79 (Robin Graham et al., eds. 2011), https://www.ncbi.nlm.nih.gov/books/NBK209539/; World Health Org., *Handbook for Guideline Development* 63 (2d Ed. 2014), https://evidence-impact.org/storage/82/WHO-Handbook-for-Guideline-Development.pdf.

as the SOC-8 and Endocrine Society guidelines.[199] Nor does HHS demonstrate that WPATH's selection process for the authors of SOC-8 was improper. Finally, HHS suggests that WPATH was "resistant to constructive criticism."[200] Yet the evidence about the development of SOC-8 shows otherwise. For example, in response to concerns that prior versions of the WPATH SOC did not account for the possibility of regret and detransition, SOC-8 explicitly discussed the issue.[201] In other words, SOC-8 accounted for the constructive criticism and discussed the possibility of regret and detransition extensively, with corresponding recommendations.

As discussed in detail above, the administration has been clear from day one that it considers the SOC-8 "junk science."[202] Accordingly, HHS manufactured its Review to reach that conclusion, often resorting to speculation about the internal workings of WPATH. For no other services has HHS ever examined how the relevant clinical practice guidelines were prepared to determine whether Medicaid and CHIP should stop covering the care. Rather, it has singled out the guidelines for treating gender dysphoria to further its political and ideological agenda.

c. The HHS Review (and thus, the Proposed Rule) misrepresents the state of coverage of gender-affirming care for youth in other countries.

The Proposed Rule relies on the HHS Review's description of a "growing international retreat" from gender-affirming care as support for prohibiting Medicaid and CHIP coverage of the care.[203] There are several problems with HHS's reasoning.

First, the HHS Review does not grapple with the fact that several of the international reports it highlights have been called into question, particularly for arriving at contradictory conclusions and for ignoring widespread evidence from other studies. For example, throughout its Review, HHS mischaracterizes and overemphasizes the Cass et al. Review

[199] *See* Kasper P. Kepp et al., *Commentary: Panel Stacking is a Threat to Consensus Statement Validity*, 173 J. CLINICAL EPIDEMIOLOGY. 111428 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11913121/.
[200] HHS Review at 171.
[201] *See, e.g.,* Coleman et al., at S47, S77.
[202] Exec. Order No. 14187, Protecting Children from Chemical and Surgical Mutilation, 90 Fed. Reg. 8771, 8771 (Feb. 3, 2025).
[203] Proposed Rule at 59444, 59445–6; HHS Review at 214.

from the U.K.[204] The Cass Review has received vast criticism.[205] While HHS acknowledges some of that criticism, it dismisses it as "disagreement [] common in science" and "part of a scientific misinformation campaign"[206] That is incorrect.

For example, experts in the field consistently point to the disconnect between the scientific evidence and the Cass Review's recommendations to restrict access to gender-affirming services for minors. Researchers and experts from Australia have commented:

> The Cass Review's internal contradictions are striking. It acknowledged that some trans young people benefit from puberty suppression, but its recommendations have made this currently inaccessible to all. It found no evidence that psychological treatments improve gender dysphoria, yet recommended expanding their provision. It found that NHS provision of [gender-affirming medical treatment] (GnRHa, oestrogen or testosterone) was already very restricted, and that young people were distressed by lack of access to treatment, yet it recommended increased barriers to oestrogen and testosterone for any trans adolescents aged under 18 years. It dismissed the evidence of benefit from [gender-affirming medical treatment] as "weak", but emphasised speculative harms based on weaker evidence. The harms of withholding [gender-affirming medical treatment] were not evaluated. The Review disregarded studies observing that adolescents who requested but were unable to access [gender-affirming medical treatment] had poorer mental health compared with those who could access [gender-affirming medical treatment]. *Despite finding that detransition and regret appear uncommon, the Review's recommendations appear to have the goal of preventing regret at any cost*.[207]

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[204] The Independent Review of Gender Identity Services for Children and Young People was a review commissioned in 2020 by NHS England and NHS Improvement and led by Hilary Cass, a retired consultant pediatrician. It dealt with gender services for children and young people, including transgender youth and those with gender dysphoria, in England. As part of the review, Dr. Cass's team commissioned six systematic reviews from the University of York's Centre for Reviews and Dissemination, which were published in Archives of Disease in Childhood. *See* Archives of Disease in Childhood, *Gender Identity Service Series*, https://adc.bmj.com/pages/gender-identity-service-series. Here, we refer collectively to Dr. Cass's final report and the underlying systematic reviews as the Cass Review. In addition to the six systematic reviews, Dr. Cass's team commissioned two papers reviewing clinical guidelines for treating gender dysphoria in youth, and a survey of treatment protocols across the European Union. *See id.* Notably, the survey of treatment protocols is not referenced in the HHS Review.

