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August 19, 2026

Jessica Jensen
American Oversight
1030 15th Street NW
Suite B255
Washington, DC 20005

RE: Request for Records

Dear Ms. Jensen:

We have completed our review of records responsive to the search criteria in your request. As a reminder, you requested:

> All email communications (including emails, email attachments, complete email chains, calendar invitations, and calendar invitation attachments) between (a) any of the officials listed below, and (b) any of the external entities listed below, and (c) containing any of the key terms listed below, from January 1, 2026, through the date the search is conducted.
>
> Office of the Attorney General Officials:
> a. Kris W. Kobach, Attorney General
> b. Joseph Sciarotta, Chief Deputy Attorney General
> c. Anthony Powell, Solicitor General
> d. James Rodriguez, Assistant Attorney General
> e. Michelle Schroeder, Chief of Staff
> f. Charles Dalton, Senior Advisor
> g. Anyone serving in the capacity of Chief of the Special Litigation and Constitutional Issues Division
> h. Anyone serving in the capacity of Chief of the Civil Division
> i. Anyone serving in the capacity of Chief of the Criminal Division
>
> External Entities:
> a. The Food and Drug Administration ("@fda.hhs.gov")
> b. The Department of Health and Human Services ("@hhs.gov")

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c. The White House ("who.eop.gov" or "whitehouse.gov")

Key Terms:
i. "abortion drug"
ii. "abortion medication"
iii. "abortion pill"
iv. "chemical abortion"
v. "in person dispensing"
vi. "in-person dispensing"
vii. "medication abortion"
viii. mifepristone-induced
ix. "Risk Evaluation and Mitigation"
x. "shield law"
xi. FAERS
xii. mifeprex
xiii. mifepristone
xiv. misoprostol
xv. REMS
xvi. "Louisiana v. FDA"
xvii. "LA v. FDA"
xviii. "Florida v. FDA"
xix. "FL v. FDA"
xx. "Missouri v. FDA"
xxi. "MO v. FDA"

Our search identified six records responsive to the criteria identified in your request. Those six records will be provided to you by electronic mail.

We hope this information is helpful. If you have any questions or require additional assistance, please contact the Office of the Attorney General at (785) 296-8495.

Sincerely,

OFFICE OF THE ATTORNEY GENERAL
KRIS W. KOBACH

Matt Bingesser
Administrative Counsel

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Supreme Court of Ohio Clerk of Court - Filed October 20, 2025 - Case No. 2025-0472

In the
Supreme Court of Ohio

MADELINE MOE, *et al.*,	)	Case No. 2025-0472
	)	
Plaintiffs-Appellees,	)	On Appeal from the Franklin County Court of Appeals,
	)	
v.	)	Tenth Appellate District
	)	
DAVE YOST, *et al.*,	)	Court of Appeals
	)	Case No. 24AO-483
Defendants-Appellants.	)	

BRIEF OF *AMICI CURIAE* STATE OF ALABAMA AND 24 OTHER STATES IN SUPPORT OF APPELLANTS AND REVERSAL

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INTRODUCTION

By its own account, the Tenth District's reasoning rises or falls with WPATH—the World Professional Association for Transgender Health. Based on its cherrypicked reading of amicus briefs since rejected by the U.S. Supreme Court in *United States v. Skrmetti*, 145 S. Ct. 1815 (2025), the Tenth District concluded that, along with the Endocrine Society, WPATH is one of the "standard-bearers in gender-affirming care" and that its guidelines "are the current prevailing standards of care for the treatment of individuals with gender dysphoria." *See Moe v. Yost*, 2025-Ohio-941 (10th Dist. Mar. 18, 2025) ("Op."), ¶¶14, 19; *see also* ¶¶13 & n.8, 70 & n.32 (discussing *Skrmetti* amicus briefs supporting WPATH). The court's legal analysis was based on this factual finding. As it wrote, the court "consider[ed] the constitutional issues in this case by accepting the Guidelines as the prevailing standards of care." Op. ¶20.

For all the reasons the Ohio Attorney General explains in his brief, it is doubtful that the Ohio Constitution outsources the State's regulation of medicine to the very interest groups whose members are being regulated. So the Tenth District's starting premise is almost certainly wrong. If the General Assembly wished to regulate the prescription of opioids, for instance, it could do so in the face of conflicting "guidelines" by the American Pain Society. So, too, could it restrict children's access to opioids—again, even if the American Pain Society, and even if the child's parents, thought differently. So it is here.

Yet even if the Tenth District's reasoning were sound, reversal would still be warranted because the WPATH guidelines are simply not trustworthy. Even Plaintiffs now tacitly acknowledge that fact. Though they built their case on the promise that "[t]he medical profession's generally accepted guidelines for treating gender dysphoria are issued by the Endocrine Society

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and the World Professional Association for Transgender Health (WPATH),"[1] Plaintiffs now say that only "[t]he Endocrine Society Guideline is the standard of care widely accepted by the medical community across our country." *See* Appellees' Mem. in Response to Jurisdiction at 2. What happened?

What happened is court-ordered discovery. In 2022, shortly after the Alabama legislature passed a law prohibiting pediatric sex-change procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[2] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[3] Its evidence-review team "found little to no evidence

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[1] Br. of Appellants, No. 24AP-483 (10th Dist.), at 11 (emphasis added).

[2] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[3] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10.

Throughout this brief, *amici* will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

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about children and adolescents."[4] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[5] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[6] WPATH obliged.

This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[7] And Plaintiffs' counsel are well aware of this evidence, having been involved in other cases where it has been discussed. *See, e.g.*, *Skrmetti*, 145 S. Ct. at 1847-49 (Thomas, J., concurring) (noting "[r]ecent revelations [that] suggest that WPATH, long considered a standard bearer in treating pediatric gender dysphoria, bases its guidance on insufficient evidence and allows politics to influence its medical conclusions" (citation omitted)). One of their expert witnesses—Dr. Antommaria—even served as an expert witness in Alabama's case and thus had direct access to the discovery there.

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[4] Ex.173(Doc.560-23):22.

[5] Ex.174(Doc.560-24):1-2.

[6] Ex.186 (Doc.700-15):32.

[7] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

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No wonder Plaintiffs are running away from WPATH. But running to the Endocrine Society guideline is no answer because WPATH helped write it, too. As the Cass Review for England's National Health Service explained, the "two guidelines" are "closely interlinked, with WPATH adopting Endocrine Society recommendations, and acting as a co-sponsor and providing input to drafts of the Endocrine Society guideline."[8] Indeed, not only did WPATH sponsor both the 2009 and 2017 Endocrine Society guidelines, but the 2017 Endocrine Society guideline and WPATH's SOC-8 were also "closely linked through overlapping authors."[9] And the groups' guidelines "influenced nearly all the other guidelines" by other organizations, so there is simply no escaping WPATH's fingerprints in any of the pro-affirming guidelines.[10] As the Cass Review concluded, "[t]he circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[11]

Plaintiffs thus cannot outrun WPATH. And they cannot escape the fact that they built their case on a faulty cornerstone. This Court should reverse.

INTEREST OF *AMICI CURIAE*

Like Ohio, *amici* States determined that sex-change procedures should not be made available to kids. That determination should not be controversial. *Amici* have always regulated healthcare. *See Dent v. West Virginia*, 129 U.S. 114, 121-24 (1889). And until a few years ago, the

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[8] *The Cass Review: Independent Review of Gender Identity Services for Children and Young People* 130 (Apr. 2024), https://perma.cc/3QVZ-9Y52; *see also* Jo Taylor et al., *Clinical Guidelines for Children and Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review of Guideline Quality (Part 1)*, ARCH. DIS. CHILD. S71 (2024), https://perma.cc/F3HW-FJAS ("These two guidelines are themselves linked through cosponsorship and like other guidelines lack a robust and transparent approach to their development.").

[9] Dep't of Health and Human Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* 133 (May 1, 2025), https://perma.cc/F236-84DW.

[10] *Cass Review*, *supra* note 8, at 130.

[11] *Id.*

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notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized. *Amici* write to share a little about how we got here.

STATEMENT

I. The WPATH Guidelines Are Not Reliable.

WPATH published Standards of Care 8 (SOC-8) in September 2022.[12] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[13] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[14] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[15] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen

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[12] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.
[13] *Id.* at S248-49.
[14] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.
[15] Ex.18(Doc.564-8):121:7-11.

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[their] position in court."[16] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[17] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[18]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[19]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[20] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[21] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[22]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[23]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[24] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens

[16] Ex.21(Doc.700-3):158:17-25.
[17] Ex.184(Doc.700-13):24.
[18] Ex.184(Doc.700-13):15.
[19] Ex.182(Doc.700-11):152.
[20] Ex.4(Doc.557-4):vi.
[21] Ex.182(Doc.700-11):151.
[22] Ex.184(Doc.700-13):14.
[23] SOC-8, *supra* note 12, at S177.
[24] Ex.180(Doc.700-9):11.

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of lawsuits in the US right now";[25] "I cannot overstate the importance of SOC 8 getting this right at this important time."[26] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[27]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[28] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[29]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[30]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter,

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[25] *Id.* at 64.
[26] Ex.181(Doc.700-10):43.
[27] *Id.* at 75.
[28] SOC-8, *supra* note 12, at S18.
[29] *Id.*
[30] Ex.181(Doc.700-10):36 (second closed parenthesis added).

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for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[31] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[32] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[33] all while authors and WPATH leaders raised such concerns internally.[34]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[35] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[36]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the

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[31] SOC-8, *supra* note 12, at S45-46.

[32] Ex.174(Doc.560-24):1-2.

[33] Ex.184(Doc.700-13):55.

[34] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[35] Ex.184(Doc.700-13):54.

[36] *See* Ex.187(Doc.700-16):4-5.

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publisher for proofreading and typesetting.[37] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[38] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[39]

After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[40] WPATH leaders met with Levine to discuss the age recommendations.[41] Levine's solution was simple: "She asked us to remove them."[42]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[43]

- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[44]

[37] Ex.170(Doc.700-4):61-64.
[38] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.
[39] Ex.170(Doc.700-4):143.
[40] Ex.186 (Doc.700-15):28.
[41] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[42] Ex.186 (Doc.700-15):11.
[43] *Id.* at 32.
[44] *Id.*

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- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[45]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[46] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[47]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[48] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[49]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[50] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same."[51] But the political reality soon set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[52] WPATH thus "remove[d] the ages."[53]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical

[45] *Id.* at 33.
[46] *Id.* at 17.
[47] *Id.* at 57.
[48] *Id.* at 17.
[49] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.
[50] Ex.187(Doc.700-16):13-14, 109.
[51] *Id.* at 100.
[52] *Id.* at 191.
[53] *Id.* at 338.

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guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[54]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[55] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[56] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[57]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[58] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[59] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[60]

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[54] Ex.21(Doc.700-3):293:25–295:16.
[55] Ex.188(Doc.700-17):152.
[56] Ex.177(Doc.700-6):124.
[57] *Id.* at 119.
[58] Ex.188(Doc.700-17):113.
[59] *Id.*
[60] Ex.177(Doc.700-6):102.

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C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[61] Among other things, it boasts that WPATH managed conflicts of interest and engaged an evidence-review team to conduct systematic literature reviews.[62] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[63] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[64]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[65] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[66]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were

[61] *See* SOC-8, *supra* note 12, at S247-51.
[62] *Id.*
[63] *Id.* at S247.
[64] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).
[65] Institute of Medicine, *supra* note 64, at 83.
[66] *Id.* (emphasis added).

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already enthusiastic about transitioning treatments.[67] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[68]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[69] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[70] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[71]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[72] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[73] Dr.

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[67] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.
[68] Ex.18(Doc.564-8):121:7-11.
[69] Institute of Medicine, *supra* note 64, at 78.
[70] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[71] SOC-8, *supra* note 12, at S177.
[72] Ex.21(Doc.700-3):230:17-23.
[73] Ex.174(Doc.560-24):7.

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Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[74] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[75] "Unfortunately," she lamented, "this was not done here."[76] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[77]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[78]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[79] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[80]

Chapter authors were then to grade the recommendation statements based on the evidence.[81] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved,"

[74] Ex.166(Doc.560-16):1.
[75] *Id.* (emphasis added).
[76] *Id.*
[77] SOC-8, *supra* note 12, at S177.
[78] Ex.21(Doc.700-3):232:13-15.
[79] SOC-8, *supra* note 12, at S250.
[80] *Id.* at S249-50.
[81] *Id.* at S250.

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"few downsides," and "a high degree of acceptance among providers."[82] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[83] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[84]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[85] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[86]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[87] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[88]

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[82] *Id.*
[83] *Id.*
[84] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.
[85] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.
[86] Ex.39(Doc.592-39):66:2–67:5.
[87] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.
[88] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

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At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[89]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[90] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[91]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[92] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[93] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

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[89] SOC-8, *supra* note 12, at S48.
[90] *Id.* at S46-47.
[91] *Id.* at S111.
[92] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.
[93] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

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E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[94] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[95] She reported: "[W]e found little to no evidence about children and adolescents."[96]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[97] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[98] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[99] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[100] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[101]

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[94] Ex.173 (Doc.560-23):22-25.
[95] *Id.* at 24.
[96] *Id.* at 22.
[97] *Id.*
[98] Ex.167(Doc.560-17):86-88.
[99] *Id.* at 37-38, 75-81.
[100] *Id.* at 37 (emphasis added).
[101] *Id.* at 38.

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This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[102] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[103]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[104]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[105]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[106] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[107] That's not an exaggeration. When asked at his

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[102] *Id.* at 91.
[103] *Id.* at 38.
[104] *Cf.* Ex.167(Doc.560-17):91.
[105] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).
[106] SOC-8, *supra* note 12, at S88.
[107] *Id.* at S88-89.

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deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[108]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[109] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[110] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[111] No matter: The guideline that Plaintiffs rely on to ask this Court to reverse the trial court's factual findings recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[112] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[113] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[114] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[115] "The fictional pornography" "includes themes such as Nazi doctors

[108] Ex.21(Doc.700-3):172:19–173:25.
[109] *Id.*
[110] Ex.182(Doc.700-11):96.
[111] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.
[112] SOC-8, *supra* note 12, at S88.
[113] *Id.*
[114] *Id.*
[115] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

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castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[116]

Despite all this, Plaintiffs told the court below that the WPATH guideline was developed "using well-accepted processes" and is "comparable to treatment guidelines used in many other areas of medicine." Br. of Appellants, No. 24AP-483 (Tenth Appellate District), at 11-12. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[117]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[118] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[119]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He

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[116] *Id.*
[117] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.
[118] Ex.190(Doc.700-18):5 (capitalization altered).
[119] *Id.*; *see* Ex.16(Doc.557-16):¶103.

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noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[120] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[121] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[122]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[123] The AAP, Dr. Coleman said, rejected WPATH's request.[124] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[125] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[126]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[127] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the

[120] Ex.190(Doc.700-18):5-6.
[121] *Id.*
[122] *Id.* at 6 (spelling corrected).
[123] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.
[124] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.
[125] Ex.189(Doc.560-39):15.
[126] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.
[127] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

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Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[128] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[129] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[130] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[131] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from

[128] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.
[129] And online: https://adc.bmj.com/pages/gender-identity-service-series.
[130] *See generally* Ex.16(Doc.557-16).
[131] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

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gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[132] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[133] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[134]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[135]

* * *

Much more could be said about how untrustworthy Plaintiffs' once-favorite medical organization is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough…. It occurred to me that how could anyone truly know

[132] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[133] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[134] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[135] Ex.176(Doc.700-5):152.

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> how important sexual function was to a relationship, to happiness? It isn't an easy question to answer….[136]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[137]

II. The General Assembly Rejects The WPATH Model Of "Care," Which The Tenth District Rules It Cannot Do.

In January 2024, the Ohio General Assembly enacted the "Saving Ohio Adolescents from Experimentation" Act to prohibit doctors from administering puberty blockers, cross-sex hormones, and sex-change surgeries to minors for the purpose of gender transition. *See* R.C. 3129.02(A)(1), (2). In doing so, the State definitively rejected the WPATH model of "care."

Following a five-day trial, the trial court upheld the State's law against challenge. Com. Pl. Op. 12 (Aug. 6, 2024). The Tenth District reversed on two grounds, both premised on the reliability of the WPATH Standards of Care. *See* Op.¶20 ("[W]e find support for our decision to consider the constitutional issues presented in this case by accepting the Guidelines as the prevailing standards of care for gender dysphoria.").

First, the court held that the Healthcare Freedom Amendment restricted the General Assembly's authority to regulate medicine to instances where the regulation is "in accordance with the prevailing standards of care." Op.¶73. Because the Act's prohibitions on sex-change procedures for minors were *not* in accordance with the WPATH Standards, the court held, the Act violated the Healthcare Freedom Amendment.

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[136] Ex.176(Doc.700-5):68.
[137] Ex.180(Doc.700-9):59.

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Second, the Tenth District held that the Act violates the Due Course of Law Clause because it interferes with "a parent's fundamental right to direct the medical care of their child" in accordance with "medically accepted standards." Op.¶87. Here again, the court reasoned, because WPATH set the "standard," and Ohio departed from WPATH, the Act was unconstitutional.

This appeal followed. This Court stayed the Tenth District's order and accepted jurisdiction and agreed to review the judgment below. *See Moe v. Yost*, 2025-Ohio-1483; *Moe v. Yost*, 2025-Ohio-2537.

ARGUMENT

This case presents a question of fundamental importance to self-governance: whether the people's representatives in the Ohio General Assembly are bound by guidelines promulgated by interest groups like WPATH or, instead, interest groups like WPATH are bound by medical regulations enacted by the General Assembly. Who regulates whom?

The answer to that question matters in this case because children deserve so much better than the WPATH Standards. After spending years conducting a comprehensive review for the National Health Service in England, Dr. Hilary Cass summed up her findings: "I can't think of another area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[138] No wonder countries in Europe are restricting minors' access to the "treatments." *See* Lavietes, *Britain Bans Puberty Blockers for Transgender Minors*, NBC NEWS (Dec. 11, 2024), https://perma.cc/3Q4SNV8E; Ghorayshi, *Scotland Pauses Gender Medications for Minors*, N.Y. TIMES (Apr. 18, 2024), https://perma.cc/4YV6- FCX5 (noting Scotland became "the sixth country in Europe to limit" access).

[138] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024), https://perma.cc/KUM3-XL2S.

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The co-chair of the adolescent chapter of WPATH's SOC-8, Annelou de Vries, does not even seem to disagree with Dr. Cass's assessment. Dr. de Vries is a seminal researcher in the field, having co-authored the original "Dutch studies" on which everything else has been built. In a recent essay, she tacitly admitted the truth of "the critique that there is insufficient evidence," and wrote to "question" the "normative assumption" that pediatric sex-change procedures "must necessarily result in 'effective' outcomes in order to be considered legitimate and essential care."[139] She suggested instead that sex-changes for kids be "provided and justified on the basis of personal desire and autonomy," that "effectiveness" be measured by how well the procedures "help individuals achieve their embodiment goals," and that any "experience of regret" be welcomed as "inherent to all lives."[140]

This case asks whether the Ohio General Assembly is powerless to disagree.

State Appellants' Proposition of Law No. 1:

> *The Due Course of Law Clause does not create a parental right to obtain drug-based "gender transitions" for a child.*

The Tenth District reasoned that Ohio's Due Course of Law Clause is coextensive with the Fourteenth Amendment's Due Process Clause, including its purported right to substantive due process. But there is no right for parents to obtain sex-change procedures for their children that is deeply rooted in our Nation's history and tradition, and the general recognition that parents can direct the medical care of their children does not afford them the ability to subject every restricted treatment to strict scrutiny (and make judges de facto medical regulators in the process). Were it

[139] Oosthoek, de Vries, et al., *Gender-affirming Medical Treatment for Adolescents*, 25 BMC MEDICAL ETHICS 154 (2024), https://perma.cc/8W4R-CEG7.
[140] *Id.*

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otherwise, parents could unlock access to vaccines before FDA approval and to euthanasia drugs that a State prohibits.

Nor does the Tenth District's restriction to "accepted standards" help matters. Op.¶103. It simply raises another problem: accepted by whom? Not the General Assembly or other government regulators, the Tenth District says, but WPATH. But our nation's "history and tradition" is that governments regulate medical providers, not the other way around. *E.g.*, *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 302 (2022) ("The Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion."). "This country does not have a custom of permitting parents to obtain banned medical treatments for their children and to override contrary legislative policy judgments in the process." *L.W. v. Skrmetti*, 83 F.4th 460, 475 (6th Cir. 2023). Indeed, "[i]f parents could veto legislative and regulatory policies about drugs and surgeries permitted for children, every such regulation—there must be thousands—would come with a springing easement: It would be good law until one parent in the country opposed it," at which point "either the parent would take charge of the regulation or the courts would." *Id.*

State Appellants' Proposition of Law No. 2:

> *The Health Care Freedom Amendment does not create a parental right to obtain drug-based "gender transitions" for a child.*

The Tenth District also wrongly deferred to WPATH when interpreting the Health Care Freedom Amendment. By its express terms, the Amendment "does not … affect any laws calculated to deter fraud or punish wrongdoing in the health care industry." Ohio Const. art. I, §21(d). The Act here does both by rejecting the fraudulent WPATH model of care and protecting minors from unproven, high-risk procedures that are justified by their primary proponents on grounds that

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children have the right to experience "regret."[141] The Health Care Freedom Amendment, enacted to prevent an individual mandate to compel insurance coverage, does nothing to the General Assembly's traditional power to regulate medicine—even when doing so departs from the wishes of the interest groups whose members are being regulated.

CONCLUSION

The Court should reverse the Tenth District's judgment.

Dated: October 20, 2025

Respectfully submitted,

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[141] Oosthoek, *supra* note 139.

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CERTIFICATE OF SERVICE

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through the Local Notice to Mariners, Broadcast Notice to Mariners, Marine Safety Information Bulletins, or Coast Guard Advisory Notices.

(b) *Definitions.* As used in this section, *Designated Representative* means a Coast Guard coxswain, petty officer, or other officer or a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the security zone.

Foreign Naval Vessel means any naval vessel of a foreign state, which is not required to be licensed for entry into the U.S. for visit purposes under 22 CFR 126.6, provided it is not undergoing repair or overhaul.

U.S. Naval Vessel means any vessel owned, operated, chartered, or leased by the U.S. Navy; any pre-commissioned vessel under construction for the U.S. Navy, once launched into the water; and any vessel under the operational control of the U.S. Navy or a Combatant Command.

(c) *Regulations.* (1) Under the general security zone regulations in subpart C of this part, you may not enter the security zones described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's Representative on VHF–FM channel 16 or by telephone at (844) NYC–USCG. Those in a security zone must comply with all lawful orders or directions given to them by the COTP or the COTP representative.

(3) The Coast Guard Northeast District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov.*

Dated: December 16, 2025.

M.E. Platt,

Rear Admiral, U.S. Coast Guard, Commander, Coast Guard Northeast District.

[FR Doc. 2025–23435 Filed 12–18–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 441 and 457

[CMS–2451–P]

RIN 0938–AV73

Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would require that a State Medicaid plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under 18 and prohibit the use of Federal Medicaid dollars to fund sex-rejecting procedures for individuals under the age of 18. In addition, it would require that a separate State Children's Health Insurance Program (CHIP) plan must provide that the CHIP agency will not make payment under the plan for sex-rejecting procedures for children under 19 and prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures for individuals under the age of 19.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–2451–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2451–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2451–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *MedicaidSRPInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background [1]

Title XIX of the Social Security Act (the Act) authorizes Federal grants to the States for Medicaid programs to

[1] This document contains links to non-U.S. Government websites. We are providing these links because they contain additional information relevant to the topics discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are providing these links for reference only; linking to a non-U.S. Government website does not constitute an endorsement by CMS, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by U.S. Government websites do not apply to third-party sites.

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provide medical assistance to persons with limited income and resources and title XXI of the Act authorizes Federal grants to States to provide child health assistance to targeted low-income children under age 19 through a separate CHIP, a Medicaid-expansion program, or a combination of the two. Separate CHIPs are programs under which a State receives Federal funding from its title XXI allotment to provide child health assistance through coverage that meets the requirements of section 2103 of the Act and 42 CFR 457.402. For the purposes of this proposed rule, the term CHIP is used to refer to separate CHIPs. Medicaid and CHIP programs are administered primarily by the States, subject to Federal oversight and approval. Each State establishes its own Medicaid and CHIP eligibility standards, benefits packages, and payment rates in accordance with (and subject to) Federal statutory and regulatory requirements. If States comply with requirements in the Federal Medicaid and CHIP statutes and regulations (such as reflected in the provisions of their Federally-approved State plans), the Federal Government will match their expenditures with Federal funds. Each State Medicaid program and CHIP must be described and administered in accordance with a Federally approved State plan. This comprehensive document describes the nature and scope of the States' Medicaid program and CHIP and provides assurances that they will be administered in conformity with applicable Federal requirements.

Under title XIX, the Federal Government makes matching payments to States for medical assistance expenditures according to the formula described in sections 1903 and 1905(b) of the Act. Under title XXI, the Federal Government makes matching payments to States for child health assistance at the enhanced Federal medical assistance percentage (FMAP) established under section 2105 of the Act. Section 1903 of the Act requires that the Secretary of Health and Human Services (the Secretary) (except as otherwise provided) pay to each State which has a plan approved under title XIX of the Act, for each quarter, an amount equal to the FMAP of the total amount expended by the State during such quarter as medical assistance under the State plan. Section 1905(b) of the Act defines the FMAP. For CHIP, section 2105 requires the Secretary to pay each State with an approved plan under title XXI of the Act, for each quarter, an amount equal to the enhanced FMAP of expenditures in the quarter, paid from the State allotment. The enhanced FMAP, as defined at section 2105(b), for a State for a fiscal year, is equal to the FMAP (as defined in the first sentence of section 1905(b)) for the State increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such FMAP for the State is less than (2) 100 percent; but in no case shall the enhanced FMAP for a State exceed 85 percent.

As relevant to this proposed rule, among the statutory requirements for Medicaid State plans, section 1902(a)(19) of the Act [2] requires that a State plan for medical assistance provide such safeguards as may be necessary to assure that care and services under the plan will be provided in a manner consistent with the best interests of the recipients. Furthermore, under section 1902(a)(30)(A) of the Act,[3] the State plan must provide such methods and procedures relating to payment for care and services as may be necessary to assure that payments are consistent with quality of care. Among the statutory requirements for CHIP State plans, under section 2101(a) of the Act, funds are provided to States to provide health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

Section 1102 of the Act requires the Secretary to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is charged under the Act. In Medicaid, these Secretarial functions would include oversight of Medicaid State programs for consistency with the requirements of sections 1902(a)(19) and 1902(a)(30)(A) of the Act. In CHIP, these Secretarial functions would include oversight of CHIP under section 2101(a), which calls for effective and efficient administration of CHIP and coordination with other health care programs, including Medicaid, and under section 2107(e) of the Act, carrying out the functions required by the Medicaid provisions that apply to title XXI in the same manner as they apply under title XIX.

On January 28, 2025, President Trump issued Executive Order (E.O.) 14187, Protecting Children from Chemical and Surgical Mutilation (E.O. 14187). Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions for specific programs, including Medicaid. The Centers for Medicare & Medicaid Services (CMS) is aware that the U.S. District Court for the Western District of Washington has issued a preliminary injunction that enjoins defendant agencies from enforcing or implementing section 4 of E.O. 14187 within the plaintiff States, as well as sections 3(e) or 3(g) of E.O. 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (E.O. 14168), to condition or withhold Federal funding based on the fact that a health care entity or health professional provides ''gender-affirming care'' within the plaintiff States. *Washington* v. *Trump*, 768 F. Supp. 3d 1239, 1282 (W.D. Wash. 2025). In addition, the U.S. District Court for the District of Maryland has issued a preliminary injunction that enjoins the Federal defendants in that case from conditioning, withholding, or terminating Federal funding under section 3(g) of E.O. 14168 and section 4 of E.O. 14187, based on the fact that a healthcare entity or health professional provides ''gender-affirming care'' to a patient under the age of 19 and required that written notice of this order be given to the aforementioned groups that Defendants may not take any steps to implement, give effect to, or reinstate under a different name the directives in section 3(g) of E.O. 14168 or section 4 of E.O. 14187 that condition or withhold Federal funding based on the fact that a healthcare entity or health professional provides ''gender-affirming medical care'' to a patient under the age of 19. *PFLAG, Inc.* v. *Trump*, 769 F. Supp. 3d 405, 455 (D. Md. 2025). We note that if this proposed rule were to be finalized, it would not conflict with those preliminary injunctions because, among other things, it would be based

[2] Section 1902(a)(19) of the Act states that a State plan for medical assistance must ''provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients.''

[3] Section 1902(a)(30)(A) of the Act states that a State plan for medical assistance must ''provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) of the Act) 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.''

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on independent legal authority and section 5(a) of E.O. 14187 and not the enjoined sections of the executive orders. In any event, any regulatory provisions on this issue would not be effective until the specified effective date of any final rule, and would not be implemented, made effective, or enforced in contravention of any court orders.

As further discussed later in this proposed rule, we propose to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act by adding a new subpart N to 42 CFR part 441 to prohibit the use of Federal Medicaid dollars to fund sex-rejecting procedures, as defined in this proposed rule, for individuals under the age of 18. In addition, we propose to implement section 2103 of the Act by revising subpart D of part 457 of the Act to prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures, as defined in this proposed rule, for individuals under the age of 19. These proposed changes would not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

A. The Rise of Sex-Rejecting Procedures for Treatment of Gender Dysphoria in Minors

Over the past decade, increasing numbers of children and adolescents have been diagnosed with gender dysphoria. The recorded prevalence of gender dysphoria/incongruence increased substantially in children and young people between 2011 and 2021, particularly in recorded females. Levels of anxiety, depression and self-harm were high, indicating an urgent need for better prevention and treatment of mental health difficulties in these patients [with gender dysphoria].[4]

Similar research in Germany showed increasing rates in the diagnosis of gender incongruence.[5] Additionally, research in England explained that ''[r]ecent increases in incidence of gender dysphoria/incongruence have a range of potential explanations, including social factors (for example, . . . increasing use of social media and networking); increasing rates of emotional distress and poor mental health in this age group, particularly for females; and changes in supply and delivery of healthcare.'' [6] The number of children receiving medical interventions for gender dysphoria rose significantly following the publication of the ''Dutch Protocol'' in an article in the *European Journal of Endocrinology in* 2006.[7] Over the past decade, increasing numbers of children have received diagnoses of gender dysphoria and received sex-rejecting procedures as recommended by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (ES).[8] [9] The WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC–8) noted that the creation of a chapter on adolescents was due in part to the ''exponential growth in adolescent referral rates.'' [10] Surveys measuring ''transgender'' identity find prevalence of 1.2 percent among adolescents and ''gender diverse'' identities as high as 9 percent.[11] WPATH also noted that female adolescents were seeking such procedures at twice to seven times the rate of males.[12]

Included in SOC–8 is the recommendation that care providers ''undertake a comprehensive biopsychosocial assessment of adolescents'' who seek medical transition [13] and ''involve relevant disciplines, including mental health and medical professionals,'' as well as parents, ''unless their involvement is determined to be harmful.'' [14]

The number of pediatric patients seeking sex-rejecting procedures can only be roughly estimated. In recent years, ''the United States—characterized by its decentralized and privatized healthcare system—saw the emergence of many new specialty gender clinics, along with a proliferation of independently practicing clinicians. According to a recent conservative estimate, as of March 2023 there were 271 clinics offering [pediatric medical transition] in the U.S., though 70 were inactive due to legislative restrictions.'' [15]

An approach for gender dysphoria, referred to in this proposed rule as sex-rejecting procedures,[16] can involve the use of puberty suppressing drugs to prevent the onset of puberty; cross-sex hormones to spur the secondary sex characteristics of the opposite sex; and surgeries including mastectomy and (in rare cases) vaginoplasty. ''Thousands of American children and adolescents have received these interventions.'' [17]

A study published in 2023 estimated that between 2016 and 2020, nearly 3,700 children between the ages of 12 and 18 diagnosed with gender dysphoria underwent surgical procedures, including over 3,200 children who had breast or chest surgery, and over 400 children who had genital surgery.[18] Another analysis found that between 2017 and 2021, more than 120,000 children ages 6 to 17 were diagnosed with gender dysphoria and, of that group, more than 4,700 started taking puberty blockers and more than 14,000 started hormonal therapy.[19] However, as discussed later in this proposed rule, current medical evidence does not support a favorable

[4] Stuart William Jarviset al., ''Epidemiology of gender dysphoria and gender incongruence in children and young people attending primary care practices in England: retrospective cohort study,'' *Archives of Disease in Childhood* 110 (2025): 612, doi:10.1136/archdischild-2024–327992.

[5] Christian J. Bachmann et al., ''Gender identity disorders among young people in Germany: Prevalence and trends, 2013–2022. An analysis of nationwide routine insurance data,'' *Deutsches Ärzteblatt International* 121 (2024): 370–371, doi:10.3238/arztebl.m2024.0098. ''Gender incongruence'' as defined by ICD–11 is ''characterized by a marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' See ''International Classification of Diseases 11th Revision (ICD–11),'' World Health Organization, accessed September 9, 2025, *https://icd.who.int/en/*.

[6] Jarvis et al., ''Epidemiology of gender dysphoria,'' 619.

[7] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, ''Clinical management of gender identity disorder in adolescents: A protocol on psychological and pediatric endocrinology aspects,'' *European Journal of Endocrinology* 155, Supp 1 (2006): S131–S137, *https://doi.org/10.1530/eje.1.02231*.

[8] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,'' *International Journal of Transgender Health* 23, Supp 1 (2022): S1–S258, *https://doi.org/10.1080/26895269.2022.2100644*.

[9] Wylie C. Hembree et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658*.

[10] E. Coleman et al., ''Standards of Care,'' S43.

[11] E. Coleman et al., ''Standards of Care,'' S43.

[12] E. Coleman et al., ''Standards of Care,'' S43.

[13] Medical transition refers to the provision of hormonal or surgical interventions, as adapted from the Department of Health and Human Services, ''Treatment for Pediatric Gender Dysphoria Review of Evidence and Best Practices,'' (November 19, 2025): 29, *https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf* [hereinafter ''HHS Review''].

[14] Jennifer Block, ''US transgender health guidelines leave age of treatment initiation open to clinical judgment,'' *BMJ* 378 (2022), *https://doi.org/10.1136/bmj.o2303*. See also E. Coleman et al., ''Standards of Care,'' S50, S56, S58.

[15] HHS Review, 57–58. See Luca Borah et al., ''State restrictions and geographic access to gender-affirming care for transgender youth,'' *JAMA* 330, no. 4 (2023): 375–378, doi:10.1001/jama.2023.11299.

[16] In this proposed rule, we have sought to use the term ''sex-rejecting procedures'' to refer to the set of procedures encompassed in the proposed definition.

[17] HHS Review, 9.

[18] Jason D. Wright et al., ''National Estimates of Gender-Affirming Surgery in the US,'' *Jama Network Open* 6, no. 8 (2023), doi:10.1001/jamanetworkopen.2023.30348.

[19] Robin Respaut and Chad Terhune, ''Putting numbers on the rise in children seeking gender care,'' *Reuters,* October 6, 2022, *https://www.reuters.com/investigates/special-report/usa-transyouth-data/*.

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risk/benefit profile for the use of chemical or surgical procedures in children to treat gender dysphoria.

B. Medical Evidence Regarding Sex-Rejecting Procedures for Minors

The existing guidelines to support the care of children and adolescents experiencing gender dysphoria around the world vary in their methodological rigor and quality.

On May 1, 2025, the United States Department of Health and Human Services (HHS) released a comprehensive review of the evidence and best practices for promoting the health of children and adolescents diagnosed with gender dysphoria.[20] On November 19, 2025, HHS published a final version of the review following conclusion of the peer review process (HHS Review).[21] The HHS Review, informed by an evidence-based medicine approach, indicated serious concerns about outcomes associated with certain medical interventions, such as puberty blockers, cross-sex hormones, and surgeries, that attempt to transition children and adolescents away from their sex.[22] The HHS Review highlights evidence pointing to significant risks associated with the use of these procedures, including irreversible harms such as infertility, and finds extremely weak evidence of benefit. Significantly, the HHS Review finds that the evidence base does not support conclusions about the effectiveness of medical and surgical interventions in improving mental health or reducing gender dysphoria symptoms, stating that ''[a]nalysis of the biological plausibility of harms is necessary, and suggests that some short- and long-term harms are likely (in some cases expected) sequalae of treatment.'' [23] Likewise, the data considered in the HHS Review indicate that the risk/benefit profile of medical and surgical interventions for children and adolescents diagnosed with gender dysphoria is unfavorable. While the HHS Review itself does not make clinical, policy, or legislative recommendations, it provides critical insights that should inform policymakers as they make decisions to promote health and safety, especially for vulnerable populations such as minors.

Specifically, the HHS Review conducted an overview of systematic reviews—also known as an ''umbrella review''—to evaluate the evidence regarding the benefits and harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria. Existing systematic reviews of evidence, including several that have informed health authorities in Europe, were assessed for methodological quality. The umbrella review found that the overall quality of evidence concerning the effects of sex-rejecting procedures on psychological outcomes, quality of life, regret, or long-term health, is very low.

Although the HHS Review acknowledges that systematic reviews offer limited evidence regarding the harms of sex-rejecting procedures in minors, it also provides plausible explanations for why evidence of harms may not have been sought, detected or reported. This may be due to several factors: the relatively recent adoption of hormonal and surgical treatment approaches, shortcomings in existing studies in consistently monitoring and reporting adverse effects, and publication bias. Even in the absence of strong evidence from large-scale population studies, the HHS Review notes, based on what is known about human physiology and the effects and mechanisms of the pharmacological agents used, there are known and plausible risks of significant harms from puberty blockers, cross-sex hormones, and surgeries. These include ''infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, psychiatric disorders, surgical complications, and regret.'' [24]

The HHS Review documents the weak evidence and growing international retreat from the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors [25] and the ''risk of significant harms.'' [26] The HHS Review explains that ''many treatments (*e.g.* surgery, hormone therapy) can lead to relatively common and potentially serious long-term adverse effects.'' [27] The HHS Review includes a methodologically rigorous assessment of evidence underpinning the use of surgical or endocrine interventions, including puberty blockers and cross-sex hormones, while also drawing on international practice evaluations such as the United Kingdom's Cass Review, described in more detail below. The HHS Review documents serious concerns regarding the lack of reliable evidence of benefits, and risks of significant harms for this model of care that have mounted in recent years, and points to psychotherapy (talk therapy) as a noninvasive alternative. The HHS Review makes clear that ''the evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain.'' [28] The HHS Review cites widely accepted principles of medical ethics to conclude that when ''medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients.'' [29]

We are aware that approximately 17 State Medicaid programs cover sex-rejecting procedures for children, citing guidelines from several major U.S. medical professional associations (American Medical Association, the American Academy of Pediatrics, and the American Psychological Association) who have issued statements deeming sex-rejecting procedures, which they refer to as ''gender-affirming care,'' safe and effective.[30] [31] [32] [33] These medical society endorsements further supported adoption of sex-rejecting procedures by clinicians across the U.S. The HHS Review explains why such guidelines, including the WPATH Standards of Care for the Health of Transgender and

[20] HHS Review, 1. ''HHS Releases Comprehensive Review of Medical Interventions for Children and Adolescents with Gender Dysphoria,'' U.S. Department of Health and Human Services, released May 1, 2025, *https://www.hhs.gov/press-room/gender-dysphoria-report-release.html.*

[21] ''HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures,'' U.S. Department of Health and Human Services, released November 19, 2025, *https://www.hhs.gov/press-room/hhs-releases-peer-reviewed-report-discrediting-pediatric-sex-rejecting-procedures.html.*

[22] See ''Information Quality Guidelines,'' Office of the Assistant Secretary for Planning and Evaluation (ASPE), accessed August 11, 2025, *https://aspe.hhs.gov/topics/data/information-quality-guidelines;* ''HHS Information Quality Peer Review,'' ASPE, accessed August 11, 2025, *https://aspe.hhs.gov/hhs-information-quality-peer-review.*

[23] HHS Review, 134.

[24] HHS Review, 10.

[25] HHS Review, 63–65.

[26] HHS Review, 10.

[27] HHS Review, 230.

[28] HHS Review, 15.

[29] HHS Review, 15.

[30] Stacy Weiner, ''States are banning gender-affirming care for minors. What does that mean for patients and providers?,'' *AAMCNews,* February 20, 2024, *https://www.aamc.org/news/states-are-banning-gender-affirming-care-minors-what-does-mean-patients-and-providers.*

[31] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' American Psychological Association, released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[32] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* January 6, 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[33] ''Criminalizing Gender Affirmative Care with Minors,'' American Psychological Association, accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

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Gender Diverse People, Version 8 (SOC–8), are not trustworthy according to accepted standards for evaluating guideline quality. As the HHS Review documents in detail, the creation of SOC–8 marked a ''clear departure from the principles of unbiased, evidence-driven clinical guideline development.'' [34] In the context of developing its recommendations, WPATH suppressed systematic reviews of evidence, failed to manage conflicts of interest, and relied on legal and political considerations rather than clinical ones.[35] A recent systematic review of international guideline quality concluded that ''[h]ealthcare professionals should consider the lack of quality and independence of available guidance when utilizing this [WPATH and Endocrine Society international guidelines] for practice.'' [36]

1. European Approaches for the Treatment of Pediatric Gender Dysphoria

The HHS Review's current findings are aligned with conclusions reached by multiple European countries. Sweden, Finland, and the United Kingdom conducted independent systematic reviews of evidence commissioned by their public health authorities. ''All three concluded that the risks of medicalization [37] may outweigh the benefits for children and adolescents with gender dysphoria at the population level, and subsequently sharply restricted access to medical gender transition interventions for minors.'' [38] These three countries now recommend exploratory psychotherapy as the first line of treatment. Sweden and Finland reserve hormonal interventions only for exceptional cases, recognizing their experimental status.[39] [40] [41]

In particular, the most influential effort to date has been the United Kingdom's Cass Review—a 4-year independent evaluation of pediatric gender medicine that was published in April 2024.[42] The findings of the Cass Review led to the closure of the United Kingdom's Gender Identity Development Service (GIDS), which had been given a rating of ''inadequate'' by the Care Quality Commission in 2021. The Cass Review recommended a restructuring of the care delivery model—away from the centralized ''gender clinic'' model of care toward a more holistic framework centering on psychosocial support, to be delivered through regional hubs. The Cass Review's findings also led the United Kingdom to ban the use of puberty blockers outside of clinical trials, and to significantly restrict cross-sex hormones. While cross-sex hormones are still officially an available treatment, the National Health Service (NHS) recently revealed that since the Cass Review was published, no minor has been found eligible to receive cross-sex hormones according to the updated policy. In the United Kingdom, minors have never received gender dysphoria-related surgery through the NHS.