[205] *See, e.g.,* D.M. Grijseels, *Biological and Psychosocial Evidence in the Cass Review: A Critical Commentary,* 27 INT'L J. TRANSGENDER HEALTH 278 (2026), https://www.tandfonline.com/doi/full/10.1080/26895269.2024.2362304; Julia K. Moore et al., *Cass Review Does Not Guide Care for Trans Young People*, 223 MED. J. AUST. 331 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12502890/; Chris Noone et al., *Critically Appraising the Cass Report: Methodological Flaws and Unsupported Claims*, 25 BMC MED. RSCH. METHODOLOGY 128 (2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12065279/; Meredithe McNamara et al., Yale L. Sch., *An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria* (2024), https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf.

[206] HHS Review, Supplement at 62–63.

[207] Moore et al., at 331 (emphasis added).

Another examination of the Cass Review identified a high risk of bias in the systematic reviews commissioned by the project, assigning "all seven reviews…an overall rating of a high risk of bias due to methodological limitations and a failure to adequately address these limitations in their interpretations and conclusions ."[208] Yet another evaluation criticized the Cass Review for referring to quantitative data without incorporating statistical measures for claims about trends and differences between key demographic groups.[209]

Even if, for the sake of argument, we take the Cass Review as valid, it does not recommend a total ban on gender-affirming care–nor a ban on coverage of gender-affirming care–for every young person, but rather an individualized, case-by-case assessment of adolescents with gender dysphoria. The Cass Review clearly indicates that medical care may be appropriate for some adolescents with gender dysphoria, that a holistic individualized assessment is necessary before receiving medical interventions, and that co-occurring mental health conditions should be treated.[210] These conclusions, in fact, are in line with the accepted standard of care in the U.S. and with guidelines from the same medical professional organizations that HHS discredits.

The HHS Review and the Proposed Rule also mischaracterize the conclusion of the Ludvigsson et al. review out of Sweden. That review found that, because there have not been randomized trials, and because the few longitudinal observational studies had methodological weaknesses, "the long-term effects of hormone therapy on psychosocial health could not be evaluated."[211] As described in detail above, the lack of high quality evidence regarding the benefits of gender-affirming care does not mean that the risks outweigh the benefits and that coverage of the care should be prohibited. In addition, the methodology of the Ludvigsson et al. review has been called into question, with researchers criticizing the authors' decision not to include relevant data that contradicted their general findings as highlighting potential bias.[212]

Second, while it is true that some European countries have tightened restrictions around access to some gender-affirming services for minors, none of the countries HHS cites to in the HHS Review and the Proposed Rule have gone as far as the Proposed Rule. For

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[208] Noone et al., at 131. Again, HHS dismisses the Noone et al. criticism by stating that: 1) HHS came to a different conclusion regarding the level of bias in certain studies based on its application of the ROBIS tool; and 2) eliminating the various studies identified by Noone et al. as problematic would not result in it reaching a different conclusion. *See* HHS Review, Supplement at 116–117. But HHS does not explain why Noone et al.'s bias analysis, which was also based on a ROBIS tool measure, should not be trusted, nor does it meaningfully rebut the concerns Noone et al. raise regarding the Cass Review studies' lack of transparency, sufficient methodological detail, or rigorous evaluation of the literature.

[209] *See* Grijseels.

[210] *See* Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report* 21, 29, 31, 35 (2024).

[211] Jonas F. Ludvigsson et al., *A systematic review of hormone treatment for children with gender dysphoria and recommendations for research*, 112 ACTA PAEDIATR. 2279, 2279 (2023), https://onlinelibrary.wiley.com/doi/10.1111/apa.16791.

[212] *See* LaFleur et al., at 42.

example, in 2022 Sweden updated its guidelines to recommend that medications to delay puberty and hormone treatment be assessed on a case-by-case basis using the Dutch Protocol and that "gender dysphoria rather than gender identity should guide access to care and treatment."[213] The Swedish guidelines, however, are clear that "treatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered in exceptional cases."[214] This conclusion is inconsistent with the Proposed Rule, which would ban Medicaid and CHIP coverage for gender-affirming services in minors in *all* circumstances. Furthermore, HHS conveniently ignores the fact that the Swedish guidelines are recommendations only, and the public health care system still covers gender-affirming care when medically necessary for a particular adolescent.

Recommendations from Finland are also inconsistent with the Proposed Rule. Whereas HHS's proposal would prohibit the use of federal Medicaid and CHIP funding in all circumstances, the recommendations from Finland's Council for Choices in Health Care in Finland (COHERE) state that medications to delay puberty "may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations."[215] Similarly, the recommendations find that hormone treatment may be considered in minors in certain circumstances.[216] In contrast, the Proposed Rule would ban coverage of gender-affirming care even for minors who meet the criteria outlined in the COHERE guidelines.