In 2022, Sweden's National Board of Health and Welfare (NBHW) reviewed and updated its guidelines for minors under the age of 18. Sweden's NBHW determined that the risks of puberty suppressing treatment with GnRH-analogues (injectable drugs that prevent the ovaries and testicles from producing sex hormones) and gender-affirming hormonal treatment likely outweigh the possible benefits.[43] Specifically, Sweden's NBHW outlined that the first line of treatment should be mental health support and exploratory psychological care. Hormonal interventions can be a last resort measure for some youth. Sweden has made the decision to no longer offer gender transition [sex-rejecting procedures] to minors outside of research settings, and restricted eligibility to the early childhood-onset of gender dysphoria.

In 2020, Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued guidelines that called for psychosocial support as the first line treatment, hormone therapy on a case-by-case basis after careful consideration, and no surgical treatment for minors. Finland has restricted eligibility for hormone therapy to minors with early childhood-onset of gender dysphoria and no mental health comorbidities.[44]

In Denmark, more than 1300 minors with gender incongruence were ''referred to the national service between 2016 and 2022 with increasing referral numbers over time,'' of which females constituted 70 percent.[45] The

[34] HHS Review, 181.

[35] HHS Review, 182.

[36] Jo Taylor et al., ''Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),'' *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65-s72, doi:10.1136/archdischild-2023–326499.

[37] ''Medicalization'' means ''the act of considering something to be a medical problem, or representing it as a medical problem.'' Cambridge Dictionary, accessed August 8, 2025, *https://dictionary.cambridge.org/us/dictionary/english/medicalization*. This definition is based on a plain meaning approach and note that the authors of the study did not otherwise supply a specific definition for the term.

[38] HHS Review, 255. See Jonas F. Ludvigsson et al., ''A systematic review of hormone treatment for children with gender dysphoria and recommendations for research,'' *Acta Paediatrica* 112, no. 11 (2023): 2279–2292, *https://doi.org/10.1111/apa.16791;* National Institute for Health and Care Excellence (NICE), ''Evidence Review: Gender Affirming Hormones for Children and Adolescents with Gender Dysphoria,'' (2020), *https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf;* National Institute for Health and Care Excellence (NICE), ''Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria,'' (2020), *https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf;* I. Pasternack et al., ''Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa: Systemaattinen katsaus [Medical approaches to treating gender dysphoria: A systematic review],'' Summaryx Oy (2019); Jo Taylor et al., ''Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review,'' *Archives of Disease in Childhood* 109, Supp 2 (2024): s33–s47, doi:10.1136/archdischild-2023–326669; Jo Taylor et al., ''Masculinising and feminising hormone interventions for adolescents experiencing gender dysphoria or incongruence: A systematic review,'' *Archives of Disease in Childhood* 109, Supp 2 (2024): s48–s56, doi:10.1136/archdischild-2023–326670.

[39] ''Children and young people's gender services: implementing the Cass Review recommendations,'' NHS England, last updated August 29, 2024, *https://www.england.nhs.uk/long-read/children-and-young-peoples-gender-services-implementing-the-cass-review-recommendations/*.

[40] ''Care of children and adolescents with gender dysphoria-summary of national guidelines,'' The Swedish National Board of Health and Welfare (Socialstyrelsen), December 2022, *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf*.

[41] ''One Year Since Finland Broke with WPATH 'Standards of Care','' Society for Evidence Based Gender Medicine, July 2, 2021, *https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors*.

[42] Hilary Cass, ''Independent review of gender identity services for children and young people: Final report,'' (2024), *https://cass.independent-review.uk/home/publications/final-report/*.

[43] ''Care of children and adolescents with gender dysphoria-summary of national guidelines,'' The Swedish National Board of Health and Welfare (Socialstyrelsen), December 2022, *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf*. See also the Swedish National Board of Health and Welfare (Socialstyrelsen), ''Care of children and young people with gender Dysphoria—national knowledge support with recommendations for the profession and decision makers,'' (2022), *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf*.

[44] Council for Choices in Healthcare in Finland, ''Summary of a recommendation by COHERE Finland,'' June 16, 2020, *https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474*.

[45] Nanna Ravnborg et al., ''Gender Incongruence in Danish Youth (GenDa): A Protocol for a Retrospective Cohort Study of Danish Children and Adolescents Referred to a National Gender Identity Service,'' *Journal of Clinical Medicine* 13 (2024), *https://doi.org/10.3390/jcm13226658*.

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increase in the number of referrals for these procedures and reports of regret or reversal of hormone-induced changes to the body led Denmark to take an approach that focuses on assessment and psychosocial support for minors, and postpones decisions on hormone therapy, including puberty blockers and cross-sex hormones, in circumstances ''when gender incongruence has been brief,'' such as ''when there are concerns about the stability of the experienced gender identity.''[46]

In Norway, the Norwegian Commission for the Investigation of Health Care Services (UKOM), an independent State-owned agency, made recommendations in 2023 on the treatment offered to children and young people with gender incongruence.[47] The recommendations consisted of: defining puberty blockers and surgical treatment for children as experimental, revising national guidelines based on a systematic knowledge summary, and consideration for a national registry to improve quality and reduce variation in patient treatment. Norway's public health authority has signaled an intention to respond to UKOM's concerns by considering whether the current treatment guidelines need to be adjusted.[48]

Other countries which have restricted various approaches to treatment for minors (or have contemplated restrictions) include: New Zealand,[49] Italy,[50] Brazil,[51] and Australia.[52]

In sum, there is growing international concern about the use of hormonal and surgical interventions for pediatric gender dysphoria. We are aware that some medical associations have endorsed sex-rejecting procedures, but as the HHS Review makes clear, their endorsement is not based on sound principles of evidence-based medicine. In addition to other issues, we solicit comment of any published findings that measure the effects of similar restrictions as proposed on insurers, providers, and patients in these countries.

2. Medical Professional Societies Supporting Sex-Rejecting Procedures

We are aware that numerous organizations[53] (including the American Medical Association (AMA),[54] the American Academy of Pediatrics (AAP),[55] and the American Psychological Association[56][57]) have issued statements supporting access to sex-rejecting procedures, including for minors. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the U.S. are the WPATH and the ES clinical practice guidelines and the AAP guidance document. We reviewed each of these documents and agree with the conclusions of a recent systematic review of international guideline quality by researchers at the University of York (the York appraisal) that found all three documents as very low quality and should not be implemented.[58]

As the HHS Review notes regarding the role of medical organizations in the treatment of pediatric gender medicine:

U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition (PMT). This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.[59]

The Endocrine Society (ES) issued clinical practice guidelines in 2017 entitled ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.''[60] As the HHS Review notes:

In WPATH and ES guidelines, the principal goal of CSH administration [cross sex hormone] is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations. Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.[61]

The HHS Review states:

The ES 2017 guideline, which used the GRADE [Grading of Recommendations Assessment, Development and Evaluation] framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base. Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents. The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a ''satisfactory physical appearance'' while putting the lowest value on avoiding physical harms. The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower

[46] Ravnborg et al., ''Gender Incongruence in Danish Youth (GenDa).''

[47] Norwegian Healthcare Investigation Board (Ukom), ''Pasientsikkerhet for barn og unge med kjønnsinkongruens [Patient safety for children and adolescents with gender incongruence],'' March 2023, *https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag.*

[48] Jennifer Block, ''Norway's guidance on paediatric gender treatment is unsafe, says review,'' *BMJ* 380 (2023), doi:10.1136/bmj.p697.

[49] Eva Corlett, ''New Zealand bans puberty blockers for young transgender people,'' *The Guardian,* November 19, 2025, *https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.*

[50] Alvise Armellini, ''Italy moves to tighten controls on gender-affirming medical care for minors,'' *Reuters,* August 5, 2025, *https://www.reuters.com/business/healthcare-pharmaceuticals/italy-moves-tighten-controls-gender-affirming-medical-care-minors-2025-08-05/.*

[51] AFP, ''Brazil prohibits hormone therapy for transgender minors,'' *MSN News,* April 20, 2025, *https://www.msn.com/en-in/news/other/brazil-prohibits-hormone-therapyfor-transgender-minors/ar-AA1D66l7.*

[52] Australian Associated Press, ''Queensland halts prescription of puberty blockers and hormones for children with gender dysphoria,'' *The Guardian,* January 28, 2025, *https://www.theguardian.com/australia-news/2025/jan/28/queensland-halts-prescription-of-puberty-blockers-and-hormones-for-children-with-gender-dysphoria.*

[53] ''Medical Organization Statements,'' Advocates For Trans Equality's Trans Health Project, accessed November 20, 2025, *https://transhealthproject.org/resources/medical-organization-statements/.*

[54] ''Clarification of Evidence-Based Gender-Affirming Care H–185.927,'' American Medical Association, last modified 2024, *https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml.*

[55] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* January 6, 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[56] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' American Psychological Association, released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[57] ''Criminalizing Gender Affirmative Care with Minors,'' American Psychological Association, accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

[58] HHS Review, 141.

[59] HHS Review, 15.

[60] Wylie C. Hembree et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658.*

[61] HHS Review, 124.

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value on avoiding harm from potentially prolonged pubertal suppression.[62]

As explained in Chapter 9 of HHS Review, the guidelines issued by the World Professional Association for Transgender Health (WPATH) ''have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines.'' [63] As the HHS Review points out: ''Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH Standards of Care guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.'' [64] In 2022, WPATH issued guidelines entitled ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8'' (SOC–8).[65] These guidelines relaxed eligibility criteria for children to access sex-rejecting procedures, and ultimately recommend that adolescents wishing to undergo sex-rejecting procedures receive them. Besides the problems identified in systematic reviews of international guidelines, as the HHS Review states, ''in the process of developing SOC–8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC–8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.'' [66]

The HHS Review goes on to explain: ''The recommendations are couched in cautious-sounding language, stating that GD should be 'sustained over time,' particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase 'several years, leaving critical decisions open to broad and subjective interpretation.' '' [67]

Regarding the WPATH guidelines, the HHS review states:

On the surface, WPATH SOC–8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a ''comprehensive biopsychosocial assessment'' prior to initiating medical interventions in order ''to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care.'' At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases (ICD–11) diagnosis of ''Gender Incongruence of Adolescence and Adulthood,'' which, unlike the DSM–5 diagnosis of ''Gender Dysphoria,'' requires only ''marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' Because SOC–8 defines transgender in a similar way (''people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth'') and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC–8 effectively recognizes transgender identification as a medical condition justifying medical interventions.[68]

The HHS Review also argues: ''Although WPATH's guidelines do not necessarily discourage mental healthcare, they likewise do not require it as a precondition for PMT [pediatric medical transition]. Some guideline authors opposed even minimal requirements for mental health support, arguing that such provisions were analogous to ''conversion therapy.'' SOC–8's only formal recommendation is for a ''comprehensive biopsychosocial assessment,'' although WPATH emphasizes that its guideline is ''flexible,'' thereby leaving room for considerable variation in clinical practice.'' [69]

While AMA and the AAP have not issued their own treatment guidelines, they support the ES and WPATH guidelines, as discussed previously in this proposed rule. AAP issued a policy statement in 2018 supporting the use of puberty blockers, cross-sex hormones, and surgeries for minors.[70] In support of sex-rejecting surgeries, AAP stated that while ''current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.'' The AAP reaffirmed its policy statement in 2023, but also stated that it was conducting its own review of the evidence and guideline development—which still have not been released.[71] Regarding the AAP policy statement, the HHS Review states:

The AAP 2018 policy statement is not technically a CPG [clinical practice guideline] but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD. Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs [puberty blockers], CSH, and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7. As noted in Chapter 2, the AAP's policy statement's use of ''gender diverse'' casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.[72]

In addition to other issues, we solicit comment of any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients in international settings as well as the U.S.

C. United States' State Bans of and Coverage of Sex-Rejecting Procedures

State lawmakers have adopted policy positions reflecting the emerging evidence of sex-rejecting procedures administered to youth. There are 27 States and one Territory that have enacted laws restricting sex-rejecting procedures.[73] These include Alabama,

[62] HHS Review, 147.

[63] HHS Review, 157.

[64] HHS Review, 157.

[65] E. Coleman et al., ''Standards of Care.''

[66] HHS Review, 14.

[67] HHS Review, 165.

[68] HHS Review, 194–195.

[69] HHS Review, 196.

[70] Jason Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, ''Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents,'' *Pediatrics* 142, no. 4 (2018), *doi.org/10.1542/peds.2018-2162*.

[71] Alyson Sulaski Wyckoff, ''AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update,'' *AAP News,* August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy.*

[72] HHS Review, 148–149.

[73] See ''Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions,'' KFF,

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Arkansas, Arizona, Florida, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Carolina, New Hampshire,[74] North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. As of August 8, 2025, some of these States have ongoing litigation proceedings impacting whether the State laws are partially or fully enjoined by a court.

There are a mix of age ranges for these bans. Of the 28 States and Territories with enacted laws/policies (in effect or not), 25 States prohibit some sex-rejecting procedures to young people under the age of 18, two States prohibit them for those under the age of 19, and Puerto Rico prohibits them for those under the age of 21.

Of the 24 States and one Territory with restriction statutes in effect as of August 8, 2025, 21 States and one Territory prohibit *both* the prescribing of at least one type of sex-rejecting medication *and* surgeries.[75] No State bans only medications without also banning surgeries. However, all the States and the Territory with restrictions provide exceptions to the law/policies. The most common exceptions include procedures to treat:

- A medically verifiable disorder of sexual development. This allows treatment for children who are born with medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other medical factors that can be medically verified.
- Any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of gender transition procedures.
- A physical disorder, physical injury, or physical illness that would otherwise place the minor in danger of death or impairment of bodily function.

We note that 12 States provide tapering off periods for patients who started puberty blockers or hormones before enactment of the State restriction, with some specifying specific dates (for example, in South Carolina services cannot go beyond January 31, 2025) and others specifying a period of time from the time of enactment (ranging between 6 months and 1 year). Ten States have grandfather clauses primarily allowing minors who were already receiving treatment to continue receiving it indefinitely. However, we note that many of these States do not provide such exceptions or grandfather clauses for purposes of prohibitions on State funding, including for State funding under the Medicaid program and CHIP, for sex-rejecting procedures.

Conversely, 14 States and the District of Columbia have shield laws protecting some or all sex-rejecting procedures, and three States have executive orders (State EOs) protecting these procedures. These States are Arizona,[76] California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. Shield laws and State E.O.s often describe various types of sex-rejecting procedures broadly, including medications and surgeries, and include these under broader definitions of protected health care activities. These laws and State E.O.s generally attempt to shield providers and recipients (of all ages) against laws in other States that restrict these services. They also often protect providers from adverse action by medical malpractice insurers and licensure boards and allow for their address to remain confidential. One State, Maine, has a shield law specific to minors that allows minors 16 and over to receive hormone therapy when the guardian has refused sex-rejecting procedures. Four States explicitly provide child abuse and child custody protections for parents who supported their children in receiving sex-rejecting procedures. Four States have requirements for sex-rejecting procedures to be covered under health plans. Arizona requires coverage for State employee health plans. Illinois, Oregon, and Vermont require some level of coverage of sex-rejecting procedures by all health insurance providers. Vermont includes an exception for services that do not comply with Federal law.

Some States may experience negative financial impacts as a result of having built their Medicaid programs and CHIPs, including policies and operations, on the understanding that we would make Federal Medicaid and CHIP payments to States for services that this proposed rule would define as sex-rejecting procedures. We believe protecting children enrolled in Medicaid and CHIP from the harms of sex-rejecting procedures, including possible long-term and irreversible harms, outweighs the possible financial costs some States may experience if they begin to pay with State funds the full cost of sex-rejecting procedures for children enrolled in Medicaid and CHIP.

Providers in these States may be concerned that this proposed regulation would interfere with the physician-patient relationship. This proposed regulation would only prohibit Federal Medicaid and CHIP payment for certain services and does not require providers to communicate certain advice or information to patients. Federal Medicaid and CHIP payments will still be available for mental health counseling and psychotherapy for gender dysphoria. We believe a prohibition on Federal Medicaid and CHIP payments for sex-rejecting procedures is needed to avoid the possibility of minors receiving irreversible or risky pharmaceutical or surgical interventions, particularly in circumstances where the minor may be of an age to not have the capacity to understand the irreversible or long-term risks of these procedures or have the capacity to continue to communicate with providers their preferences regarding treatment after treatment has already begun.

Certain medical providers may also be relying on continued Federal funding for sex-rejecting procedures. These providers may face financial harm by the loss of the revenue from the proposed limitations on Federal payment for these procedures; however, these providers have other avenues to continue to receive compensation for providing medical care. Providers may continue to receive payment for pharmaceutical or surgical interventions for purposes of aligning a child's physical appearance or body with an asserted identity that differs from the child's sex from sources other than Medicaid or CHIP. Providers may also receive payment for these services when

last updated June 18, 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker;* ''Equality Maps: Bans on Best Practice Medical Care for Transgender Youth,'' Movement Advancement Project, accessed August 11, 2025, *https://www.lgbtmap.org/equality-maps/healthcare/youth_medical_care_bans.*

[74] New Hampshire's laws go into effect January 1, 2026 under NH HB712 and NH HB377.

[75] Arizona and New Hampshire currently do not prohibit sex-rejecting procedures using medications; however, New Hampshire has a new policy (NH HB377) taking effect January 1, 2026, that would restrict sex-rejecting procedures using medications for minors. Nebraska currently restricts, but does not fully ban, access to sex-rejecting procedures using medications, so it was not included in this count.

[76] Arizona banned pediatric sex-rejecting surgeries in 2022. However, in 2023 the governor issued an executive order which removes the exclusion of coverage for sex-rejecting surgery under the state's healthcare plan for state employees and prohibits investigative assistance to impose criminal or civil liability or professional sanctions on persons or entities for providing, assisting, seeking, or obtaining gender affirming care.

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providing these procedures for the exempted purposes as outlined in the proposed rule. Lastly, providers may be paid through Medicaid and CHIP for providing other types of care for individuals diagnosed with gender dysphoria, such as psychotherapy.

We also recognize that Medicaid and CHIP beneficiaries and their families would be impacted by this proposed rule. Families of these beneficiaries may look to obtain other health insurance or privately pay for these services. Medicaid and CHIP beneficiaries who are unable to find alternative means to pay for these services may either have to rely on other methods of intervention such as psychotherapy or mental health counseling, or never begin receiving these services because of this proposed rule, if finalized. We are concerned about the difficulties that these minors may experience and encourage other, less invasive, ways to support these individuals, such as encouraging psychotherapy as a first line of treatment.

This proposed rule would help to protect these children from the risks of adverse effects of sex-rejecting procedures. CMS carefully considered the scope of its limitation on Federal Medicaid and CHIP payments and permits coverage of other procedures, such as psychotherapy, which does not carry the same concerns of pharmaceutical or surgical interventions included in the definition of sex-rejecting procedures. Moreover, CMS does not believe Federal Medicaid and CHIP payment for these sex-rejecting procedures is consistent with quality of care given the state of the research into the effectiveness of these procedures for the purposes included in our proposed definition of this term, namely as treatments for gender dysphoria. In light of the HHS Review, CMS believes State reliance on certain medical organizations and the SOC–8 to justify covering sex-rejecting procedures is misplaced.

In addition to other issues, we solicit comment on any published studies or findings that measure the effects of similar restrictions as proposed (or laws protecting these procedures) on insurers, providers, and patients in these States.

Recently, the U.S. Supreme Court in United States v. Skrmetti, 605 U.S. 495 (2025), upheld Tennessee's law restricting certain surgical and chemical interventions for minors diagnosed with gender dysphoria (and similar conditions), referred to as Senate Bill 1 or ''SB1'' in litigation challenging that law under the Equal Protection Clause of the U.S. Constitution. SB1 prohibits a healthcare provider from performing medical procedures, including surgery, and prescribing puberty blockers, for a minor for the purpose of enabling the minor to identify with a purported identity inconsistent with the minor's sex. At the same time, SB1 allows healthcare providers to perform medical procedures for minors if the procedure is to treat a minor's congenital defect, precocious puberty, disease, or physical injury. On June 18, 2025, the Court found that SB1's prohibition of certain medical procedures for minors diagnosed with gender dysphoria incorporates classifications based on age and medical use—not the minor's sex. Because the classifications turned on age and medical use rather than sex, the Court held that SB1 was not subject to heightened scrutiny under the Equal Protection Clause of the Fourteenth Amendment and went on to find the law satisfied rational basis review. As discussed in more detail later in this proposed rule, like the law at issue in *Skrmetti,* this proposed rule would not discriminate on the basis of sex and it is not based on an invidious discriminatory purpose. The proposed rule is animated by significant child safety concerns when sex-rejecting procedures are used for certain medical uses–that is to align a child's physical appearance or body with an asserted identity that differs from the child's sex.