HHS also points to Norway as a country that has limited access to gender-affirming care for minors, but that does not appear to be the case. As an initial matter, it is important to note that the Proposed Rule cites to an article explaining the guidelines adopted by the Norwegian Healthcare Investigation Board (UKOM), but all official documents from the board are only available in Norwegian.[217] If HHS had the documents translated in English, it did not provide citations or links to the copies of the translated documents, and we were not able to find them. As a result, HHS has failed to reveal the data it relied on to reach its conclusions, depriving the public of an opportunity to provide meaningful comment.[218]

Nonetheless, based on the document HHS cites, and as HHS acknowledges, Norway has not taken any concrete action that would restrict access to and coverage for gender-affirming care for minors, despite recommendations from UKOM.[219] Importantly, UKOM did not recommend a complete ban on gender-affirming care for minors or a ban on coverage

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[213] Nat'l Board of Health and Welfare, *Care of children and adolescents with gender dysphoria – summary of national guidelines* 4 (Dec. 2022), https://www.socialstyrelsen.se/contentassets/444af6c0a5fb429c9b56fd51b931a816/2023-1-8330.pdf.
[214] *Id.* at 3.
[215] COHERE, *Recommendation of the Council for Choices in Health Care in Finland (PALJKO/COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* 9 (2020), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf.
[216] *Id.* at 5.
[217] HHS Review at 64; Proposed Rule at 59446.
[218] *See, e.g.*, *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227 (D.C. Cir. 2008).
[219] *See* HHS Review at 64.

for that care. In fact, UKOM is quoted as stating: "We're concerned that there may be *undertreatment*, overtreatment, and the wrong treatment, with variation in safeguarding and the extent of multidisciplinary involvement…"[220] In other words, their conclusion was not that gender-affirming care should not be available, but that additional protocols are needed to guide provision of the care.[221] Further, unlike other UKOM guidelines, the UKOM guidelines on gender-affirming care were not based on a systematic review of the evidence.[222] As such, reliance on the UKOM recommendations to prohibit coverage of gender-affirming care for adolescents in Medicaid and CHIP is misplaced.

Without citing any official documents, HHS uses several other countries to justify its proposal to ban Medicaid and CHIP funding for gender-affirming care in minors. HHS mischaracterizes the situation in those countries as well. For instance, while HHS suggests that Australia has restricted gender-affirming care, the care is widely provided and covered for minors throughout Australia; the government is currently in the process of reviewing the Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents, as HHS acknowledges.[223] HHS merely cites to a news report outlining how the state government of Queensland decided to pause the provision of medications to delay puberty and hormone treatment to new patients pending further review, while ignoring that other Australian states do in fact provide gender-affirming care for minors when clinically appropriate.[224]

HHS also cites a move by the New Zealand government to restrict access to medications to delay puberty for minors beginning in December 2025. HHS, however, conveniently ignores that the policy in New Zealand would maintain availability of these medications for individuals already undergoing treatment, recognizing the harmful effects a ban would have on this population.[225] As opposed to the New Zealand policy, the Proposed Rule makes no exception whatsoever that would allow states to continue using federal Medicaid and CHIP funds to cover gender-affirming services for minors already undergoing treatment. Further, the High Court in New Zealand granted an application for interim relief from the restriction, finding that "[t]he evidential justification for such a ban is scant."[226]

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[220] Jennifer Block, *Norway's guidance on paediatric gender treatment is unsafe, says review*, 380 BMJ 697 (2023), https://www.bmj.com/content/bmj/380/bmj.p697.full.pdf (emphasis added).
[221] *See id.*
[222] *Id.*
[223] *See* Dep't of Health, Disability, and Ageing, *Health care for trans and gender diverse Australian children and adolescents* (Jan. 31, 2025), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/health-care-for-trans-and-gender-diverse-australian-children-and-adolescents?language=en; HHS Review at 64–65. *See also* Trascend Australia, *Access to gender-affirming care for young people in Australia – February 2025* (2025), https://gendercentre.org.au/downloads/userupload/fact-sheets-new/Gender-Affirming%20Care%20Updates_v1.1_2025-02-05.pdf.
[224] *See* HHS Review at 64–65; Proposed Rule at 59446.
[225] The Guardian, *New Zealand bans puberty blockers for young transgender people* (Nov. 19, 2025), https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.
[226] *See Pro. Ass'n for Transgender Health Aotearoa Inc., v. Minister of Health*, HC Wellington CIV-2025-485-869, 17 December 2025 (attached). There, the court explained: "The total ban appears to

The Proposed Rule also overstates the reach of limitations on gender-affirming care for minors in Italy. HHS merely cites to a news report documenting that the Italian government has approved a bill that would subject provision of puberty suppressing medications and hormone treatment to minors to situations that follow certain protocols, which have not yet been drafted or approved.[227] The HHS Review also cites to an article describing updated guidance from the Italian National Bioethics Committee (CNB) on the use of medications to delay puberty to treat gender dysphoria. The official document of these guidelines is in Italian. Again, if HHS had the guidelines translated in English, it did not provide a citation or link to that translation (and we could not find one), depriving the public of an opportunity to provide meaningful comment.[228] In addition, the English article quotes the guidelines as stating that these medications should only be prescribed after the documented failure of psychotherapy interventions, and that use of these medications outside of clinical trials "must adhere to the same rigorous criteria, with all data transmitted to a national registry."[229] The guidelines certainly do not appear to recommend a complete ban on gender-affirming care for minors or coverage of such services.

Finally, HHS highlights a list of countries where there has been some move to limit access to gender-affirming care for minors but ignores other similarly situated countries that provide widespread coverage of gender-affirming care for minors when medically necessary. Some of those countries include Austria, France, Germany, Iceland, and Switzerland.[230] The evidence is clear: while some countries have proposed or established guidelines to restrict access to gender-affirming services for minors, the vast majority of similarly situated jurisdictions support access to services at least on a case-by-case basis.

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make negative consequences inevitable for some transgender youth and there is an argument that it is discriminatory. That is because there is no doubt that puberty blockers are regarded as sufficiently safe to treat precocious puberty, and children begin puberty blockers earlier and remain on them for longer when used for that purpose. The concerns about bone density do not apparently justify a ban on puberty blockers generally but only when used for gender dysphoria or gender incongruence." *Id*.

[227] Proposed Rule at 59446.

[228] Comitato Nazionale Per La Bioetica, *Risposta Al Quesito Del Ministero Della Salute Sull'utilizzo Della Triptorelina Nel Caso Di Diagnosi Di "Disforia Di Genere"* (2024), https://bioetica.governo.it/media/idynlfxa/triptorelina_testo-finale.pdf.

[229] *See* SEGM, *Italy Joins the List of Countries Recommending Restrictions on Puberty Blockers for Gender Dysphoria* (Dec. 19, 2024), https://segm.org/Italy-Puberty-Blockers-Therapy-Bioethics.

[230] *See, e.g.,* Germ. Ass'n Sci. Med. Soc'ies, *Gender Incongruence and Gender Dysphoria in Childhood and Adolescence – Diagnosis and Treatment (English Version)* (2025), https://register.awmf.org/assets/guidelines/028_D_G_f_Kinder-_und_Jugendpsychiatrie_und_-psychotherapie/028-014eng_S2k_Geschlechtsinkongruenz-Geschlechtsdysphorie-Kinder-Jugendliche_2025-06.pdf (guidelines for Austria, Germany, and Switzerland); François Brezin et al., *Endocrine Management of Transgender Adolescents: Expert Consensus of the French Society of Pediatric Endocrinology and Diabetology Working Group*, ARCHIVES PEDIATRIE (2024), https://www.sciencedirect.com/science/article/pii/S0929693X24001763#tbl0001 (guidelines for France); Gov't of Iceland, *Gender Autonomy*, https://www.government.is/topics/human-rights-and-equality/equality/legislation/gender-autonomy/ (guidelines for Iceland); *see also* Ruth Hall et al., Gender Services for Children and Adolescents Across the EU-15+ Countries, 109 ARCH. DIS. CHILD. (SUPP. 2) S83 (2024), https://adc.bmj.com/content/109/Suppl_2/s83.

III. The Proposed Rule Will Cause Harm to Transgender Individuals Across the U.S. and Unduly Burden States During Implementation.

a. The Proposed Rule would join a growing list of stigmatizing laws and regulations that harm transgender and gender-diverse youth.

Transgender and gender diverse youth experience documented health disparities.[231] Even prior to the increase in state bans on gender-affirming care in 2020, transgender students reported attempting suicide in the prior 12 months at rates far surpassing their non-transgender peers.[232] Research suggests that various forms of stigma–structural (*e.g.*, stigmatizing policies and health care access barriers), interpersonal (*e.g.*, discrimination, family rejection, and violence), and individual (*e.g.*, internalization of stigma)–are "a fundamental cause of adverse health in transgender populations," in part because they "work directly to induce stress (a key driver of morbidity and mortality)."[233] Studies consistently show that transgender youth experience higher levels of violence or threats of violence than non-transgender peers.[234] Transgender youth also experience rejection from their families at higher rates than non-transgender youth.[235] The unrelenting governmental attacks on transgender people over the past year (discussed in Section II.b.1 above) have caused heightened stigma and added stressors for transgender and gender diverse youth. The Proposed Rule will do the same. By dismissing transgender identity as mere "ideology," using dishonest and dehumanizing rhetoric to describe gender-affirming care, and preventing access to that care for low-income adolescents, the Proposed Rule will

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[231] *See, e.g.*, Alexandria M. Delozier et al., *Health Disparities in Transgender and Gender Expansive Adolescents: A Topical Review From a Minority Stress Framework*, 45 J. PEDIATRIC PSYCH. 842, 842-43 (2020) (attached) (summarizing evidence showing increased risk for anxiety, depression, self-harm, suicidal ideation, suicide attempts, substance misuse, and HIV); Lauren S. H. Chong et al., *Experiences and Perspectives of Transgender Youths in Accessing Health Care*, 175 JAMA PEDIATRICS 1159 (2021) (attached).