D. Psychotherapy as the First Line Treatment for Children Diagnosed With Gender Dysphoria

Since 2010, there has been a significant increase in mental health conditions among teens and young adults.[77] Current research has not revealed a simple explanation for this rise in the need for youth mental health services. The etiology of gender dysphoria remains understudied.[78] However, patients presenting to pediatric gender medicine clinics have a high rate of comorbid mental health conditions.[79]

We believe interested parties supporting the use of sex-rejecting procedures to treat gender dysphoria in children may state that limiting access to these treatments (which prohibiting Federal Medicaid and CHIP funding for them could do) will exacerbate these comorbidities and lead to adverse mental health outcomes and increase suicide risks. As noted previously, the Cass Review emphasized the lack of robust evidence regarding the effectiveness of interventions such as puberty blockers and cross-sex hormones to treat gender dysphoria and incongruence in children and adolescents.[80] Taylor et al. recently conducted a review of 23 international, national, and regional clinical guidelines that contained recommendations about the management of children/adolescents experiencing gender dysphoria. They found that the majority of these guidelines were developed without an independent or evidence-based approach and raised questions about the credibility of available guidance.[81] As Sweden's national health authority has recommended, ''[p]sychosocial support that helps adolescents deal with natal puberty without medication needs to be the first option when choosing care measures.'' [82]

While evidence on the benefits of medical and surgical interventions to improve mental health or reduce symptoms of gender dysphoria is lacking, psychotherapy has been proven to be an effective intervention for many of the neurodevelopmental disorders and mental health conditions that are highly prevalent in children and adolescents, including those frequently co-occurring in patients diagnosed with gender dysphoria.[83] Psychotherapy and mental health counseling are non-invasive interventions that would remain available to youth under Medicaid's mandatory Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions in section 1905(r) of the Act. EPSDT requires the provision of screening, vision, dental, and hearing services, and such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects and physical and mental illness and conditions discovered by the screening services, whether or not such services are covered under the State plan. Most children enrolled in Medicaid are entitled to coverage of robust and comprehensive psychotherapy services under EPSDT . We note that under a State's EPSDT program, States may only include tentative limits on services and must take into account the individual needs of the child. Thus, EPSDT is key

[77] Patrick McGorry et al., ''The Lancet Psychiatry Commission on youth mental health,'' Lancet Psychiatry 11, no. 9 (September 2024): 731–774, doi:10.1016/S2215–0366(24)00163–9.

[78] HHS Review, 257.

[79] HHS Review, 68.

[80] Cass, ''Cass Review.''

[81] Jo Taylor et al., ''Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),'' *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65-s72, doi:10.1136/archdischild–2023–326499.

[82] HHS Review, 256.

[83] HHS Review, 257–260.

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to ensuring that children receive appropriate mental health screenings and treatments. Furthermore, we have developed numerous resources to provide information regarding services and good practices for children and youth with mental health conditions.[84] While EPSDT is not a required CHIP benefit for States that have separate CHIPs, many States with such programs have opted to provide EPSDT services that mirror the Medicaid standards set out at section 1905(r) of the Act to children enrolled in CHIP. In addition, section 2103(c)(7) of the Act requires States to provide mental health services in CHIP that are applied in the same manner as required under section 2726(a) of the Public Health Service Act [([42 U.S.C. 300gg–26(a)])] for group health plans under such section.

E. States' Duty To Ensure Medicaid and CHIP Services for Children Are Consistent With Quality of Care and the Best Interests of Beneficiaries

Under section 1902(a)(19) of the Act, State Medicaid agencies are required to ensure that Medicaid-covered services are in the best interests of beneficiaries; as relevant to this proposed rule, children under age 18. Additionally, States are required, under section 1902(a)(30)(A) of the Act, to ensure that Medicaid payments for Medicaid covered services are consistent, in relevant part, with quality of care. Under section 2101(a) of the Act, CHIP programs are required to provide health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children, including State Medicaid programs. The research described previously in this proposed rule indicates that sex-rejecting procedures lack the necessary outcomes data to reasonably rely on for evidence of long-term effectiveness.

On April 11, 2025, we issued a letter to State Medicaid Directors to ensure Medicaid agencies were aware of growing utilization of certain interventions offered to children to treat gender dysphoria, and to remind States of their statutory responsibilities to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interests of recipients.[85] In the letter, we also stated that due to the underdeveloped body of evidence, the use of sex-rejecting procedures to treat gender dysphoria lacks reliable evidence of long-term benefits for minors and are now known to cause long-term and irreparable harm for some children.[86] A second letter, issued on May 28, 2025, was sent to a number of hospitals to address significant issues concerning quality standards and specific procedures affecting children diagnosed with gender dysphoria. The letter requested hospitals to provide information on their policies and procedures related to the adequacy of informed consent protocols for children diagnosed with gender dysphoria, including how children are deemed capable of making these potentially life changing decisions and when parental consent is required; changes to clinical practice guidelines and protocols that the institution plans to enact in light of the recent comprehensive review and guidance released by the Department; medical evidence and any adverse events related to these procedures, particularly children who later look to detransition; and complete financial data for all pediatric sex-rejecting procedures performed at the institution and paid, in whole or in part, by the Federal Government.[87]

As outlined previously in this proposed rule, we take very seriously the absence of rigorous scientific data demonstrating the effectiveness of sex-rejecting procedures and the considerable evidence regarding the risks. Given the potential risks and lack of clear benefits associated with sex-rejecting procedures, we believe that covering them with Federal Medicaid or CHIP funding would be, for Medicaid beneficiaries, inconsistent with their best interests and with quality of care; and, for CHIP beneficiaries, inconsistent with the provision of health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. In this section, we describe how this proposed rule would intersect with existing statutory and regulatory provisions.

1. Intersection With Nondiscrimination (Section 1557 of the Patient Protection and Affordable Care Act)

This proposed rule is not a form of sex discrimination in violation of section 1557 of the Patient Protection and Affordable Care Act (Affordable Care Act).[88] Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities, any part of which is receiving Federal financial assistance.

A Federal court recently considered the question of whether the prohibition on sex discrimination found in section 1557 of the Affordable Care Act includes discrimination on the basis of gender identity. On October 22, 2025, in *State of Tennessee et al* v. *Kennedy et al,*[89] the district court declared that ''HHS exceeded its statutory authority when (1) it interpreted Title IX, as incorporated into Section 1557, to prohibit discrimination on the basis of gender identity, and (2) when it implemented Section 1557 regulations concerning gender identity and 'gender affirming care.' '' Accordingly, the Court vacated the following regulations to the extent that they expand Title IX's definition of sex discrimination to include gender-identity discrimination: 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(b)(3), and 460.112(a), and 45 CFR 92.101(a)(2)(iv), 92.206(b)(1)–(4), § 92.207(b)(3) through(5), 92.8(b)(1), 92.10(a)(1)(i), and 92.208.[90]

[84] ''Children and Youth,'' Medicaid, accessed June 12, 2025, *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/children-and-youth.*

[85] CMS, ''Puberty Blockers, Cross-sex Hormones, and Surgery Related to Gender Dysphoria,'' April 11, 2025, *https://www.cms.gov/files/document/letter-stm.pdf.*

[86] CMS, ''Puberty Blockers.''

[87] Department of Health & Human Services, Centers for Medicare and Medicaid Services, Urgent Review of Quality Standards and Gender Transition Procedures, May 28, 2025, *www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.*

[88] The Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1049), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA''.

[89] *Tennessee* v. *Kennedy*, ---F. Supp. 3d---,1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025).

[90] As part of a 2024 rulemaking implementing section 1557 of the Affordable Care Act, HHS amended 42 CFR 440.262, 438.3(d) and 438.206(c)(2) to specifically include discrimination based on ''gender identity'' as a form of ''sex discrimination,'' and amended 42 CFR 457.495 to cross-reference amended 440.262. The amendments to sections 438.3(d) and 438.206(c)(2) also apply to CHIP managed care through cross references in §§ 457.1201(d) and 457.1230(a) that predated the section 1557 rulemaking. These amendments to the Medicaid and CHIP rules were based on sections 1902(a)(4), 1902(a)(19), and 2101(a) of the Act. See Nondiscrimination in Health Programs and Activities, 89 FR 37522 (May 6, 2024). In *Tennessee* v. *Kennedy*, ---F. Supp. 3d---, 1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025), the court vacated 42 CFR 440.262, 438.3(d)(4), and 438.206(c)(2) (among others) ''to the extent that they expand Title IX's definition of sex discrimination

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Notwithstanding the outcome of this litigation, the Court's holding in *Skrmetti,* as explained previously in this proposed rule and expounded upon below, supports our position that this proposed rule would not discriminate on the basis of sex. In 2023, Tennessee enacted a State law,[91] SB1, which, in relevant part, prohibits a healthcare provider from performing certain medical procedures, including surgery, and from prescribing puberty blockers, for a minor for the purpose of enabling the minor to identify with a purported identity inconsistent with the minor's sex.[92] SB1 does not prohibit healthcare providers from providing those procedures if done to treat a minor's congenital defect, precocious puberty, disease, or physical injury. The U.S. Supreme Court analyzed SB1 under the Equal Protection Clause of the Fourteenth Amendment and held that SB1 does not turn on sex-based classifications, noting ''the law does not prohibit conduct for one sex that it permits for the other.'' [93]

Like SB1, this proposed rule would apply uniformly to all children regardless of the child's sex. This proposed rule would treat all children the same when it would prohibit a State Medicaid or CHIP agency from covering, as part of its Federally funded Medicaid program and CHIP, the procedures that the proposed rule would define as sex-rejecting procedures. At the same time, this proposed rule would permit State Medicaid and CHIP agencies to continue to so cover procedures when the child has a medically verifiable disorder of sexual development, needs the procedure for a purpose other than attempting to align the child's physical appearance or body with an asserted identity that differs from the child's sex, or has complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Further, this proposed rule would be neither arbitrary nor based on an invidious discriminatory purpose. Rather, based on the review of current research and the reasoning for similar conclusions reached and actions taken by multiple European countries discussed previously in this proposed rule, we believe that Medicaid and CHIP coverage and payment of sex-rejecting procedures are not in the best interests of minors and not consistent with quality of care or the effective and efficient standard required under section 2101(a) of the Act. Therefore, we are proposing to prohibit Federal funding for these procedures in Medicaid and CHIP. This proposal is based on careful consideration of the facts as described in detail in section I.B. of this proposed rule and on our determination that the risks of sex-rejecting procedures for children outweigh the benefits. We continue to support Medicaid and CHIP coverage of services for children that research shows may be helpful for treating gender dysphoria in children without the risks of harm. Further, while State laws may differ, State Medicaid agencies are not currently specifically prohibited under Federal law from covering sex-rejecting procedures for Medicaid beneficiaries who are 18 years of age and older.

2. Intersection With Sufficiency of Amount, Duration, and Scope (§ 440.230(c))

This proposed rule would also be consistent with 42 CFR 440.230, which provides that a Medicaid State plan must specify the amount, duration, and scope of covered services. CMS has long afforded State Medicaid agencies considerable flexibility under § 440.230 to establish the amount, duration, and scope of covered Medicaid services, and to develop State-specific medical necessity criteria and utilization control procedures for covered services. State-specific limits on amount, duration, and scope are frequently applied based on an assessment of a beneficiary's specific circumstances, rather than being blanket limitations. In addition to specifying the amount, duration, and scope of covered services, historically, States have determined whether, and how, to cover services and we make Federal Medicaid payments to States if the services otherwise complied with Federal law and regulation. Within CHIP, under § 457.402(x), States have the ability to add coverage of additional services if recognized by State law.

Some States may be using the authorities under sections 1905 and 2110 of the Act, such as sections 1905(a)(6) and 2110(a)(24) of the Act,[94] to cover sex-rejecting procedures as services that are recognized under State law.

However, this flexibility under § 440.230 is not absolute. Section 440.230 requires State Medicaid agencies to comply with certain guidelines when determining the amount, duration, and scope of covered services. States must detail their proposed coverage of services in a State plan amendment and submit the State plan amendment to CMS for approval. We review the State plan amendment to ensure that States meet these guidelines. For example, under § 440.230(b), State Medicaid agencies must ensure that any covered service is sufficient in amount, duration, and scope to reasonably achieve its purpose. If a state limits the amount, duration or scope of a service without exception for medical necessity, the State must explain to us the reasoning and evidence to support the limitation prior to CMS approving the State's submission. Similarly in CHIP, the flexibility under § 457.402(x) is not absolute. Section 457.60 requires States to submit a State plan amendment when a State is making a change in policy or operation of the program that affects the benefits provided. Like in Medicaid, States must detail their proposed coverage of services in a State plan amendment and submit the State plan amendment to CMS for approval. We review the State plan amendment to ensure that States meet these guidelines.

For this proposed rule, we have considered the risk/benefit profile of sex-rejecting procedures for the purposes included in our proposed definition and the alternative treatments available, before determining that a national response prohibiting Federal Medicaid funding for sex-rejecting procedures for children under age 18 enrolled in Medicaid and under age 19 enrolled in CHIP is warranted. This prohibition includes circumstances in which a provider may determine that a sex-rejecting procedure is medically necessary for a child diagnosed with gender dysphoria.

to include gender identity discrimination'' and declared HHS had ''exceeded its statutory authority when (1) it interpreted Title IX, as incorporated into Section 1557, to prohibit discrimination on the basis of gender identity, and (2) when it implemented Section 1557 regulations concerning gender identity and 'gender affirming care.'" See also Texas v. Becerra, No. 6:24–CV–211–JDK (E.D. Tex. Aug. 30, 2024), in which the court entered a nationwide stay of certain regulations of the final rule, including 42 CFR 440.262, 438.3(d)(4), and 438.206(c)(2). Given *Skrmetti's* holding, we believe that the outcome of this litigation will not affect the proposed rule. As a result, CMS does not further discuss 42 CFR 440.262, 438.3, and 438.206 in this proposed rule.

[91] Tenn. Code Ann. § 68–33–101 *et seq.*

[92] As defined by SB1, ''minor'' means an individual under eighteen (18) years of age. Tenn. Code Ann. § 68–33–102.

[93] *United States* v. *Skrmetti,* 145 S. Ct. 1816 (2025).

[94] Section 1905(a)(6) of the Act states ''medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law'' and section 2110(a)(24) of the Act defines ''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 . . . (24) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services . . . if recognized by State law . . .''

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Lastly, this proposed rule is consistent with § 440.230(c), which prohibits State Medicaid agencies from arbitrarily denying or reducing the amount, duration, or scope of a covered service to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition. This proposed rule reflects the agency's efforts to address significant concerns about the risk/benefit profile of sex-rejecting procedures for the uses included in our proposed definition of that term, due to the safety concerns, risks of irreversible harm, long-term health outcomes, and unestablished effectiveness associated with those uses, as explained previously. This proposed rule takes into account the different risk/benefit profiles of different uses of these procedures, which is why it focuses on purposes that might be associated with a particular diagnosis, type of illness or condition. Our proposed definition of sex-rejecting procedures would exclude from the definition certain uses of these procedures for which the risk/benefit profile creates less significant concerns. Additionally, other treatments, such as mental health treatment, would remain Federally funded for children diagnosed with gender dysphoria.

As discussed previously in this proposed rule, we have considered the concerns of States, providers, and beneficiaries who have relied on CMS making Federal Medicaid and CHIP payment for these services. Notwithstanding the potential financial burden to States, providers, and individuals, and the psychological and physical impact on beneficiaries who wish to receive these services, a nationwide prohibition on Federal Medicaid and CHIP payments for these services is warranted. We believe that the concerns of States, providers and beneficiaries described previously in this proposed rule are outweighed by the potential harm of sex-rejecting procedures for minors, including potential long-term harm, especially when the possible benefits of these services are unproven and the procedures are irreversible. More data is needed on how the procedures that the proposed rule would define as sex-rejecting procedures in children under age 18 in Medicaid and under age 19 in CHIP affect the long-term health of such individuals, including any impact on fertility, and whether these procedures result in, or increase the risk of, sexual dysfunction, impaired boned density, adverse cognitive impacts and other health deviations, as mentioned previously.

3. Intersection With Early and Periodic Screening, Diagnostic and Treatment (EPSDT)

This proposed rule also would be consistent with States' obligations under the EPSDT requirement, even though it would limit States' longstanding flexibility to develop State-specific processes for determining when a service is medically necessary for an EPSDT-eligible beneficiary under section 1905(r)(5) of the Act. Under EPSDT, States must cover medically necessary services described in section 1905(a) of the Act for most Medicaid eligible children under the age of 21. Children eligible for EPSDT generally include beneficiaries under the age of 21 enrolled: in Medicaid through a categorically needy group; in Medicaid through a medically needy group in a State that has elected to include EPSDT in the medically needy benefit package; in a Medicaid-expansion CHIP program; or in a separate CHIP program that has elected to cover EPSDT. This includes beneficiaries with an institutional level of care who are eligible for Medicaid by virtue of their enrollment in a home and community-based services (HCBS) waiver under section 1915(c) of the Act. EPSDT is not available to beneficiaries without satisfactory immigration status who are eligible only for treatment of an emergency medical condition and other groups of individuals under age 21 who are eligible only for limited services as part of their Medicaid eligibility, such as, for example, family planning services.

Under this proposed rule, sex-rejecting procedures for the uses included in our proposed definition would no longer be Federally funded as Medicaid-covered services for individuals under the age of 18 or as CHIP-covered services for individuals under the age of 19, because such services may pose a risk of harm to children, including long-term irreversible harm, and result in adverse outcomes on their health including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, and psychiatric disorders. We are not endorsing or requiring any particular treatment modality for gender dysphoria.

In our prior EPSDT coverage guidance,[95] [96]we discuss how States should approach their determination of whether a service is medically necessary. In this prior guidance, we emphasize that States (or their delegated entity) must take into account the particular needs of the child. We explain that States should consider the child's long-term needs, not just what is required to address the immediate situation. The State should consider all aspects of a child's needs, including nutrition, social development, and mental health and substance use disorders. Accordingly, while sex-rejecting procedures have been covered by some State Medicaid programs to address gender dysphoria to alleviate its symptoms, these procedures can involve use of puberty suppressing drugs to prevent the onset of puberty and cross-sex hormones to spur the secondary sex characteristics of the opposite sex. For children under 18 (or under 19 in CHIP) who have undergone the suppression of puberty, these procedures may pose a significant risk of harm, including possible long-term harm to a child's health, including the risk of infertility and bone density loss, as discussed previously.

As discussed previously in this proposed rule, some State Medicaid programs and CHIPs have relied upon clinical guidelines that have failed to meet the principles of unbiased, evidence-driven clinical guideline development. As a result of this reliance, State Medicaid programs and CHIPs have developed coverage criteria which may not have considered the full effects of all aspects of a child's needs (including long-term needs) as required under EPSDT.

F. Prohibition on Federal Funding and Coverage in a Separate CHIP

Title XXI of the Act allows States to implement CHIP as a separate CHIP, a Medicaid-expansion program, or a combination of the two. Title XXI-funded Medicaid expansion programs generally follow Medicaid rules. This section relates to separate CHIPs.

States with separate CHIPs receive Federal funding from the title XXI allotment to provide child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act and regulations at § 457.402. Section 2101(a) of the Act calls for the provision of CHIP in a manner that is effective and efficient and coordinated with other sources of

[95] CMS, ''EPSDT–A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,'' June 2014, *https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf.*

[96] CMS, State Health Official Letter #24–005, ''Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements,'' September 26, 2024, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf.*

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health benefits coverage for children, notwithstanding section 2110(a)(24) of the Act that allows States to cover additional services that are recognized by State law. While CMS recognizes the considerable State flexibility provided to States under section 2110(a)(24) of the Act, CMS has concluded that it is in the best interest of children under age 19 enrolled in CHIP to no longer permit Federal funding for coverage of procedures when utilized for purposes of sex-rejecting procedures because such services may result in adverse outcomes on their health including infertility/sterility, sexual dysfunction, impaired bone density accrual, diverse cognitive, cardiovascular disease and metabolic disorders, and psychiatric disorders. Therefore, CMS has concluded it is most efficient and effective, and in the best interests of children, for CHIP to align and coordinate with the Medicaid program.

Section 2103 of the Act and § 457.410 allow States to choose any of the following four types of health benefits coverage for separate CHIPs: (1) Benchmark coverage in accordance with § 457.420; (2) Benchmark-equivalent coverage in accordance with § 457.430; (3) Existing comprehensive State-based coverage in accordance with § 457.440; and (4) Secretary-approved coverage in accordance with § 457.450. Regardless of the type of health coverage selected by a State, States are required to provide all services identified at § 457.410(b) to children enrolled in CHIP. In addition to these services, States have the flexibility to cover additional services at § 457.402, which lists the services included in ''child health assistance.'' In addition to the specified services, § 457.402(x) permits states to select additional services and treatments that it will cover. The majority of separate CHIP States have elected Secretary-approved coverage. Under Secretary-approved coverage at § 457.450, the Secretary currently has the discretion to determine whether the coverage provided by a State is appropriate coverage for the population of targeted low-income children covered under the program. Recently, there have also been changes to allowable procedures under the benchmark coverage options for CHIP under § 457.420 as described later in this proposed rule.

On June 20, 2025, we issued the ''Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability,'' final rule (90 FR 27074) (referred to hereafter as the ''2025 Marketplace final rule''), which prohibits issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to the essential health benefit (EHB) requirements—from providing coverage for ''specified sex-trait modification procedures'' as an EHB beginning with Plan Year 2026. This prohibition was proposed and finalized because section 1302(b)(2)(A) of the ACA requires that the scope of the EHB be equal to the scope of benefits provided under a typical employer plan, and coverage of such procedures is not typically included in employer-sponsored plans.[97] In addition, on January 31, 2025, the U.S. Office of Personnel Management issued letter 2025–01A, which prohibited coverage of certain surgeries and hormone treatments for covered individuals in Federal Employees Health Benefits (FEHB) and Postal Service Health Benefits (PSHB) Programs under age 19. That letter was amended by letter 2015–01B, issued on August 15, 2025, which eliminated the age limit and advised that for Plan Year 2026, chemical and surgical modification of an individual's sex traits through medical interventions (to include ''gender transition'' services) will no longer be covered under the FEHB or PSHB Programs. Specifically, it excludes hormone treatments that pertain to chemical and surgical modification of an individual's sex traits (including as part of ''gender transition'' services) and clarifies that carriers should not exclude coverage for entire classes of pharmaceuticals. For example, GnRH agonists may be prescribed during in vitro fertilization (IVF), for reduction of endometriosis or fibroids, and for cancer treatment or prostate cancer/tumor growth prevention.[98]

As previously noted, section 2101(a) of the Act provides 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. As outlined previously in this proposed rule, while the prohibitions on coverage are not identical, they will effectively result in prohibition of coverage of sex-rejecting procedures in both the FEHB Program and as an EHB beginning with Plan Year 2026. Therefore, we are proposing to add a new section § 457.476 to prohibit Federal financial participation for sex-rejecting procedures under CHIP, to align CHIP with Medicaid, the FEHB Program, and EHBs. Although title XXI of the Act does not apply EHB rules under a separate CHIP, the services which must be covered under title XXI also are EHBs. We note that similar to Medicaid, this proposed change in CHIP would not prohibit Federal payment for procedures undertaken to treat a child with a medically verifiable disorder of sexual development; for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

We also note that section 2107(e) of the Act applies numerous provisions in Medicaid in the same manner to title XXI as would be the case under this proposed rule.