[232] 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/mm6803a3.htm.

[233] J.M. White Hughto et al., *Transgender Stigma and Health: A Critical Review of Stigma Determinants, Mechanisms, and Interventions*, 147 SOC. SCI & MED. 222 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4689648/. *See Stress effects on the body*, Am. Psych. Ass'n, https://www.apa.org/topics/stress/body (Oct. 21, 2024). The minority stress theory summarizes the negative health effects of stigma. *See, e.g.*, White Hughto et al.; Delozier et al. *See generally* Ilan H. Meyer, *Prejudice, social stress, and mental health in lesbian, gay, and bisexual populations: conceptual issues and research evidence*, 129 PSYCH. BULL. 674 (2003), https://pmc.ncbi.nlm.nih.gov/articles/PMC2072932/ (proposing a minority stress model to explain the higher prevalence of mental health conditions among lesbian, gay, and bisexual people).

[234] Michelle M. Johns et al.

[235] Juline A. Koken et al., *Experiences of Familial Acceptance-Rejection Among Transwomen of Color*, 23 J. FAM. PSYCH. 853 (2009), https://pmc.ncbi.nlm.nih.gov/articles/PMC2840628/; *see* Ankit Rastogi et al., *Health and Wellbeing: A Report of the 2022 U.S. Transgender Survey* (June 2025), https://transequality.org/sites/default/files/2025-06/USTS_2022Health%26WellbeingReport_WEB.pdf (finding those who experienced family rejection were more likely to report considering or attempting suicide).

have a negative effect on the health of transgender and gender diverse youth.[236] Further, it will harm their parents and guardians as well.[237]

b. The Proposed Rule will further harm low-income youth with gender dysphoria by depriving them of medically necessary care.

Given the eligibility requirements of Medicaid and CHIP, individuals impacted by the Proposed Rule are, by definition, low-income; as a result, they are highly unlikely to be able to purchase "other health insurance or privately pay for these services," as HHS asserts.[238] Most adolescent Medicaid and CHIP enrollees with gender dysphoria will simply be unable to afford the gender-affirming care that they need, with serious consequences to their health.

While access to gender-affirming services for youth has improved over the last decade, many barriers still persist, including cultural competency and availability of services in certain regions.[239] Inadequate health insurance presents another challenge.[240] Lack of insurance coverage of gender-affirming care is part of the reason why 19% of transgender individuals report cost-related barriers to care.[241]

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[236] *See, e.g.*, Stephanie L. Budge et al., *Gender Affirming Care Is Evidence Based for Transgender and Gender-Diverse Youth*, 75 J. ADOLESCENT HEALTH 851 (2024) (noting the growing body of research finding "the current sociopolitical environment, rife with misinformation about TGD identities and active threats to the accessibility of GAC is [] negatively impacting TGD people's mental health"); Jaclyn M. White Hughto et al., *Uncertainty and Confusion Regarding Transgender Non-discrimination Policies: Implications for the Mental Health of Transgender Americans*, 19 SEX. RSCH. & SOC. POL'Y 1069 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC9640180/ (finding that more than half of transgender adults participating in survey feared that their rights would be taken away, and this fear was associated with elevated odds of depression, anxiety, and PTSD).

[237] *See, e.g.*, Roberto L. Abreu et al., *"I Am Afraid for Those Kids Who Might Find Death Preferable": Parental Figures' Reactions and Coping Strategies to Bans on Gender Affirming Care for Transgender and Gender Diverse Youth*, 9 PSYCH. SEXUAL ORIENTATION & GENDER DIVERSITY 500 (2021) (attached).

[238] Proposed Rule at 59449.

[239] *See, e.g.*, Kedryn Berrian et al., *Barriers to Quality Healthcare Among Transgender and Gender Nonconforming Adults*, 60 HEALTH SERVS. RSCH. 1 (2024), https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14362; Brief of Elliot Page et al. in support of Petitioner, *U.S. v. Skrmetti*, No. 23-477 (U.S. Sup. Ct. Sep. 3, 2024), https://www.supremecourt.gov/DocketPDF/23/23-477/323861/20240903094453528_23-477%20Brief.pdf.

[240] *See, e.g.*, Berrian et al.; Alexa B. D'Angelo et al., *Navigating Payment and Policy Barriers to Gender-Affirming Care for Transmasculine Individuals: A Qualitative Study and Policy Assessment*, 366 SOC. SCI. & MED. 117666 (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11821434/. *See also* Hannah MacDougall et al., *Access to Health Care for Transgender and Gender-Diverse Adults in Urban and Rural Areas in the United States*, 81 MED. CARE RSCH. REV. 68 (2024) (attached) (finding that transgender and gender diverse individuals were more likely than cisgender individuals to delay care due to cost); Gilbert Gonzales & Carrie Henning-Smith, *Barriers to Care Among Transgender and Gender Nonconforming Adults* 95 MILBANK Q. 726 (2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5723709/.

[241] *See* Wyatt Koma et al., Kaiser Fam. Found., *Demographics, Insurance Coverage, and Access to Care Among Transgender Adults* (2020), https://www.kff.org/affordable-care-act/demographics-insurance-coverage-and-access-to-care-among-transgender-adults/; *see also* Brief of Fla. Pol'y

In the Proposed Rule, HHS expresses concern about "the difficulties that [transgender] minors may experience" due to the prohibition on coverage. However, HHS does not grapple with those difficulties, which include the negative effects of untreated gender dysphoria. Instead, it "encourages" affected youth to seek psychotherapy.[242] As Section II.b.3 above explains, there is no evidence to support the notion that psychotherapy alone is an effective treatment for gender dysphoria. On the other hand, the evidence does show that obstructing access to other gender-affirming services for minors, including medications to delay puberty, hormone treatment, and medically necessary surgery, causes significant physical and mental health harms. For instance, a study conducted in New Zealand identified the lack of public funding as a key driver of unmet health needs among transgender youth and found that 42% of youth had been unable to access necessary hormone treatment. Those who lacked access to treatment were twice as likely to have attempted suicide in the previous year.[243] They also had significantly higher rates of psychological distress and life dissatisfaction than similarly situated transgender youth who had been able to access hormone treatment.[244]

Being unable to access gender-affirming care is particularly harmful for adolescents. When compared to individuals who accessed hormone treatment during adolescence, individuals who were unable to do so have higher rates of suicidal ideation and other mental health symptoms in adulthood.[245] Additional research shows that when adolescents experience a delay in accessing gender-affirming care, their health suffers.[246] Extended waiting periods are associated with higher levels of psychosocial distress, poorer health, increasing health care consumption, and increased inequality and feelings of marginalization.[247] For these reasons, ethicists have concluded that the risks associated with not providing gender-affirming care to adolescents far outweigh the risks associated with providing the services, making access "ethically required."[248]

Inst. & Fla. Voices Health in support of Plaintiffs at 4-8, *Dekker v. Weida*, No. 4:22-CV-00325-RH-MAF (N.D. Fla. Apr. 28, 2023), https://files.eqcf.org/wp-content/uploads/2024/01/190-FPI-and-FVFH-Amicus-Brief-w-mtn-to-file.pdf.

[242] Proposed Rule at 59449.

[243] Kyle K.H. Tan et al., *Unmet Need for Gender-Affirming Care as a Social Determinant of Mental Health Inequities for Transgender Youth in Aotearoa/New Zealand*, 45 J. PUB. HEALTH (OXF) e225 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC10273389/; *see also* Brief of Trevor Project as Amici Curiae in Support of Plaintiff-Appellants at 4-11, *Dekker v. Florida*, No. 23-12155 (11th Cir. Dec. 4, 2023), https://www.thetrevorproject.org/wp-content/uploads/2023/12/Dekker-Trevor-Project-Amicus.pdf.

[244] Tan et al.

[245] Turban et al., *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults*. While the HHS Review dismisses several of the studies cited herein as low quality, that does not negate their findings, as explained in detail above.

[246] *See, e.g.*, Tim C. van de Grift et al., *Waiting for Transgender Care and Its Effects on Health and Equality: A Mixed-Methods Population Study in the Netherlands*, 73 THE LANCET 102657 (2024), https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(24)00236-0/fulltext.

[247] *Id.*; *see also* Julia C. Sorbara et al., *Mental Health and Timing of Gender-Affirming Care* 146 PEDIATRICS e20193600 (2020) (attached).

[248] Maung et al.; *see also* Jeffrey Kirby, *A Multi-Lens Ethics Analysis of Gender-Affirming Care for Youth with Implications for Practice and Policy*, 25 AM. J. BIOETHICS 57 (2025),

Further, the Proposed Rule will have a disproportionate effect on minors who are currently receiving gender-affirming care through Medicaid or CHIP. In sharp contrast with the experience in states and other countries cited by HHS (*e.g.*, New Zealand) that have limited access to gender-affirming care for minors, the Proposed Rule makes no attempt to ensure any continuity of care for youth currently receiving services that would be excluded from coverage. Without the financial means to continue accessing gender-affirming care, adolescent Medicaid and CHIP beneficiaries who are currently receiving services will most likely be forced to suddenly detransition against their wishes and contrary to all medical evidence and the recommendations of their treating providers. HHS cites to various studies in support of the Proposed Rule, yet none of these studies conclude that forced and abrupt detransitioning is a better alternative than continuing the services for individuals who are already receiving them. In contrast, various studies have found that transgender youth in jurisdictions that have implemented bans on gender-affirming care have suffered significant health consequences post-ban, such as increased rates of stress, anxiety, and suicide, and heightened problems with daily activities, such as attending school.[249]

c. HHS underestimates the cost and administrative burden imposed by the Medicaid/CHIP ban on gender-affirming care.