We take very seriously the weak evidence base supporting the safety or effectiveness of sex-rejecting procedures in minors, and the plausible evidence of harm, for the purposes included in our proposed definition. Based on these factors, we propose to prohibit Federal CHIP funds for sex-rejecting procedures for the purposes included in our proposed definition. It is also important to reiterate that these regulatory changes would not prohibit the use of Federal CHIP dollars for mental health treatments for conditions such as gender dysphoria.

II. Provisions of the Proposed Regulations

A. General Discussion

We propose to exercise our separate authorities under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to add a new subpart N to part 441 to prohibit Federal Financial Participation (FFP) in Medicaid for sex-rejecting procedures for the purposes included in our proposed definition for individuals under the age of 18, as this is the age of majority in most States. For CHIP, we

[97] Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 FR 27152 (June 25, 2025). While portions of the ''Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability,'' final rule (90 FR 27074), have been challenged, the requirement that issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to the essential health benefit (EHB) requirements—cannot provide coverage for ''specified sex-trait modifications'' as an EHB will begin with Plan Year 2026.

[98] U.S. Office of Personnel Management (OPM) FEHB Program Carrier Letter, Letter Number 2025–01A, ''Addendum to Call Letter for Plan Year 2026,'' January 31, 2025, *https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-1a.pdf.* Amended by OPM FEHB Programs Carrier Letter, Letter Number 2025–01B, ''Subject: Chemical and Surgical Sex-Trait Modification Services for Plan Year 2026 Proposals,'' August 15, 2025, *https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-01b.pdf.*

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propose to exercise our authority under section 2103(c) of the Act to revise subpart D of 42 CFR part 457 to prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures for the purposes included in our proposed definition for individuals under the age of 19, as this age aligns with the statutory definition of ''child'' at 2110(c)(1) of the Act. While this proposal aligns with section 5(a) of E.O. 14187, we are also proposing this change based on current evidence, which does not conclusively support the use of sex-rejecting procedures to treat gender dysphoria in children. It is important to emphasize that these proposed regulatory changes would not prohibit the use of Federal Medicaid or CHIP dollars for mental health treatments for conditions such as gender dysphoria. Nor would these proposed changes prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP. We note that this proposed rule also does not prohibit Federal reimbursement of procedures undertaken (i) to treat a child with a medically verifiable disorder of sexual development; (ii) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (iii) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

B. Prohibition on Medicaid Payment for Sex-Rejecting Procedures (§ 441.800)

We propose to add a new subpart N to 42 CFR part 441 to protect Medicaid beneficiaries and ensure Medicaid payments are consistent with quality of care by prohibiting Federal Medicaid payments to States for sex-rejecting procedures provided to children under the age of 18. The basis and purpose of proposed subpart N (as described previously in this proposed rule) is reflected in proposed § 441.800.

Within new subpart N, we propose at § 441.802(a) that State Medicaid plans must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18. Per 42 CFR 430.10, the State plan is the vehicle through which States assure that their Medicaid programs will be administered in conformity with title XIX of the Act (including sections 1902(a)(19) and 1902(a)(30)(A) of the Act) and CMS' implementing regulations, and the State plan must also contain all information necessary for CMS to determine whether the plan can serve as a basis for FFP. Proposed § 441.802(a) would not preclude States from covering sex-rejecting procedures with State-only funding outside of their Federally-matched Medicaid programs. We propose at § 441.802(b) that FFP would not be available in State expenditures for sex-rejecting procedures for children under the age of 18.

Proposed § 441.801 would define sex-rejecting procedures as any pharmaceutical or surgical intervention that attempts to align a child's physical appearance or body with an asserted identity that differs from the child's sex either by: (1) intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or (2) intentionally altering a child's physical appearance or body, including amputating, minimizing, or destroying primary or secondary sex-based traits such as the sexual and reproductive organs. However, our proposed definition also provides that the term sex-rejecting procedures would not include procedures undertaken: (i) to treat a child with a medically verifiable disorder of sexual development; (ii) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (iii) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Given States' obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to assure care and services are provided consistent with the best interests of Medicaid recipients and that payments are consistent with quality of care, respectively, we believe that our proposed prohibition of FFP in State expenditures for sex-rejecting procedures for children under age 18 is necessary given the lack of an adequate evidence base for the effectiveness of these treatments for the purposes that would be included in our proposed definition and the significant potential for negative and irreversible side effects.

We note that CMS has imposed age limitations on the availability of Federal funding for certain procedures in the Medicaid program before. CMS has long prohibited, at § 441.253, Federal funding for permanent sterilizations furnished to individuals under age 21, motivated by concerns about potential coercion, informed consent, and patient regret that were based on data specifically related to permanent sterilizations (see preamble discussion at 43 FR 52146, 52151 through 52153). In this context, our concerns about the effectiveness of sex-rejecting procedures and the plausible evidence of harm motivate our proposal to prohibit Federal funding for sex-rejecting procedures for children under the age of 18. Specifically, this proposed rule recognizes that the more cautious approach of psychosocial support to treat individuals diagnosed with gender dysphoria prior to age 18—the legal age of majority in nearly all U.S. States and Territories [99] [100]—better protects children and youth from adverse effects of any such procedures.

Three states have a different, higher age of majority. Alabama and Nebraska's age of majority is 19 and Mississippi has the highest age of majority at 21.[101] This rule would not conflict with the age of majority in Alabama, Nebraska and Mississippi because these States recognize higher ages of majority than this proposed rule. Under this proposed rule, sex-rejecting procedures would be available for Medicaid coverage at age 18, which is a lower age than the age of majority in these States. Additionally, nothing in this proposed rule preempts State authority to regulate the age of majority in their State, nor does it interfere with a State's ability to fund these services with State-only funds. Further, it is clear that in making policy choices for the administration of a Federal program, State law is not controlling. This proposed rule would make age 18 the floor of Federal coverage for sex-rejecting procedures under the Medicaid program, should a State include such procedures in their program.

We originally considered establishing the prohibition on Federal reimbursement of sex-rejecting procedures to individuals under age 19 as we are now proposing for CHIP.

[99] CMS is aware that 3 States—Alabama, Nebraska, and Mississippi—recognize higher ages as the age of majority. See ''Age of Majority by State 2025,'' World Population Review, accessed August 11, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.* CMS is proposing to prohibit FFP in State expenditures within the Medicaid program for sex-rejecting procedures for children under the age of 18 to correspond to the legal age of majority used by the overwhelming majority of States and Territories. Because section 2110(c)(1) of the Act defines ''child'' for purposes of CHIP as an individual under age 19, CMS is proposing to prohibit FFP in State expenditures within CHIP for sex-rejecting procedures for children under age 19.

[100] ''Age of Majority by State 2025,'' World Population Review, accessed September 9, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.*

[101] ''Age of Majority by State 2025,'' World Population Review, accessed September 9, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.*

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However, age 19 has no specific meaning for the Medicaid program and, as stated, is a year older than the legal age of majority in nearly all U.S. States and Territories. By comparison, this is not true under CHIP, as the statutory definition of a child in CHIP under section 2110(c)(1) of the Act is an individual under 19 years of age. In addition to other issues, we solicit comment on the operational feasibility of States in implementing the under age 18 prohibition in Medicaid and the under age 19 prohibition in CHIP.

As discussed previously, States have obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to ensure that Medicaid-covered care and services are provided in a manner consistent with the best interests of beneficiaries and to assure that payments for Medicaid-covered care and services are consistent with quality of care. For the reasons discussed in this proposed rule, CMS believes prohibiting Federal Medicaid funding for sex-rejecting procedures for children under the age of 18 is warranted to help ensure that States meet these statutory obligations.

We believe that the proposed definition of sex-rejecting procedures provides an appropriate degree of clarity and certainty regarding which sex-rejecting procedures would and would not be subject to the prohibitions at proposed § 441.802. We believe the proposed definition is narrowly tailored and appropriate to exclude only treatments CMS has determined to lack sufficient evidence of safety for their intended purposes. Examples such as procedures to treat precocious puberty, therapy subsequent to a traumatic injury, or the use of hormone replacement therapy to treat a growth hormone deficiency would not fall under the proposed definition of sex-rejecting procedures, and Federal Medicaid payment for such procedures would therefore not be prohibited for individuals under the age of 18, when medically necessary. As the HHS Review explains, central precocious puberty and gender dysphoria are distinct clinical entities. In addition, because the proposed definition is narrowly tailored in this way, we believe that States will be able to administer Medicaid coverage for drugs in a manner that is consistent with both the proposed rule and the requirements in section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, if manufacturers enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act, payment is available for the CODs covered under that NDRA for medically accepted indications.[102] As defined in section 1927(k)(6) of the Act, ''medically accepted indications'' mean use for a COD approved under the Federal Food, Drug, and Cosmetic Act or approved for inclusion in any of the compendia described in subsection 1927(g)(1)(B)(i) of the Act. 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. In addition, we note that this proposed rule only applies to pharmaceuticals that are used in the proposed definition and would not apply to other pharmaceuticals that are prescribed to a child.

As noted previously, the proposed definition of sex-rejecting procedures categorically would exclude procedures undertaken (1) to treat a child with a medically verifiable disorder of sexual development; (2) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (3) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s). We reiterate that these proposed regulatory changes would not prohibit the use of Federal Medicaid dollars for mental health treatments for conditions such as gender dysphoria.

In addition, to further explain the meaning of terms used in the proposed sex-rejecting procedures definition, we also propose definitions at new § 441.801 that would apply to subpart N of part 441. We propose to define FFP for purposes of subpart N of part 441 as Federal financial participation, recognizing the longstanding term used in the Medicaid program to describe the Federal Government's matching arrangement with States and Territories. We also propose to define ''female'' as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We propose to define ''male'' as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. We propose to define ''sex'' as a person's immutable biological classification as either male or female.

A landmark study of and model for anisogamy established that differences in gamete size, and the associated differences in gamete production time, lead to stable sexual dimorphism and the establishment of two biological sexes: ovum producers (females) and sperm producers (males).[103] Additionally, more recent literature acknowledges differences in sex roles but maintains that such differences can still be traced to the concept of anisogamy and the resultant sexual dimorphism that remain the root cause of sex specific selection, the sex roles, and the determination of biological sex.[104] We believe our proposed definitions of female, male, and sex are appropriately rooted in this concept and biological reality. In addition to other issues, we solicit comments on whether these proposed definitions of ''sex'', ''male'', and ''female'' could pose challenges to States in operationalizing this proposed prohibition on Federal reimbursement of sex-rejecting procedures or other aspects of the Medicaid program or CHIP.

Given the weak evidence base underlying sex-rejecting procedures for children and the potential risk of harm, including long-term harm, we believe this proposed rule appropriately implements the directives to States under sections 1902(a)(19) and 1902(a)(30)(A) of the Act that care and treatment provided under Medicaid must be in the best interests of recipients, and that payment for services must be consistent with quality of care.

C. Prohibition on CHIP Payment for Sex-Rejecting Procedures

We propose to revise subpart D in 42 CFR part 457 to prohibit Federal CHIP payments to States for sex-rejecting procedures provided to children. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with section 2101(a) of the Act by prohibiting Federal financial participation in payments by

[102] The NDRA does not have a specific OMB number, however the OMB package that contains all of the information a manufacturer has to report once entering into an NDRA is included in CMS 367a–367e.

[103] G.A. Parker et al., ''The origin and evolution of gamete dimorphism and the male-female phenomenon,'' *Journal of Theoretical Biology* 36, no. 3 (1972): 529–553, *https://doi.org/10.1016/0022-5193(72)90007-0.*

[104] Lukas Schärer et al., ''Anisogamy, chance and the evolution of sex roles,'' *Trends in Ecology & Evolution* 27, no. 5 (2012): 260–264, *https://doi.org/10.1016/j.tree.2011.12.006.*

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States for sex-rejecting procedures for a child under the age of 19. This would create consistency between CHIP coverage and Medicaid.

The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. The definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

We believe that our proposed prohibition of Federal CHIP payment for sex-rejecting procedures is necessary given the need to align CHIP coverage with coverage of these services in Medicaid, the lack of scientific evidence regarding the effectiveness of these treatments, and the significant potential for negative and often irreversible side effects when used for the purposes included in our proposed definition in children.

For each of these provisions outlined previously in this proposed rule, we anticipate stopping the Federal reimbursement of sex-rejecting procedures immediately upon the effective date of the rule finalizing these provisions, for both Medicaid and CHIP.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule (CMS–2451–F, RIN 0938–AV73), if this proposed rule is finalized.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Statistics for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialist	13–1000	43.76	43.76	87.52
General and Operations Manager	11–1021	64.00	64.00	128.00

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Definitions (§ 441.801)

We anticipate that the proposed definitions (adding and defining ''female'', ''male'', ''sex'', and ''sex-rejecting procedure'') may result in the need for some States to amend existing policy/manual documents where those items are inconsistent with the parameters of this proposed rule. However, we do not anticipate that this would impact any active claims/billing forms or their instructions.

We estimate a potential of 56 Medicaid respondents and 56 CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. Based on research discussed in section I.1.C. (United States' State Bans of and Coverage of Sex-Rejecting Procedures) of this proposed rule, approximately 27 States and one Territory have laws enacted restricting some or all of the *sex*-rejecting *procedures* that would be covered by this proposed rule. For these States and Territories, we do not anticipate State staff will need to conduct a review of policy documents for Medicaid or CHIP as these procedures are currently banned (or will be banned).

For the remainder of States and Territories, we assume that State staff will conduct a review for both Medicaid policy documents and CHIP policy documents. As a result, we estimate 28 States and Territories that would need to amend their existing policy documents consistent with these definitions. We estimate it will take 3 hours at $87.52/hr for a Business Operations Specialist to review existing State policy documents to ensure consistency with the proposed definitions and 1 hour at $128.00/hr for a General and Operations Manager to review and approve the necessary State policy document changes.

In aggregate we estimate a one-time State burden of 112 hours (28 States × 4 hr/response) at a cost of $10,936 [(3 hr × $87.52/hr × 28 States) + (1 hr × $128.00/hr × 28 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of $5,468 ($10,936 * 0.5). We assumed all services meeting the proposed definition would no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

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2. ICRs Regarding the Prohibition on Payment for Sex-Rejecting Procedures (§ 441.802)

If this proposed rule is finalized, the following changes and associated SPA template will be made available for public review/comment under control number CMS–10398 #97, OMB 0938–1148) via the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, the following scores the potential impact for preparing and submitting the SPA. We will revisit these preliminary estimates during the standard PRA process and revise if needed.

Under the proposed provision, States and Territories would be required to submit SPAs specifically indicating adherence to the prohibition on claiming Federal funding of sex-rejecting procedures for individuals under the age of 18 for Medicaid and for individuals under the age of 19 for CHIP. The content of the SPA would be a simple recitation of the prohibition. As indicated above, the template will be made available for public review and comment if this proposed rule is finalized. We intend to require all States and Territories to submit this template for approval as part of their State plan.

We estimate a potential of 56 Medicaid and CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. We estimate it will take 2 hours at $87.52/hr for a Business Operations Specialist to prepare an initial SPA and 1 hour at $128.00/hr for a General and Operations Manager to review and approve the SPA for submission to CMS.

In aggregate, we estimate a one-time State burden of 168 hours (56 States × 3 hr/response) at a cost of $16,970 [(2 hr × $87.52/hr × 56 States) + (1 hr × $128.00/hr × 56 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of $8,485 ($16,970 * 0.5). We assumed all services meeting the proposed definition would no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

C. Summary of Proposed Requirements and Burden Estimates

TABLE 2—PROPOSED REQUIREMENTS/BURDEN ESTIMATES

Regulation section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Respondents	Responses (per State)	Total responses	Time per response (hr)	Total time (hr)	Labor costs ($/hr)	Total cost ($)	State cost ($)
§ 441.801	N/A	28 States and Territories	1	28	4	112	Varies	10,936	5,468
§ 441.802	CMS–10398 #97, OMB 0938–1148.	56 States and Territories	1	56	3	168	Varies	16,970	8,485
Total		56	2	84	Varies	280	Varies	27,906	13,953

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the proposed rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the proposed rule (CMS–2451–P, RIN 0938–AV73), the ICR's CFR citation, and the OMB control number.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Statement of Need

Throughout the U.S., thousands of children are receiving sex-rejecting procedures for the purpose of attempting to align their bodies with an asserted identity that differs from their sex. As outlined in this proposed rule, however, the current medical evidence does not support conclusively these interventions and indicates that they might lack clear benefits while posing a health and safety risk to children. To help ensure that Medicaid services are provided in a manner consistent with the best interests of the recipients and that Medicaid payments are consistent with quality of care, we are proposing a prohibition on State Medicaid Agencies from providing payment under the plan for sex-rejecting procedures for children under the age of 18 and proposing a prohibition on State CHIPs from providing payment under the plan for sex-rejecting procedures for children under the age of 19.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan

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programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Impacts on Federal Expenditures and Other Transfers

We estimate that this proposal would reduce Federal Medicaid spending by about $188 million from fiscal year 2027 through fiscal year 2036 (in real 2027 dollars). To estimate the impact of this proposal, we analyzed data from T–MSIS TAF v8.0 for 2023. We selected all claims with a gender dysphoria diagnosis and in the following claims categories: inpatient hospital with surgical procedure; outpatient hospital with surgical procedure; and professional services and prescription drugs with hormone therapy. We included fee-for-service and managed care encounter data. We also analyzed this data by beneficiary age group and counted only spending for individuals ages 17 and younger. We note that the proposed policy would not prohibit payment by a State Medicaid agency for these services for those age 18, and those individuals and costs are not included as part of the estimates. This data also includes CHIP expenditures for these services.

For 2023, we identified about $31 million in total computable Medicaid and CHIP spending for these services and individuals. States that had not banned gender dysphoria treatments for children as of 2023 accounted for 76 percent of spending, including 92 percent of inpatient treatment with surgery and 87 percent of outpatient treatment with surgery.

TABLE 3—MEDICAID EXPENDITURES ON GENDER DYSPHORIA TREATMENT BY CATEGORY OF SERVICE AND AGE GROUP, 2023

	Age 6–12	Age 13–14	Age 15–18	Total
Inpatient hospital with surgery	$0	$0	$180,553	$180,553
Outpatient hospital with surgery	15,526	23,534	2,145,082	2,184,142
Professional services hormone therapy	482,924	1,180,610	3,089,948	4,753,482
Prescription drug hormone therapy	2,566,749	6,130,955	14,779,884	23,477,588
Total	3,065,198	7,335,099	20,195,468	30,595,765

Source: Analysis of T–MSIS TAF v8.0.
Note: The T–MSIS data includes enrollment and spending by age groups, which includes ages 15–18 as one group. The policy in this proposed rule would only affect Medicaid enrollees under age 18 (ages 15–17), but the table above includes spending for individuals age 18. We note that we have adjusted for this when developing the estimates in the RIA.

We projected this spending forward from 2023 through 2035 using projected growth in Medicaid and CHIP spending on children from the Mid-Session Review of the President's fiscal year 2026 Budget. We assumed all services would no longer be covered by Medicaid or CHIP, and thus not eligible for Federal matching funds. We solicit comment on whether states that currently cover services would continue to cover these services absent FFP as described in this proposed rulemaking.

States that currently cover these services under Medicaid would see the largest reductions in Medicaid spending. We also assumed about 3 percent of spending would be delayed until individuals reach age 18, reflecting 50 percent of the surgical procedures being paid by Medicaid and CHIP in the future. Absent data or analysis on the impact of prohibitions on these procedures, we assumed some individuals would ultimately receive these services once eligible and believe 50 percent is reasonable (considering that some individuals would no longer be eligible for Medicaid in the future and some individuals may find other sources of coverage).

Table 4 shows the annual impact of the proposal on total and Federal Medicaid and CHIP spending in millions of dollars. These estimates assume the policies in the proposed rule would be effective as of October 1, 2026. Total Medicaid and CHIP spending would be reduced by $318 million over 10 years, Federal spending would be reduced by $188 million, and State spending would be reduced by $130 million (in real 2027 dollars). Actual impacts may vary from these estimates. We have relied on the most recently available program data for this analysis and projections of future enrollment and spending. Actual future costs may vary if enrollment and spending are higher or lower than projected.

TABLE 4—PROJECTED IMPACTS OF PROHIBITING COVERAGE OF SEX-REJECTING PROCEDURES FOR INDIVIDUALS UNDER 18 ON MEDICAID SPENDING

[In millions of real 2027 dollars]

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027–2036
Total	−30	−30	−30	−31	−32	−32	−32	−33	−34	−34	−318
Federal	−18	−18	−18	−18	−19	−19	−19	−19	−20	−20	−188
State	−12	−12	−12	−13	−13	−13	−13	−14	−14	−14	−130

We have made reasonable assumptions about how individuals may use these services in the future. A greater or lesser number of individuals may still receive coverage for these services upon reaching age 18 than we have assumed. In addition, it is possible some individuals may find alternative coverage for these services (for example,

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States covering services without Federal funding, or private insurance). We have also not estimated if there would be any other impacts on Federal expenditures (for example, increases in other healthcare services related to gender dysphoria).