HHS insists that it will take states about two hours to prepare and submit a state plan amendment (SPA) containing a "simple recitation of the prohibition" to certify compliance.[250] However, implementing these bans for different age groups in Medicaid and separate CHIP programs and demonstrating compliance will be much more burdensome and expensive than HHS acknowledges.

HHS asserts that 27 states have laws restricting at least some of the prohibited services, and goes on to indicate that none of these states will need to review Medicaid or CHIP

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https://pubmed.ncbi.nlm.nih.gov/40476795/ (attached); Samuel Mann & Harry Barbee, *Public Health and Ethical Risks of Rollbacks on Medicaid Coverage for Gender-Affirming Care*, 334 JAMA 853 (2025) (attached).

[249] *See* Natacha Kennedy, *Harming children: the effects of the U.K. puberty blocker ban*, J. GENDER STUDIES (2025), https://www.tandfonline.com/doi/epdf/10.1080/09589236.2025.2521699?needAccess=true; Good Law Project, *New data shows surge in trans kids' suicides following health care rollbacks* (Feb. 7, 2026), https://goodlawproject.org/new-data-shows-surge-in-trans-kids-suicides-following-healthcare-rollbacks/?utm_source=substack&utm_medium=email; Wilson Y. Lee et al., *State-level anti-transgender laws increase past-year suicide attempts among transgender and non-binary young people in the USA*, 8 NATURE HUM. BEHAV. 2096 (2024) (attached) (finding an increase of 72% in suicide attempts among transgender youth a year after their state implemented anti-transgender legislation). *See also* Movement Advancement Project, *New Survey Reveals Dramatic Changes for LGBTQ Adults Since November 2024* (2025), https://www.mapresearch.org/2025-norc-survey-report; Jeffrey M. Jones, *LGBTQ+ Identification in U.S. Rises to 9.3%*, GALLUP (Feb. 20, 2025), https://news.gallup.com/poll/656708/lgbtq-identification-rises.aspx (identifying patterns of transgender and non-binary individuals leaving their home states in the wake of anti-transgender legislation and discrimination in their local or state governments).

[250] Proposed Rule at 59457.

policy documents "as these procedures are currently banned."[251] But that cannot be true for states with bans that do not overlap completely with the Medicaid coverage exclusion. It seems that states will need to crosswalk their own state-specific bans to determine if and how they overlap with the Medicaid exclusion. This process will be time-consuming.

In addition, HHS fails to address the difficulties associated with ensuring that Medicaid and CHIP beneficiaries do not receive coverage of the services at issue to treat gender dysphoria, but continue to receive coverage of the services to treat other conditions. Individual providers, hospital systems, managed care plans, and state agencies will need to develop, test, implement, and evaluate systems to distinguish between permissible and impermissible uses of these important and medically necessary services. This process will be even more burdensome given that the definition of "sex rejecting procedures" differs from the definition of "specified sex trait modification procedures" in the EHB rule. For example, a managed care organization could offer: a Medicaid Alternative Benefit Plan (ABP) that is subject to the EHB prohibition and the Proposed Rule; a Medicaid plan subject to the prohibition in the Proposed Rule for people under 18; and a separate CHIP plan where the Proposed Rule also applies to adults who are 18. These multiple requirements will create an implementation nightmare for state Medicaid and CHIP programs, managed care organizations, providers, and beneficiaries.

Without question, beneficiary access to even permissible uses of these services will be severely impaired, as providers and agencies issue blanket care denials for fear of recoupment or legal consequences.