2. Costs

In addition, the proposed rule may result in several costs. States would need to update State plans or waivers to comply with the proposed changes to covered benefits. Those impacts are described in section III. of this proposed rule. In addition, the changes in this proposed rule may prevent or delay individuals from receiving these healthcare services.

3. Alternatives

As an alternative to this proposed rule, we considered taking no action to require that a State Medicaid or CHIP plan must provide that the Medicaid or CHIP agency will not make payment under the plan for sex-rejecting procedures for children in Medicaid under the age of 18 and children in CHIP under the age of 19 and to prohibit the use of Federal Medicaid or CHIP dollars to fund sex-rejecting procedures for these individuals. On January 28, 2025, President Trump issued E.O. 14187, Protecting Children from Chemical and Surgical Mutilation. Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children including regulatory and sub-regulatory actions for specific programs, including Medicaid. In alignment with the Executive Order and the evidence outlined in section I.B. of this proposed rule, CMS decided to pursue this proposed policy. These proposed changes would not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

D. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant economic impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all hospitals and other healthcare providers are small entities as that term is used in the RFA (including small businesses, small nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other healthcare providers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, approximately 96 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards. According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards,* the health care industries impacted fall in the North American Industrial Classification System (NAICS) 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; and 622110 General Medical and Surgical Hospitals. Table 5 shows the industry size standards for each of these health care industries.

TABLE 5—HEALTH CARE INDUSTRY SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/ small entity threshold (million)	Total small businesses
446110	Pharmacies and Drug Stores	$37.5	18,461
621111	Offices of Physicians (except Mental Health Specialists)	16.0	129,117
621112	Offices of Physicians, Mental Health Specialists	13.5	12,325
621493	Freestanding Ambulatory Surgical and Emergency Centers	19.0	5,569
621498	All Other Outpatient Care Centers	25.5	9,801
622110	General Medical and Surgical Hospitals	47.0	1,169

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html*.

Tables 6 through 11 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These tables aim to provide an understanding of the disproportionate impacts among firms, between small and large firms.

TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES

[$37.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	18,461	100	$3,930,615.08
<$100K	560	3	50,953.57
$100K–$499K	1,733	9	292,525.68
$500–$999K	1,764	10	753,448.41
$1M–$2.499M	4,810	26	1,760,637.01
$2.5M–$4.999M	5,159	28	3,606,681.53
$5M–$7.499M	2,137	12	6,079,067.38
$7.5M–$9.999M	869	5	8,624,350.98
$10M–$14.999M	762	4	11,934,971.13
$15M–$19.999M	318	2	16,805,396.23
$20M–$24.999M	146	1	21,375,342.47
$25M–$29.999M	98	1	26,077,561.22
$30M–$34.999M	64	0	27,529,546.88
$35M–$39.999M	41	0	30,746,414.63

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TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES—Continued

[$37.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
LARGE FIRMS			
Receipts>$40M	396	N/A	672,827,431.82

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 7—NAICS 621111 OFFICES OF PHYSICIANS (EXCEPT MENTAL HEALTH SPECIALISTS)

[$16.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	129,117	100	$1,463,302.41
<$100K	11,119	9	51,195.79
$100K–$499K	44,138	34	296,376.77
$500–$999K	30,224	23	712,231.21
$1M–$2.499M	24,522	19	1,559,970.11
$2.5M–$4.999M	10,388	8	3,475,423.18
$5M–$7.499M	3,799	3	6,048,868.65
$7.5M–$9.999M	1,945	2	8,498,150.64
$10M–$14.999M	2,003	2	11,844,361.46
$15M–19.999M	979	1	16,517,796.73
LARGE FIRMS			
Receipts >$20M	3,782	N/A	116,848,659.18

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 8—NAICS 621112 OFFICES OF PHYSICIANS, MENTAL HEALTH SPECIALISTS

[$13.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	12,325	100	$634,311.40
<$100K	2,125	17	52,448.00
$100K–$499K	6,341	51	261,018.29
$500–$999K	2,092	17	686,686.90
$1M–$2.499M	1,206	10	1,496,716.42
$2.5M–$4.999M	338	3	3,331,017.75
$5M–$7.499M	111	1	5,735,522.52
$7.5M–$9.999M	52	0	8,039,461.54
$10M–$14.999M	60	0	10,485,850.00
LARGE FIRMS			
Receipts >$15M	212	N/A	14,421,103.77

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 9—NAICS 621493 FREESTANDING AMBULATORY SURGICAL AND EMERGENCY CENTERS

[$19.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	5,569	100	$2,713,466.15
<$100K	353	6	48,246.46
$100K–$499K	1,249	22	287,140.11
$500–$999K	867	16	724,727.80
$1M–$2.499M	1,265	23	1,648,132.81
$2.5M–$4.999M	845	15	3,602,647.34
$5M–$7.499M	413	7	5,999,140.44
$7.5M–$9.999M	223	4	8,392,170.40
$10M–$14.999M	241	4	11,472,634.85
$15M–19.999M	113	2	16,496,955.75
LARGE FIRMS			
Receipts >$20M	610	N/A	46,366,978.69

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

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TABLE 10—NAICS 621498 ALL OTHER OUTPATIENT CARE CENTERS

[$25.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	9,801	100	$2,124,005.00
<$100K	1,079	11	48,916.59
$100K–$499K	2,925	30	283,037.26
$500–$999K	1,832	19	719,524.02
$1M–$2.499M	1,990	20	1,545,938.69
$2.5M–$4.999M	790	8	3,409,083.54
$5M–$7.499M	289	3	5,739,238.75
$7.5M–$9.999M	193	2	7,644,943.01
$10M–$14.999M	292	3	10,567,616.44
$15M–$19.999M	184	2	13,609,652.17
$20M–$24.999M	137	1	16,169,890.51
$25M–$29.999M	90	1	21,218,188.89
LARGE FIRMS	.....	.....	.....
Receipts >$30M	1,008	N/A	55,938,203.37

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 11—NAICS 622110 GENERAL MEDICAL AND SURGICAL HOSPITALS

[$47.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	1,169	100	$17,598,603.93
<$100K	59	5	49,491.53
$100K–$499K	150	13	270,466.67
$500–$999K	54	5	696,814.81
$1M–$2.499M	28	2	1,522,000.00
$2.5M–$4.999M	28	2	3,739,428.57
$5M–$7.499M	35	3	6,512,657.14
$7.5M–$9.999M	51	4	8,550,588.24
$10M–$14.999M	124	11	11,777,798.39
$15M–$19.999M	132	11	16,993,166.67
$20M–$24.999M	121	10	22,389,727.27
$25M–$29.999M	100	9	26,686,900.00
$30M–$34.999M	99	8	31,329,858.59
$35M–$39.999M	66	6	35,617,636.36
$40M–44.999M	122	10	42,184,385.25
$45M–$49.999M	1,169	5	17,598,603.93
LARGE FIRMS	.....	.....	.....
Receipts >$50M	1,404	N/A	884,790,689.46

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

Individuals and States are not included in the definition of a small entity.

As shown in Table 12, all the industries combined, according to the 2022 Economic Census, earned approximately $2,364,153,884,000, while the small firms for all the industries combined earned approximately $325,819,624,000. Table 13 in section V.E. estimates a $31.6 million reduction in total annualized monetized transfers from the Federal Government and States to health care providers. This total estimated reduction represents less than 1 percent of the total revenues of the health care industries impacted and the total revenues of the small firms in the health care industries impacted. It also represents less than 1 percent of the total revenues of each health care industry impacted and the total revenues of the small firms in each health care industry impacted. As a result, this proposed rule if finalized would result in a change in revenue of less than 1 percent for the impacted health care industries.

TABLE 12—TOTAL REVENUES, ALL FIRMS AND SMALL FIRMS, BY NAICS CLASSIFICATION

NAICS	Total revenues (all firms)	Revenue test* (%)	Total revenues (small firms)	Revenue test* (%)
446110 Pharmacies and Drug Stores	$339,002,748,000.00	0.01	$72,563,085,000.00	0.04
621111 Offices of Physicians (except Mental Health Specialists)	630,858,846,000.00	0.00	188,937,217,000.00	0.02
621112 Offices of Physicians, Mental Health Specialists	10,875,162,000.00	0.29	7,817,888,000.00	0.40
621493 Freestanding Ambulatory Surgical and Emergency Centers	43,395,150,000.00	0.07	15,111,293,000.00	0.21
621498 All Other Outpatient Care Centers	77,203,082,000.00	0.04	20,817,373,000.00	0.15

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TABLE 12—TOTAL REVENUES, ALL FIRMS AND SMALL FIRMS, BY NAICS CLASSIFICATION—Continued

NAICS	Total revenues (all firms)	Revenue test* (%)	Total revenues (small firms)	Revenue test* (%)
622110 General Medical and Surgical Hospitals	1,262,818,896,000.00	0.00	20,572,768,000.00	0.15
Total	2,364,153,884,000.00	0.00	325,819,624,000.00	0.01

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html*.
*Calculated using an estimated reduction in total annualized monetized transfers of $31.6 million (as shown in Table 13) as a percentage of total revenues.

As its measure of significant economic impact on a substantial number of small entities,

HHS uses a change in revenue of more than 3 to 5 percent. According to Table 12, we do not believe that the 3 to 5 percent threshold will be reached by the proposed requirements in this rule for NAICS 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; or 622110 General Medical and Surgical Hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities in these industries.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. The proposed rule would not mandate significant spending costs on State, local, or Tribal governments in the aggregate, or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. This proposed rule will have a substantial direct effect on the ability of States to receive Federal Medicaid funds for sex-rejecting procedures furnished to children under age 18 and on the ability of States to receive Federal CHIP funds for sex-rejecting procedures furnished to children under age 19.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 13 showing the classification of the impact associated with the provisions of this proposed rule.[105]

TABLE 13—ACCOUNTING STATEMENT

Transfers	Estimate (million)	Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($/year)	$18.7	2027	7	2027–2036
	18.7	2027	3	2027–2036
Quantitative:				
• Estimated reduction in transfers from Federal Government to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				
Annualized Monetized ($/year)	12.9	2026	7	2027–2036
	12.9	2026	3	2027–2036
Quantitative:				
• Estimated reduction in transfers from States to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				

Table 13 shows the annualized monetized transfer values required under OMB Circular A–4. At a discount rate of 7 percent, the annualized monetized transfers are $18.7 million to the Federal government and $12.9 million to the States, reflecting a reduction in payment for these services to healthcare providers. At a discount rate of 3 percent, the annualized monetized transfers are also $18.7 million to the Federal government and $12.9 million to the States.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid

[105] The effects attributable to this proposed rule might be lower in magnitude than the aggregates presented here if other actions, such as the HHS/CMS proposal titled ''Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures on Children,'' are finalized before finalization of this proposal.

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Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

Grant programs—health, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 1. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Part 441 is amended by adding subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.
441.800 Basis and purpose.
441.801 Definitions.
441.802 General rules.

§ 441.800 Basis and purpose.

Basis and purpose. The purpose of this section is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

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

(1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat a child with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or.

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) A State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 457.476 is added to subpart D to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) Basis and purpose. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23464 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Medicare and Medicaid certified hospitals must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of children and reflect HHS' review of recent information on the safety and efficacy of sex-rejecting procedures (SRPs) on children. The revisions to the requirements would prohibit hospitals from performing sex-rejecting procedures on children.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3481–P.

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Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

Grant programs—health, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

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■ 1. The authority citation for part 441 continues to read as follows:

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■ 2. Part 441 is amended by adding subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.
441.800 Basis and purpose.
441.801 Definitions.
441.802 General rules.

§ 441.800 Basis and purpose.

Basis and purpose. The purpose of this section is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

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

(1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat a child with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or.

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) A State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 457.476 is added to subpart D to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) Basis and purpose. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Medicare and Medicaid certified hospitals must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of children and reflect HHS' review of recent information on the safety and efficacy of sex-rejecting procedures (SRPs) on children. The revisions to the requirements would prohibit hospitals from performing sex-rejecting procedures on children.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3481–P.

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Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3481–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3481–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: CMS Office of Communications, Department of Health and Human Services; email *press@cms.hhs.gov.*

For technical inquiries: CMS Center for Clinical Standards and Quality. Department of Health and Human Services. *HospitalSRPInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background

On January 28, 2025, President Trump signed Executive Order (E.O.) 14187 ''Protecting Children from Chemical and Surgical Mutilation.'' [1] In particular, Section 5(a) of the order directs the Secretary of HHS consistent with applicable law to ''take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and subregulatory actions, which may involve [. . .]: Medicare or Medicaid conditions of participation or conditions for coverage.'' CMS has developed this proposed rule in compliance with this E.O. As further discussed in this proposed rule, we describe CMS' statutory authority related to patient health and safety standards (known as Medicare ''Conditions of Participation'' (CoPs), ''Conditions for Coverage'' (CfCs), or simply ''Requirements''), summarize data on the rise of sex-rejecting procedures (SRPs) on children, review the latest information on SRPs in children as described in the HHS Review (the Review), provide an overview of State laws, as well as prior CMS actions on this topic. We propose to add a new section to 42 CFR part 482, subpart C that would prohibit Medicare-participating hospitals from performing sex-rejecting procedures (SRPs) on any child (§ 482.46(a)).

A. Statutory Authority

CMS has broad statutory authority under the Social Security Act (the Act) to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of children. Section 1861(e)(9) of the Act, applicable to hospitals that participate in the Medicare program, explicitly gives CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in a hospital, while section 1871 of the Act gives CMS the authority to prescribe regulations as necessary to carry out the administration of the program. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, entitled ''Conditions of Participation'' for Hospitals. Section 1905(a) of the statute provides that Medicaid payments from States may be applied to hospital services. Under regulations at §§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii), hospitals that provide inpatient and outpatient services, respectively, to Medicaid enrollees are required to meet the Medicare CoPs to also participate in Medicaid. In this way, the CoPs regulate the safety of all patients in a facility that is subject to 42 CFR part 482, regardless of payor (for example, Medicare, Medicaid, private insurance, and self-pay).

The CoPs for hospitals include specific, process-oriented requirements for certain hospital services or departments. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals.

B. Sex-Rejecting Procedures for Children With Gender Dysphoria

1. The Rise of Chemical and Surgical Interventions for Children as Part of Sex-Rejecting Procedures for Gender Dysphoria

Gender dysphoria is a condition defined by the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM–5–TR) as a ''marked incongruence between one's experienced/expressed gender and assigned gender'' that ''must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.'' [2] [3] Over the past decade, increasing numbers of children have been diagnosed with gender dysphoria and been treated with SRPs.[4] [5] SRPs can encompass a range of hormonal and surgical interventions: pharmacological interventions including puberty blocking medications to delay the onset of puberty, cross-sex hormone therapy to promote secondary sexual

[1] ''Protecting Children from Chemical and Surgical Mutilation.'' *The White House,* 28 Jan. 2025, *https://www.whitehouse.gov/presidential-actions/2025/01/protecting-children-from-chemical-and-surgical-mutilation/.*

[2] Coleman, E., et al. ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online,* doi:10.1080/26895269.2022.2100644.

[3] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders.* 5th ed. Edition, Text Revision, American Psychiatric Publishing,2022, *https://doi.org/10.1176/appi.books.9780890425787.*

[4] Coleman Eli, et. al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022 pp. S1–S259. *Taylor & Francis Online, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.*

[5] Hembree, Wylie C., et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.'' *The Journal of Clinical Endocrinology & Metabolism,* vol. 102, no. 11 (13 September 2017, pp. 3869–3903, *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

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characteristics associated with the opposite biological sex, and surgical procedures (such as chest/breast and genital surgery).[6] [7]

The recorded prevalence of SRPs for children with gender dysphoria varies across sources. A study published in 2023 estimated that between 2016 and 2020, nearly 3,700 children aged 12 to 18 years old diagnosed with gender dysphoria underwent SRPs (2.50 per 100,000),[8] including an estimated 3,200 chest/breast procedures (2.17 per 100,000) [9] and 400 genital surgeries (0.27 per 100,000).[10] [11] Another study documented that almost 0.2 percent (or almost 2 in every 1,000) of 17-year-olds [12] with private insurance received SRP hormone treatment between 2018 through 2022.[13] [14]

While Medicare does not pay for a significant number of SRP procedures for children, we conclude that, based on the previously cited data, hospitals that participate in Medicare perform a considerable number of these procedures every year. We further note that the Medicare hospital CoPs apply to hospitals providing services to patients receiving Medicaid covered services ((§§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii)). Approximately half of U.S. children receive health care through Medicaid.

2. Medical Evidence Regarding Sex-Rejecting Procedures in Children

The rising numbers of children seeking and receiving SRPs in recent years [15] has spurred ongoing debates regarding the safety and efficacy of these interventions.

a. The HHS Review

In compliance with Executive Order (E.O.) 14187, ''Protecting Children from Chemical and Surgical Mutilation'' [16] signed on January 28, 2025 (as discussed previously in this proposed rule), HHS released a preliminary comprehensive review of the evidence and best practices for treating pediatric gender dysphoria on May 1, 2025.[17] On November 19, 2025, HHS published a final version following the conclusion of a peer review process.[18] the Review provides an overview of systematic reviews—also known as an ''umbrella review''—to evaluate the evidence of the benefits and harms of SRPs in children. Several existing systematic reviews of evidence that have informed health authorities in Europe were assessed for methodological quality.

The Review itself does not provide clinical or policy recommendations. Instead, it analyzes evidence and best practices for children experiencing gender dysphoria. The Review also contains an ethics review that applies widely accepted principles of medical ethics to the practice of SRPs in children.[19] Accordingly, the Review states:

''As demonstrated throughout this Review, the presuppositions that guide [pediatric medical transition (PMT)] have not been shown to be valid; the nature, probability and magnitude of risks associated with PMT have not been distinguished with sufficient clarity; PMT proponents' estimates of the probability of harm and benefit have not been shown to be reasonable, as judged by known facts and available studies; and the risks of serious impairment that PMT involves have not been shown to be justified. For these reasons, administering PMT to adolescents, even in a research context, is in tension with well-established ethical norms for human subjects research.'' [20]

The Review (as further discussed in Section I.B.c. of this proposed rule) provides evidence of the clinical realities of SRPs in the United States, documenting the abandonment of medical guardrails. For example, the Review highlights how a protocol establishing SRPs in minors originated in the Netherlands and quickly spread to other Western countries without rigorous testing, and was codified in medical guidelines, which later did away with some of their already contested safeguards.[21] The Endocrine Society (ES) incorporated puberty blockers and hormones into their 2009 and 2017 clinical practice guidelines, recommending hormonal interventions for certain pediatric patients with gender dysphoria while also acknowledging the lack of reliable evidence for these treatments.[22] ES justified this recommendation in a ''values and preferences'' statement that places a higher priority on ''avoiding a[n] unsatisfactory physical outcome when secondary sex characteristics have

[6] Coleman, Eli, et al. ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[7] Hembree, Wylie C., et. al. ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.'' *The Journal of Clinical Endocrinology & Metabolism.* vol. 102, no. 11, 1 November 2017, *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

[8] CMS calculation: The annual number of overall SRPs (Breast/chest surgery, genital surgery, and other cosmetic procedures) on children aged 12 to 18 years is 740. The annual estimated number of children aged 12 to 18 according to U.S, Census Bureau data is 29,600,770. This results in annual estimate of 2.17 chest/breast procedures per 100,000 children aged 12 to 18 ((643/29,600,770) × 100,000 =2.50)). This calculation assumes 1 SRP per person.

[9] CMS calculation: The annual number of breast/chest surgeries on children aged 12 to 18 years is 643. The annual estimated number of children aged 12 to 18 according to U.S, Census Bureau data is 29,600,770. This results in annual estimate of 2.17 breast/chest surgeries per 100,000 children aged 12 to 18 ((643/29,600,770) × 100,000 =2.17)). This calculation assumes 1 breast/chest surgery per person.

[10] CMS calculation: The annual number of genital surgeries on children aged 12 to 18 years is 81. The annual estimated number of children aged 12 to 18 according to U.S. Census Bureau data is 29,600,770. This results in annual estimate of 0.27 genital procedures per 100,000 children aged 12 to 18 ((81/29,600,770) × 100,000 =0.27)). This calculation assumes 1 genital surgery is done per person.

[11] Wright J. D., et al. ''National estimates of gender-affirming surgery in the US.'' *JAMA Network Open,* vol. 6, no. 8, e2330348, 23 Aug. 2023, *http://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707.*

[12] CMS calculation: Per the article, the highest rate of hormone treatment occurs at age 17 with 140 AFAB adolescents (assigned female at birth) receiving testosterone (per 100,000 is 0.14% (140/100,000) ×100=0.14%)) and 82 AMAB adolescents (assigned male at birth) receiving estrogen (per 100,000 is 0.082% (82/100,000) ×100 =0.082%). This results in 222 (82+140= 222) per 100,000 or 0.222 (0.14% + 0.082% = 0.222). This calculation assumes 1 sex rejecting hormone treatment is done per person.

[13] Hughes Landon D., et al., ''Gender-affirming medications among transgender adolescents in the US.'' *JAMA Pediatrics,* 179,3 (2025): 342–344. doi:10.1001/jamapediatrics.2024.6081, *https://pubmed.ncbi.nlm.nih.gov/39761053.*

[14] CMS calculation: 140 + 82 = 222. This results in an estimate of 222 SRP hormone treatment per 100,000 children aged 17, between 2018 through 2022. This calculation assumes 1 SRP hormone treatment is done per person.

[15] Wright, Jason D., et al.. ''National Estimates of Gender-Affirming Surgery in the US.'' *JAMA Network Open,* vol. 6, no. 8, 23 Aug. 2023, doi:10.1001/jamanetworkopen.2023.30348, *http://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707.*

[16] 90 FR 8771 (February 3, 2025).

[17] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office Of Population Affairs,* 1 May 2025. *https://opa.hhs.gov/gender-dysphoria-report.*

[18] U.S. Department of Health and Human Services (HHS), ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,*19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report.*

[19] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 218–246.

[20] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg., 246.

[21] Biggs, M. (2023b). The Dutch Protocol for juvenile transsexuals: Origins and evidence. *Journal of Sex & Marital Therapy, 49*(4), 348–368.

[22] Hembree, Wylie C., et al. ''Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline.'' *Journal of Clinical Endocrinology & Metabolism,* vol. 94, 9, 2009: 3132–52/doi:10.1210/jc.2009–0354.

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become manifest and irreversible'' than on ''avoiding potential harm from early pubertal suppression.'' [23]

The World Professional Association for Transgender Health (WPATH) endorsed a similar approach and most recently recommend these in their Standards of Care, Version 8 (SOC–8).[24] However, as carefully documented in the Review, the creation of SOC–8 marked ''a clear departure from the principles of unbiased, evidence-driven clinical guideline development.'' [25] The HHS Review cites court documents containing internal WPATH communications used when developing SOC–8 that show WPATH suppressed systematic reviews of evidence after learning that these reviews would not support its preferred medical approach. WPATH also failed to manage conflicts of interest and eliminated age minimums for hormones and most surgeries due to political pressures.[26] A recent systematic review of international guidelines did not recommend either the WPATH or ES guidelines for clinical use after determining they ''lack developmental rigour and transparency.'' [27]

b. International Reviews of SRPs in Children

The Review also describes practice reversals in several European countries (Norway, Finland, Sweden, Denmark, United Kingdom) following systematic reviews of evidence.

In 2020, Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued guidelines stating that ''gender reassignment of minors is an experimental practice.'' While not banning SRPs outright, the guidelines state ''based on studies examining gender identity in minors, hormonal interventions [puberty blockers, hormone therapy] may be considered before reaching adulthood in those with firmly established transgender identities, but it must be done with a great deal of caution, and no irreversible treatment should be initiated.'' [28] For children with gender dysphoria prior to and worsening at the onset of puberty, the report recommends that ''puberty suppression treatment [that is, puberty blockers] may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications.'' This is similar to past recommendations, and as before, these treatments would be limited to research settings for payment by the nation's health service. For children with gender dysphoria that have undergone puberty, the guidelines recommend that decisions regarding initiation of hormone treatment that alter sex characteristics be ''based on thorough, case-by-case consideration, [. . .] [and] only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria [. . .] and that no contraindications [that is, mental health conditions] are present.'' Previously, recommendations noted that hormone therapy should not begin before age 16 in this group and that patients under 18 may receive 3 to 6 months of puberty blockers prior to beginning hormone therapy. The current report mentions no age or month specific treatment guidelines. The report continues to recommend that all such interventions be done in a research setting. The report adds that ''[i]nformation about the potential harms of hormone therapies is accumulating slowly and is not systematically reported'' and calls for further rigorous research of the benefits and risks of these treatments. Consistent with past recommendations, the report adds that ''surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors.'' [29]

In 2022, Sweden's National Board of Health and Welfare (NBHW) reviewed and updated its guidelines for treatment of children with gender dysphoria.[30] [31] At the population level, NBHW issued ''weak, negative recommendation as guidance to the healthcare system'' that the risks of hormone treatment (which included gonadotropin releasing hormones (GnRH) also known as puberty blockers) and mastectomy likely outweigh the expected benefits for most adolescents. NBHW concludes that ''existing scientific evidence is insufficient for assessing the effects of puberty suppressing and gender-affirming hormone therapy on gender dysphoria, psychosocial health and quality of life of adolescents with gender dysphoria.'' While not banning access to SRPs, NBHW suggests restricting such treatments to exceptional circumstances or research settings, and adhering to the original ''Dutch protocol'' criteria including ''existence of the incongruence since childhood, the stability of gender identity over time, clear distress caused by the onset of puberty, and the absence of factors that complicate the diagnostic assessment.'' [32] The report did not discuss SRP surgeries aside from mastectomy.

In the United Kingdom, the National Health Service (NHS) commissioned a comprehensive review of the existing literature on SRPs and the prevailing service model. The 4-year independent evaluation of pediatric gender medicine (PGM), known as the ''Cass Review,'' was published by Dr. Hilary Cass in April 2024. The Cass review concluded that the evidence base for SRPs in children is ''remarkably weak'' and recommended restructuring of the service model towards prioritization of psychotherapy.[33]

In terms of research quality, the Cass Review notes that the number of studies on gender dysphoria treatment in children is very low, with small study sizes that have inconsistent metrics, low

[23] Hembree, Wylie C., et al. ''Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. Endocrine Practice,'' 23(12), 2017: 1437–1437.

[24] Coleman, Eli, et al. ''Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7.'' *International Journal of Transgenderism,* 13(4), 165–232.

[25] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,,* p. 181.

[26] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* p. 157–186.

[27] Taylor, Jo, et al. ''Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review.'' *Archives of Disease in Childhood,* vol. 109, Suppl. 2, s33-s47, 30 Oct. 2024, doi:10.1136/archdischild–2023–326669.

[28] Council for Choices in Health Care Finland. ''Finnish 2020 COHERE Guidelines for Minors Finland)'' certified translation. IFTCC Archives, 2020, *https://archive.iftcc.org/finnish-2020-cohere-guidelines-minors-finland-certified-translation.*

[29] Council for Choices in Health Care Finland. ''Finnish 2020 COHERE Guidelines for Minors Finland)'' certified translation. IFTCC Archives, 2020, *https://archive.iftcc.org/finnish-2020-cohere-guidelines-minors-finland-certified-translation.*

[30] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and adolescents with gender dysphoria: Summary of National Guidelines.'' Dec. 2022. *https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330.*

[31] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and young people with gender Dysphoria—National knowledge support with recommendations for the profession and decision makers.'' 16 Dec. 2022. *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf.*

[32] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and adolescents with gender dysphoria-summary of national guidelines.'' Dec 2022, *https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330/.*

[33] Cass, Hilary ''Cass Review Final Report.'' *The National Archives,* Apr. 2024, *https://cass.independent-review.uk/home/publications/final-report.*

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quality methods (uncontrolled observational studies), results of low certainty, and lack of longitudinal data (that is, do not follow youth into adulthood; average duration of hormone treatment is between 1 year and 5.8 years). The Cass Review notes that this weak evidence base makes conclusions regarding the benefits versus risk of gender dysphoria treatment in children extremely difficult to assess. The Cass Review also critiques WPATH guidelines, noting that WPATH's own systemic review acknowledges a high risk of bias in study designs, small sample sizes, and confounding variables.

Regarding guideline development, the Cass Review notes that most current guidelines have not followed the international standards for guideline development, including the WPATH guidelines. As such, the Cass Review only recommends two guidelines: the Finnish guideline (2020) and the Swedish guideline (2022) as discussed above. However, the Cass Review notes that even these guidelines lack clear recommendations regarding certain aspects of practice and ''would be of benefit if they provided more detailed guidance on how to implement recommendations.''

While not banning access to puberty blockers, Dr. Cass concluded in a July 2023 letter that ''because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, [puberty blockers] should only be offered under a research protocol [for treatment of pediatric gender dysphoria].'' NHS England and National Institute for Health and Care Research (NIHR) have enacted this recommendation as of December 2024. Exceptions are permitted for non-gender dysphoria-related medical conditions (*i.e.* precocious puberty) and for those patients already on treatment.[34] For hormone interventions, the Cass Review highlights a lack of high-quality research assessing the (long-term) outcomes of hormone interventions in children with gender dysphoria. Given this weak evidence base, Dr. Cass notes that ''no conclusions can be drawn about the effect [of hormone interventions] on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health.'' the Cass Review ultimately calls for caution, better research (prospective studies with long-term outcome data), honest communication with patients about the limitations of current knowledge, and development of evidence-based guidelines that acknowledge the limitations of current evidence. Of note, in the United Kingdom, children have never received gender dysphoria related surgery as paid by the NHS; Cass therefore did not systemically review evidence for gender dysphoria related surgeries in children.

Norway and Denmark are exploring or have enacted similar restrictions, though neither have issued direct bans of SRPs. In 2023, the Norwegian Commission for the Investigation of Health Care Services (Ukom), an independent State-owned agency, made recommendations on the treatment for youth with gender dysphoria.[35] The recommendations consisted of: defining SRPs (that is, puberty blockers, hormonal therapies, and surgical treatment) as ''experimental treatment,'' revising national guidelines based on a systematic knowledge summary, and consideration for a national registry to improve quality and reduce variation in patient treatment.While not banning access to SRPs, Norway's public health authorityhas signaled an intention torespond to UKOM's concerns with an adjustment to the current treatment guidelines.[36] While also not banning access to SRPs, Denmark has also taken a cautious approach to hormone interventions (that is, puberty blockers and cross-sex hormones) pending more evidence of its beneficial effects becoming available.[37] Notably, Denmark does not offer surgical treatment to children with gender dysphoria before age 18 as paid for by its national health service.[38] Other countries that have considered or restricted various gender dysphoria treatments for children include Italy,[39] Brazil,[40] New Zealand,[41] and Australia.[42]

c. Medical Professional Societies Supporting SRPs

We are aware that major medical organizations [43] (including the American Medical Association (AMA),[44] the American Academy of Pediatrics (AAP),[45] and the American Psychological Association [46] [47]) have issued statements supporting access to SRPs, including for children. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the U.S. are the WPATH and the ES clinical practice guidelines and the AAP guidance document.[48] We reviewed

[34] Department of Health and Social Care. ''Ban on puberty blockers to be made indefinite on experts' advice.''*GOV.UK,* 11 Dec. 2024. *https://www.gov.uk/government/news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice.*

[35] Norwegian Healthcare Investigation Board (Ukom). ''Pasientsikkerhet for barn og unge med kjønnsinkongruens [Patient safety for children and adolescents with gender incongruence].'' March 2023, *https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag.*

[36] Block, Jennifer. ''Norway's guidance on paediatric gender treatment is unsafe, says review,'' *BMJ (Clinical research ed.)* vol. 380 697, 23 Mar. 2023, doi:10.1136/bmj. p697.

[37] Hansen, Mette Vinther et al., ''Sundhedsfaglige tilbud til børn og unge med kønsubehag [Healthcare services for children and adolescents with gender dysphoria],'' *Ugeskrift for Laeger [The Journal of the Danish Medical Association]* 3 July 2023, *https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag.*

[38] Hansen, Mette Vinther et al., ''Sundhedsfaglige tilbud til børn og unge med kønsubehag [Healthcare services for children and adolescents with gender dysphoria],'' *Ugeskrift for Laeger [The Journal of the Danish Medical Association]* 3 July 2023, *https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag.*

[39] Armellini, Alvise. ''Italy moves to tighten controls on gender-affirming medical care for minors.'' *Reuters.* 5 Aug. 2025. *https://www.reuters.com/business/healthcare-pharmaceuticals/italy-moves-tighten-controls-gender-affirming-medical-care-minors-2025-08-05.*

[40] AFP. ''Brazil prohibits hormone therapy for transgender minors.'' *MSN News.* 17 Apr. 2025. *https://www.msn.com/en-in/news/other/brazil-prohibits-hormone-therapyfor-transgender-minors/ar-AA1D66l7.*

[41] Corlett, Eva. ''New Zealand Bans Puberty Blockers for Young Transgender People.'' *The Guardian,* Guardian News and Media, 19 Nov. 2025, *https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.*

[42] Australian Associated Press. ''Queensland halts prescription of puberty blockers and hormones for children with gender dysphoria.'' *The Guardian,* 28 Jan. 2025. *https://www.theguardian.com/australia-news/2025/jan/28/queensland-halts-prescription-of-puberty-blockers-and-hormones-for-children-with-gender-dysphoria.*

[43] Advocates For Trans Equality. ''Medical Organization Statements.'' *A4TE's Trans Health Project, https://transhealthproject.org/resources/medical-organization-statements/.*

[44] ''Clarification of Evidence-Based Gender-Affirming Care H–185.927,'' *American Medical Association Policy Finder,* American Medical Association, 2024, *https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml.*

[45] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* 6 Jan. 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[46] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' *American Psychological Association,* released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[47] ''Criminalizing Gender Affirmative Care with Minors,'' *American Psychological Association,* accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

[48] The American Academy of Pediatrics' (AAP) 2018 Policy Statement was reaffirmed in 2023 (Rafferty et al., 2018); the Endocrine Society's (ES) published in 2017 represents the most recent published version (Hembree et al., 2017); the World Professional Association for Transgender Health's (WPATH) most recent clinical practice guideline is

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each of these documents and agree with the HHS Review that discusses the conclusions of a recent systematic review of international guideline quality by researchers at the University of York (the York Appraisal) that found all three documents are very low quality and should not be implemented.[49]

As the HHS Review notes regarding the role of medical organizations in the treatment of pediatric gender medicine:

''U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition. This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.'' [50]

The Endocrine Society (ES) issued clinical practice guidelines in 2017 entitled ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.'' [51] As the HHS Review notes:

''In WPATH and ES guidelines, the principal goal of CSH administration is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations. Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.'' [52]

The HHS Review states:

''The ES 2017 guideline, which used the GRADE [Grading of Recommendations Assessment, Development and Evaluation] framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base. Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents. The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a ''satisfactory physical appearance'' while putting the lowest value on avoiding physical harms. The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower value on avoiding harm from potentially prolonged pubertal suppression.'' [53]

As explained in Chapter 9 of HHS Review, the guidelines issued by the World Professional Association for Transgender Health (WPATH) ''have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines.'' [54] As the HHS Review points out: ''Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH Standards of Care guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.'' [55] In 2022, WPATH issued guidelines entitled ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8'' (SOC–8).[56] These guidelines relaxed eligibility criteria for children to access sex-rejecting procedures and ultimately recommends that adolescents wishing to undergo sex-rejecting procedures receive them. Besides the problems identified in systematic reviews of international guidelines, as the HHS Review states, ''in the process of developing SOC–8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC–8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.'' [57] The HHS Review goes on to explain: ''The recommendations are couched in cautious-sounding language, stating that GD should be ''sustained over time,'' particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase ''several years'', leaving critical decisions open to broad and subjective interpretation.[58]

Regarding the WPATH guidelines, the HHS review states:

''On the surface, WPATH SOC–8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a ''comprehensive biopsychosocial assessment'' prior to initiating medical interventions in order ''to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care.'' [59]At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases (ICD–11) diagnosis of ''Gender Incongruence of Adolescence and Adulthood,'' which, unlike the DSM–5 diagnosis of ''Gender Dysphoria,'' requires only ''marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' [60] Because SOC–8 defines transgender in a similar way (''people whose gender identities and/or gender expressions are not what is typically

Standards of Care, Version 8 (SOC–8) (Coleman et al., 2022).

[49] HHS Review pg. 141.

[50] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 15.

[51] Wylie C. Hembree et al. ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658.*

[52] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 124.

[53] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 147.

[54] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 157.

[55] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 157.

[56] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[57] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 14.

[58] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 165.

[59] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[60] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 194.

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expected for the sex to which they were assigned at birth'') and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC–8 effectively recognizes transgender identification as a medical condition justifying medical interventions.'' [61]

While AMA and the AAP have not issued their own treatment guidelines, they support the ES and WPATH guidelines, as discussed previously in this proposed rule. AAP issued a policy statement in 2018 supporting the use of puberty blockers, cross-sex hormones, and surgeries for minors.[62] In support of sex-rejecting surgeries, AAP stated that while ''current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.'' The AAP reaffirmed its policy statement in 2023 but also stated that it was conducting its own review of the evidence and guideline development—which still has not been released.[63]

Regarding the AAP policy statement, the HHS Review states:

''The AAP 2018 policy statement is not technically a CPG [clinical practice guideline] but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD [gender dysphoria].[64] Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs [puberty blockers], CSH [cross-sex hormones], and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7. As noted in Chapter 2, the AAP policy statement's use of ''gender diverse'' casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.'' [65]

We solicit comment of any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients in international settings as well as the U.S.

3. U.S. Legal Landscape Regarding Sex-Rejecting Procedures

The United States has seen a high level of activity both at the State level and within the judicial system on this topic in recent years.

a. U.S. State Laws

Several States and territories have adopted laws reflecting their views of the evidence on SRPs for children with 28 restricting and 15 protecting this treatment. As of August 2025, 27 States and one territory have laws limiting or prohibiting some or all SRPs for children.[66] These include Alabama, Arkansas, Arizona, Florida, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Carolina, New Hampshire, North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. Of these, 2 States' laws or policies (Montana and Arkansas) are pending resolution of ongoing legal challenges (as of August 2025).

States with such laws or policies apply them to varying age ranges. Twenty-five States prohibit certain SRPs in individuals under the age of 18. Two States (Nebraska and Alabama) prohibit them for those under the age of 19. Puerto Rico prohibits such procedures for those under the age of 21.

Which SRPs (that is puberty blockers, hormone therapy, and surgery) are banned for children varies by State. As of August 2025, 25 States have laws that prohibit access to puberty blockers, hormone therapies, and gender dysphoria related surgeries for children. Two States (New Hampshire and Arizona) have restrictions on surgery (but permit endocrine SRPs) for this population. No State bans only medications without also banning surgical procedures.[67]

All the States and the territory with restrictions provide exceptions to the law/policies. The most common exceptions include:

- Children born with medically verifiable disorder of sex development. This allows treatment for children who are born with medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other factors that can be medically verified.
- Children who have been diagnosed with a disorder of sexual development by a physician through genetic or biochemical testing.
- Treatment for any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of SPRs.
- Children suffering from physical disorders, physical injuries, or physical illnesses that would otherwise place the children in danger of death or impairment of bodily function.

We note that 12 States provide tapering off periods for patients who started puberty blockers or hormones before enactment of the restriction, with some specifying specific dates (for example, in South Carolina services cannot go beyond January 31, 2025) and others specifying a period of time from the date of enactment (ranging between 6 months and 1 year). Ten States have grandfather clauses primarily allowing children who were already receiving treatment to continue receiving it indefinitely.

Conversely, 14 States and the District of Columbia have shield laws protecting SRPs, and three other States have E.O.s protecting these procedures.[68] These

[61] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 194–195.

[62] Rafferty, Jason, et al. ''Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents.'' *Pediatrics,* vol. 142, no. 4, 1 Oct. 2018, doi:10.1542/peds.2018–2162.

[63] Wyckoff, Alyson Sulaski. ''AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update.'' *AAP News,* August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy.*

[64] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 148.

[65] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 148, 149.

[66] Dawson, L., Kates, J. ''Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions.'' *KFF,* 21 Aug. 2025 [24 Nov. 2025], *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker.*

[67] American Psychological Association. ''Navigating the legal landscape: FAQs on gender affirming care for minors.'' *American Psychological Association,* 28 Jun. 2024, *https://www.apaservices.org/practice/legal/managed/legal-landscape-gender-care-minors.*

[68] ''Equality Maps: Transgender Healthcare 'Shield' Laws.'' *Movement Advancement Project,*

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States are (not including the District of Columbia): Arizona,[69] California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. Shield laws and State E.O.s often describe SRPs broadly, including medications and procedures, and include these under broader definitions of protected healthcare activities. These laws often protect providers from adverse action by medical malpractice insurers and licensure boards and allow for their address to remain confidential. One State (Maine) has a shield law that allows children 16 and over to receive hormone therapy when the guardian has refused SRPs. Four States explicitly provide child abuse and child custody protections for parents who supported their children in receiving specified procedures. Four State shield laws and E.O.s have requirements for SRPs to be covered under health plans. Arizona requires coverage for State employee health plans. Illinois, Oregon, and Vermont require some level of SRPs coverage by all health insurance providers. Vermont includes an exception for services that do not comply with Federal law.

b. United States Supreme Court

Recently, the Supreme Court in *United States* v. *Skrmetti*, 145 S. Ct. 1816 (2025) upheld Tennessee's law (referred to as Senate Bill 1; SB 1) banning certain surgical and chemical interventions for children with gender dysphoria, in litigation challenging that law under the Equal Protection Clause of the U.S. Constitution. SB1 prohibits a healthcare provider from performing medical procedures, including surgery, and prescribing puberty blockers, for a child for the purpose of enabling the child to identify with a purported identity inconsistent with the child's sex. At the same time, SB1 allows healthcare providers to perform medical procedures for children if the procedure is to treat a child's congenital defect, precocious puberty, disease, or physical injury. On June 18, 2025, the Court found that SB1's prohibition of certain medical procedures for children with gender dysphoria incorporates classifications based on age and medical use—not the child's sex. As a result of these classifications based on age and medical use, the Court held that SB1 was not subject to heightened scrutiny under the Equal Protection Clause of the Fourteenth Amendment and the law satisfied so called ''rational basis'' review.