IV. There are Alternatives to the Proposed Rule.

In the Proposed Rule, HHS indicates that it considered two alternatives: the Proposed Rule and no action.[252] However, there are other alternatives that would address HHS's asserted concerns while preserving access to medically necessary care. HHS expressed concerns that minors might not "understand the irreversible or long-term risks of these procedures."[253] HHS ignores that: 1) parents/guardians are required to provide informed consent to care for minors, with adolescent minors providing assent; 2) not all of the services at issue have irreversible effects, as described above; and 3) Medicaid and CHIP cover a range of other services for adolescents that have some of the same side effects as gender-affirming services or have different side effects that are irreversible.[254] Further, it

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[251] *Id.* at 59456
[252] *Id.* at 59459.
[253] *Id*. at 59448; *see id*. at 59450 (expressing concerns about informed consent protocols).
[254] For example, thousands of children are prescribed Chronic Oral Corticosteroids to treat autoimmune and inflammatory conditions, despite the fact that these medications can cause growth suppression and bone mineral loss (glucocorticoid-induced osteoporosis with increased fracture risk), as well as other serious side effects. *See* Kenneth G. Saag & Daniel E. Furst, *Major Adverse Effects of Systemic Glucocorticoids*, UPTODATE (2024), https://www.uptodate.com/contents/major-adverse-effects-of-systemic-glucocorticoids; Karine Briot & Christian Roux, *Glucocorticoid-Induced Osteoporosis*, 8 RMD OPEN e000014 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4613168/. As another example, inhaled Corticosteroids (ICS) are used to treat asthma in millions of children

ignores that Medicaid covers the *same services* when used to treat conditions other than gender dysphoria. For example, as described in Section II.b.2, Medicaid and CHIP cover medications to delay puberty when they are prescribed to treat central precocious puberty, even though the medications carry the same risks of side effects when used for that purpose. Nevertheless, to address its purported concerns, HHS could consider requiring states to ensure that providers follow a reasonable informed consent process as a condition of coverage.

In addition, HHS expressed concerns that minors are being misdiagnosed and/or not adequately assessed prior to receiving gender-affirming care.[255] There is no evidence to support those concerns. However, HHS could consider requiring states to impose certain utilization controls to ensure that Medicaid and CHIP are only covering medically necessary gender affirming care for adolescents. These controls could include requiring adolescents to have a diagnosis from a qualified mental health provider who has training and expertise working with gender diverse adolescents before receiving medication or surgery. Likewise, utilization controls could address HHS's concerns about the risks of gender-affirming care. For example, HHS could consider requiring states to ensure that youth who receive testosterone to treat gender dysphoria have appropriate blood tests done to monitor their testosterone levels and prevent any adverse effects (consistent with the existing standard of care).

Further, HHS repeatedly expressed concerns about infertility. Under the existing standards of care, providers counsel adolescents (and their parents/guardians as appropriate) about the potential for gender-affirming care to affect fertility and their options for fertility preservation.[256] Indeed, the WPATH SOC-8 devotes an entire chapter to reproductive care.[257] Yet, to address its concerns, HHS should consider expanding coverage of and access to fertility preservation services or funding advancements in fertility preservation techniques.

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and youth, despite the fact that long-term ICS use is linked to slowed linear growth (length or height over time, driven by skeletal development) in children. *See, e.g.,* Yoon Kong Loke et al., *Impact of Inhaled Corticosteroids on Growth in Children with Asthma: Systematic Review and Meta-Analysis,* 10 PLOS ONE e0133428 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4507851/; H.W. Kelly et al., *Effect of Inhaled Glucocorticoids in Childhood on Adult Height,* 367 New Eng. J. Med. 904 (2012), https://www.nejm.org/doi/full/10.1056/NEJMoa1203229. In addition, Aminoglycoside Antibiotics are also routinely used to treat serious bacterial infections in children and youth, even though they can cause irreversible ototoxicity in children, including permanent sensorineural hearing loss. *See, e.g.*, Tobi Frymark et al., Am. Speech-Language Hearing Ass'n, *Evidence-Based Systematic Review (EBSR): Drug-Induced Hearing Loss— Aminoglycosides* (2010), https://www.asha.org/siteassets/uploadedFiles/EBSRAminoglycosides.pdf.

[255] *See* Proposed Rule at 59447.

[256] Coleman et al., at S156–57.

[257] *See id*. at S156–162.

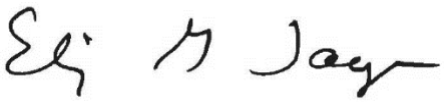
Finally, given its concerns that the research on pediatric gender-affirming care is low quality, HHS should consider funding more high-quality research, as frequently called for by experts in the field.[258]

V. Conclusion

For the reasons stated above, we urge HHS to withdraw the Proposed Rule. We have included numerous citations to supporting research, including direct links to research. We direct HHS to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to comment on this proposed rule. If you have any questions or concerns, please feel free to contact Héctor Hernández-Delgado at hernandez-delgado@healthlaw.org, Abbi Coursolle at coursolle@healthlaw.org, or Catherine McKee at mckee@healthlaw.org.

Sincerely,



Elizabeth G. Taylor
Executive Director

[258] *See, e.g.*, Budge et al. ("We must champion emerging, ethically based, and methodologically sound research that includes [transgender and gender-diverse] individuals in its creation and implementation. We cannot allow cherry-picked data or unsound research methodologies to drive clinical care, agency policies, or legislation, to the detriment of health equity for [transgender and gender-diverse] youth.")