4. CMS Actions

The proposed rule is animated by significant child safety concerns when SRPs are used for certain medical uses—that is to align a child's physical appearance or body with an asserted identity that differs from the child's biological sex. CMS published a formal guidance letter to State Medicaid Directors regarding SRPs on April 11, 2025, reminding States of their responsibility to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interest of recipients.[70] In addition, the Administrator of CMS sent a letter issued on May 28, 2025, to a number of hospitals addressing significant issues concerning quality standards and specific procedures affecting children. The letter requested that the recipient hospitals provide CMS with copies of certain hospital policies and procedures on the adequacy for informed consent protocols for children with gender dysphoria, including how hospitals determine that children are capable of making these potentially life changing decisions and when parental consent is required; describe any changes to clinical practice guidelines and protocols that the institution plans to enact in light of the recent comprehensive review and guidance released by the Department; provide CMS with medical evidence of any adverse events related to these procedures, particularly in children who later sought to detransition; and complete financial data for all pediatric SRPs performed at the institution and paid, in whole or in part, by the Federal Government.[71]

In addition, on May 28, 2025, Secretary Kennedy wrote to hospitals, health care providers, health care risk managers, and State medical boards across the nation, asking them to read the HHS Review, and to make necessary updates to their ''treatment protocols and training for care for children and adolescents with gender dysphoria to protect them from these harmful interventions.'' [72]

These letters reaffirmed CMS' and HHS' commitment to following the highest standards of care and to adhering closely to the foundational principles of medicine, especially relating to doing no harm to America's children and in alignment with CMS's obligations to ensure baseline quality standards at institutions participating in the Medicare and Medicaid programs.

II. Provisions of the Proposed Regulations

We have undertaken a review of the current hospital health and safety standards (known as the CoPs) as well as the latest information regarding SRPs in children to ensure hospitals are best protecting the health and safety of children. The evidence as presented in the Review (see section I.B.2. of this proposed rule) indicates that SRPs lack the necessary outcomes data on safety and long-term effectiveness. CMS takes very seriously the absence of rigorous scientific data demonstrating the safety and effectiveness of SRPs and the considerable evidence regarding the risks. Based on this, we believe that certain SRPs (namely pharmaceutical and surgical interventions) are not consistent with the health and safety of children, given the risk of significant (long term) harms, known complications, and weak and uncertain evidence of benefits.

We therefore propose to add a new section to 42 CFR part 482, subpart C that would prohibit Medicare and Medicaid-participating hospitals from performing sex-rejecting procedures (SRPs) on any child (§ 482.46(a)). As set out in proposed § 482.46(a)(5), we propose to define SRPs as any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with a stated identity that differs from the individual's sex by either (1) intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits or (2) intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.

n.d., accessed 11 August 2025, *https://www.lgbtmap.org/equality-maps/healthcare/trans_shield_laws.*

[69] Arizona banned SRPs for transgender minors in 2022, but in 2023 the governor issued an executive order with ''shield'' style protections for SRPs that are still legal in the State.

[70] Department of Health & Human Servies, Centers for Medicaid & CHIP Services. ''Puberty blockers, cross-sex hormones, and surgery related to gender dysphoria.'' Received by State Medicaid Director, 7500 Security Blvd. Mail Stop S2–26–12, 11 Apr. 2025, Baltimore, Maryland, *https://www.cms.gov/files/document/letter-stm.pdf.*

[71] Department of Health & Human Services, Centers for Medicare and Medicaid Services. ''Urgent Review of Quality Standards and Gender Transition Procedures.'' 28 May 2025, Washington, DC, *www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.*

[72] U.S. Department of Health & Human Services [@HHSGov]. *X* (formerly Twitter), 28 May 2025, *https://x.com/HHSGov/status/1927791449476567043.*

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We propose at § 482.46(a)(1) through (4) to include several additional definitions critical to interpreting the proposal. We propose that the term ''child'' be defined as any individual younger than 18 years of age. We further propose that the term ''female'' be defined as an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We propose that the term ''male'' be defined as an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. Finally, we propose that the term ''sex'' is defined as an individual's immutable biological classification as either male or female.

At § 482.46(b), we are proposing exceptions to § 482.46(a) to protect the health and safety of children in certain rare and exceptional circumstances. Proposed exceptions include:

- *Procedures to treat an individual with a medically verifiable disorder of sexual development (§ 482.46(b)(1)).* This allows treatment for children who are born with certain medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other medical factors that can be medically verified and documented. Examples include a child with external biological sex characteristics that are irresolvably ambiguous, such as those born with 46 XX chromosomes with virilization, 46 XY chromosomes with under-virilization, or having both ovarian and testicular tissue.
- *Procedures for purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex (§ 482.46(b)(2)).* This permits procedures that are done for reasons entirely separate from changing a child's physical appearance to match a gender identity that differs from their biological sex, including procedures for children with a physical disorder, injury, or physical illness. In other words, the procedure must have a purpose separate from intending to change the body to not correspond to one's biological sex.
- *Treating Complications (§ 482.46(b)(3)).* This exception allows treatment for any infections, injuries, diseases, or other medical disorders that were caused by or made worse by previous SRPs. This exception allows physicians or other licensed practitioners to treat complications that arise from these procedures.

While we are proposing certain exceptions, any procedures or treatments under these exceptions must still be performed with the consent of the child's parent or legal guardian, as currently required under the patient rights CoP at § 482.13(b)(2), the medical records CoP at § 482.24 (c)(4)(v), the surgical services CoP at § 482.51(b)(2), and in compliance with applicable State law(s).

Practice of Medicine

Under Section 1801 of the Act, CMS may not ''exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, (42 U.S.C. 1395). However, we believe that providing the SRPs for children is not healthcare and hence are not subsumed under the term of ''the practice of medicine.'' Therefore, the proposed rule would not regulate the practice of medicine. As the Review notes regarding SRPs, when ''medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients.'' [73] As the Review states, ''in the domain of pediatrics, these norms limit the authority not only of patients (who in any case lack full decision-making capacity) but of parents as well.'' [74] The first obligation of the physician, under the Hippocratic Oath, originating in the fourth century BC, is to first do no harm, as the purpose of the practice of medicine is to heal. SRPs introduce a unique set of iatrogenic harms, especially, ''surgeries to remove healthy and functioning organs.'' [75] The Review states: ''to discharge their duties of nonmaleficence and beneficence, clinicians must ensure, insofar as reasonably possible, that any interventions they offer to patients have clinically favorable risk/benefit profiles relative to the set of available alternatives, which includes doing nothing.'' [76] As related previously in this proposed rule, the risk-benefit profile of these procedures for children is extremely poor. At the same time,'' the Review notes, ''there is increasing recognition of the risk and harms associated'' with pediatric sex-rejecting procedures, including ''possible outcomes, such as impaired cognitive function, greater susceptibility to hormone-sensitive cancers, cardiac disease, reduced bone density, sexual dysfunction, infection, and infertility [that] are objectively detrimental to health'' The Review concludes that''[s]uch medical harms, or plausible risks thereof, should not be imposed on children or adolescents in the absence of a reasonable expectation of proportionate medical benefit.'' [77]

There are other considerations for why the regulations proposed in this rule do not regulate the practice of medicine. A person's body (including its organs, organ systems, and processes natural to human development like puberty) are either healthy or unhealthy based on whether they are operating according to their biological functions. Organs or organ systems do not become unhealthy simply because the individual may experience psychological distress relating to his or her sexed body. For this reason, removing a patient's breasts as a treatment for breast cancer is fundamentally different from performing the same procedure solely to alleviate mental distress arising from gender dysphoria. The former procedure aims to restore bodily health and to remove cancerous tissue. In contrast, removing healthy breasts or interrupting normally occurring puberty to ''affirm'' one's ''gender identity'' involves the intentional destruction of healthy biological functions. This is not health care and hence imposing restrictions as this rule proposes does not limit the practice of medicine. The Review further notes there is lack of clarity about what SRPs' fundamental aims are, unlike the broad consensus about the purpose of medical treatments for conditions like appendicitis, diabetes, or severe depression.[78] Rather as discussed above, these procedures lack strong evidentiary foundations, and our

[73] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov, 2025. *https://opa.hhs.gov/gender-dysphoria-report* Pg. 15.

[74] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report* Pg. 225.

[75] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 128.

[76] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 226.

[77] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report* Pg. 227–228.

[78] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,*19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 24–26.

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understanding of long-term health impacts is limited and needs to be better understood. Nothing in this proposed rule prohibits or permits the basic legality of SRPs. Rather, this proposed rule would ensure patient safety and medical integrity. CMS would no longer directly or indirectly support harm to children by allowing facilities that engage in such harmful practices to receive Medicare and Medicaid funds.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements (ICRs).

A. Hospital Notifications to Patients

Proposed § 482.46 would require that hospitals not perform sex-rejecting procedures (SRPs) on children, barring certain exceptions. We expect that hospitals that are currently performing these procedures on children would need to inform the child and their parents or legal guardian who are seeking such procedures that they no longer perform such procedures. Based on our experience, we expect that the child's physician or the licensed practitioner providing this care would spend an average of 30 minutes writing each notification. In addition, they would spend 30 minutes answering any questions from the child and their parents or legal guardian. This leads to a total burden of 1 hour per patient.

To calculate the total provider burden across all patients, we first examined State laws and found that 25 States have active laws restricting SRPs.[79] Given these State laws that already prohibit these procedures, we do not expect that physicians or licensed practitioners in these States would be writing a significant number of notifications. While acknowledging that some children living in these States may be traveling to States that permit SRPs for children, we do not expect that this is a large number of children for two reasons. First, across States with these restrictions, nearly 45 percent of children were enrolled in Medicaid or CHIP as of March 2025 and these programs would not fund SRPs outside the State.[80] Second, a recent study showed that across States with restrictions on SRPs, the average driving time to the nearest clinic in a State without restrictions was 5.3 hours, with the average time in Florida reaching 9 hours.[81] As such, we base our estimate on the number of children affected for children in States that currently do not have restrictions but seek comments on this assumption.

The second step was to identify the number of individuals under the age of 18 who live in States that allow SRPs. We combined information on State restrictions with Census Bureau population estimates[82] and found that there are approximately 8,674,717 females and 9,165,563 males between the ages of 10 and 17 living in States that do not have active laws restricting SRPs. While acknowledging that children younger than 10 may be receiving SRPs, we believe this is a reasonable estimate of the population affected by the proposed requirement.

The third step was to identify the number of individuals under 18 years of age who may be receiving SRPs. A recent study[83] found that among children between the ages of 8 and 17 covered by private insurance, males received puberty blockers and hormones at a rate of 15.22 per 100,000 and 25.34 per 100,000, respectively. Meanwhile, females received puberty blockers and hormones at a rate of 20.81 per 100,000 and 49.9 per 100,000, respectively. Applying these rates to the number of males and females in States without active laws restricting SRPs,[84] we estimate that there are approximately 6,651 individuals receiving hormones and 3,200 individuals receiving puberty blockers for a total of 9,851 individuals. As the authors note, these rates are more likely to be generalizable to patients with private insurance in large care plans and they expect lower rates for those utilizing Medicaid and in less comprehensive care plans. Another study[85] used national data to estimate the rate of sex rejecting surgical procedures and found that in 2019, there were approximately 85 sex-rejecting surgical procedures for children with a gender dysphoria diagnosis. The same as our estimates for the number of children receiving puberty blockers and hormones, this estimate is for insured patients and there may be lower rates for those utilizing Medicaid and in less comprehensive care plans. Given the overlap in treatment for some patients who may receive both surgical procedures and hormones, we estimate that a maximum of 9,851 individuals under the age of 18 are receiving SRPs.

While hospitals often prescribed puberty blockers and hormone replacement therapy as part of sex-rejecting procedures, primary care providers and endocrinologists outside of hospitals, who would not be affected by these requirements, can also prescribe these treatments. A recent analysis found that approximately 52 percent of primary care physicians were not affiliated with a hospital.[86] We do not know the share of children receiving puberty blockers or hormone replacement therapy outside the hospital setting and, therefore, would not need to receive notification that

[79] Dawson, L., Kates, J. ''KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming Care.'' *KFF,* 24 Nov. 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/.*

[80] Centers for Medicare & Medicaid Servies. ''State Medicaid and CHIP Applications, Eligibility Determinations, and Enrollment Data.'' *Data.Medicaid.gov, https://data.medicaid.gov/dataset/6165f45b-ca93-5bb5-9d06-0db29c692a360/data.* Accessed 6 Aug.2025.

[81] Borah, Luca et. al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA,* vol. 330,4 (2023): 375–378. doi: 10.1001/jama.2023.11299.

[82] U.S. Census Bureau, U.S. Department of Commerce. ''Age and Sex.'' American Community Survey, ACS 1-Year Estimates Subject Tables, Table S0101, *https://data.census.gov/table/ACSST1Y2023.S0101?q=population+by+age+by+state.* (Accessed 26 Jul. 2025).

[83] Hughes Landon D. et al. ''Gender-Affirming Medications Among Transgender Adolescents in the US, 2018–2022.'' *JAMA Pediatrics,* vol. 179, 3, (2025): p.342–344. doi:10.1001/jamapediatrics.2024.6081.

[84] Dawson, L., Kates, J. ''KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming *Care.*'' *KFF,* 24 Nov. 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/.*

[85] Dai Dannie, et al. ''Prevalence of Gender-Affirming Surgical Procedures Among Minors and Adults in the US.'' *JAMA Network Open,* vol. 7, 6, 27 Jun. 2024, doi:10.1001/jamanetworkopen.2024.18814.

[86] Singh, Yashaswini et al. ''Growth of Private Equity and Hospital Consolidation in Primary Care and Price Implications.'' *JAMA Health Forum* vol. 6,1 e244935. 3 Jan. 2025, doi:10.1001/jamahealthforum.2024.4935.

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SRPs were no longer offered. Assuming that 25 percent of children are receiving care from primary care physicians or endocrinologists and that 52 percent of these providers are outside the hospital system, then 8,570 of the 9,851 children receiving treatment as identified above would need to receive notices and have discussions with their treating physician or licensed practitioner. We seek comments on data sources on the number of children receiving puberty blockers or hormone replacement therapy outside the hospital setting who would not be affected by the proposed requirement.

To estimate the total cost for this requirement, we assumed that a physician would write these notices. We calculated the physician's hourly rate by doubling the national mean salary for physicians (occupation code 29–1210) using the BLS' May 2024 National Occupational Employment and Wage Estimates for hospitals (NAICS code 622000),[87] leading to an hourly cost of $226.18 ($113.09 × 2). We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs. Utilizing these data, in Table 1, we estimate that this requirement would cost $1,938,363. We seek comments on the estimated time burden for physicians to provide written notices to their patients that the hospital is no longer providing SRPs.

TABLE 1—NOTIFICATION LETTERS TO PATIENTS

Employee type	Average hourly rate (a)	Hours per patient (b)	Number of patients (c)	Total cost (d = a × b × c)	Total hourly cost (e = b × c)
Physician	$226.18	1	8,570	$1,938,363	8,570

B. Updating Hospital Policies and Procedures

In addition to sending out notices to patients that they are no longer providing SRPs, hospitals will need to update their policies and procedures to ensure that they align with the proposed requirements.

To estimate the cost for hospitals to update their policies and procedures, we used data from the BLS' May 2024 National Occupational Employment and Wage Estimates for hospitals (NAICS code 622000),[88] and doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. Based on our experience, we estimate that updating the hospital's policies and procedures related to SRPs for children would take 3 hours of work from a physician (occupation code 29–1210) at $678.54 ($226.18 × 3 hours) and a member of the clerical staff (occupation code 43–6010) at $143.40 ($47.80 × 3 hours), and 3 hours of work from a lawyer (occupation code 23–1010) at $650.16 ($216.72 × 3 hours) to review the updated policies and procedures to ensure that they meet the legal guidelines. This leads to a total per facility cost of $1472.10.

To estimate the number of hospitals that would need to update their policies and procedures, we first used the CMS' Q2 2025 Provider of Services File—Hospitals & Non-Hospital Facilities dataset and identified a total of 4,832 Medicare/Medicaid certified hospitals.[89] We expect that even in States that have active bans on SRPs, some hospitals would still need to update their policies and procedures since many of these States have exceptions that conflict with the requirements in this proposed rule. We recognize, however, that not all hospitals offer SRPs for children, and increasingly more hospitals nationwide are ending these services.[90] Given these uncertainties, we assume that 75 percent, or 3,624 hospitals would need to update their policies and procedures. Using this estimate, we expect that hospitals would spend $5,334,890 updating their policies and procedures. We seek comments on this estimate, specifically whether there are data sources to more accurately estimate the number of hospitals nationwide that currently offer SRPs for children.

TABLE 2—COST FOR UPDATING FACILITY POLICIES AND PROCEDURES

Per hospital cost (a)	Hospitals (b)	Per hospital hourly cost (c)	Total cost (a × b)	Total hourly cost (b × c)
$1,472.10	3,624	9	$5,334,890	32,616

The information collections will be sent to OMB for approval under the OMB Control number: 0938–NEW.

If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this proposed rule.

[87] U.S. Bureau of Labor Statistics. ''Occupational Employment and Wage Statistics (OEWS) Tables.'' *Occupational Employment and Wage Statistics,* BLS.gov, May 2024, *https://www.bls.gov/oes/tables.htm.* Accessed 23 Jul. 2025.

[88] U.S. Bureau of Labor Statistics. ''Occupational Employment and Wage Statistics (OEWS) Tables.'' *Occupational Employment and Wage Statistics,* BLS.gov, May 2024, *https://www.bls.gov/oes/tables.htm.* Accessed 23 Jul. 2025.

[89] Centers for Medicare and Medicaid Services. ''Provider of Services File—Hospital & Non-Hospital Facilities, Q2 2025.'' *Data.CMS.gov, https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data.* Accessed 13 Aug. 2025.

[90] Cowan, Jill Cowan. ''Hospitals Are Limiting Gender Treatment for Trans Minors, Even in Blue States.'' *The New York Times,* 22 Jul. 2025, *https://www.nytimes.com/2025/07/22/us/trump-transgender-healthcare-california-hospitals.html.* Accessed 6 Aug. 2025.

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IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

Throughout the United States, thousands of children are receiving sex-rejecting procedures (SRPs), specifically pharmacological and surgical interventions, for gender dysphoria. As outlined in section I. and II. of this proposed rule, however, recent HHS and international analyses question the efficacy and safety of SRPs in children. To protect children's health and safety, we are proposing to prohibit hospitals subject to part 482 from performing SRPs on any child with certain exceptions to best protect children's health and safety.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96 354); section 1102(b) of the statute; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities. The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f) of Executive Order 12866.

As noted above in Table 1 and Table 2, estimated costs of approximately $7.3 million are due to the time that a physician or licensed practitioner would spend providing patients with notification that the hospital no longer provides these procedures and for hospitals to update their policies and procedures related to SRPs for children. Below, we estimate additional impacts from the proposed requirement.

1. Costs and Transfers

We estimated the value of treatments in hospitals that would change in response to the proposed requirements using data from a study analyzing the per person cost of these treatments based on commercial claims data from 1993 to 2019.[91] This study estimated that for SRPs that included testosterone, estrogens and anti-androgens, and GnRH, there was an average combined cost to payors of $755 per person in 2019 dollars. Adjusting for inflation,[92] this leads to an average cost of approximately $909 per patient in 2024 dollars. For surgical procedures, there was an average per procedure cost of $28,367 in 2019 dollars. Adjusting for inflation, this leads to an average cost of approximately $34,165 in 2024 dollars. Utilizing our estimate in the collection of information section that 8,570 children would be affected by our rule and that there are 85 surgical SRPs on children annually, we estimate an annual value of $7,790,130 (8,570 patients × $909) for non-surgical SRPs and $2,904,025 (85 patients × $34,165) for surgical SRPs, for a total annual value of $10,694,155.

For children who are currently receiving SRPs at hospitals, there is likely to be bifurcation in their response to the proposed requirement. Some of these children may no longer receive SRPs at non-hospital providers that are not covered by the proposed requirement due to factors, such as difficulty in identifying in-network providers that have available space and longer commute times to these providers.[93] [94] The end of SRPs for these children would result in a reduced payments from payors, including insurance companies and private persons, to hospitals. Other children, however, are likely to switch to other provider types that are not affected by this proposed requirement. For these children, the proposed requirement would result in a change in transfers from Medicare-certified hospitals to other providers.

In the absence of data showing the likely share of patients in each category, we assumed that 50 percent of affected children would fall into each of the categories described above. Using this percentage, we estimate that the proposed requirements would result in $5,347,077 in reduced costs for payors and a $5,347,077 change in transfers from hospitals to other provider types annually. We seek comments on our assumption regarding the share of patients in each group.

For children who continue receiving SRPs, there are the costs associated with switching providers. Dahl and Forbes (2023) estimate that 46-percent of individuals are willing to pay over $600 per person (in 2011 dollars, or approximately $821 when updated for inflation) to avoid switching medical providers.[95] [96] The full willingness-to-pay (WTP) distribution is not reported, but for purposes of this regulatory

[91] Baker, Kellan, and Arjee Restar. ''Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population.'' *The Journal of Law, Medicine & Ethics,* vol. 50,3 (2022): 456–470. doi:10.1017/jme.2022.87

[92] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBIl1dfQ==*. Accessed 3 Dec. 2025.

[93] Borah, Luca et al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA* vol. 330,4 (2023): 375–378. doi:10.1001/jama.2023.11299.

[94] Gridley, Samantha J et al. ''Youth and Caregiver Perspectives on Barriers to Gender-Affirming Health Care for Transgender Youth.'' *The Journal of Adolescent Health,* vol. 59,3 (2016): 254–261. doi:10.1016/j.jadohealth.2016.03.017.

[95] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBIl1dfQ==*. Accessed 18 Aug. 2025.

[96] Dahl, Gordon B., and Forbes, Silke J. ''Doctor switching costs.'' *Journal of Public Economics* vol. 221, May (2023): pp. 104858.

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impact analysis, it is assumed that $821 is a reasonable estimate of an average that includes the 46-percent of WTP amounts above it and the 54-percent below. Applying this $821 amount to the above-estimated 8,570 affected patients (including 4,285 patients who would switch providers and 4,285 patients for whom the switching-cost estimate is a lower bound on the WTP to avoid the experience of being unable to switch [97] yields a cost estimate of $7,035,970 that declines over several years to an annual $3,517,985. Because the Dahl and Forbes estimate is derived from a choice between retaining or switching primary-care physicians—where finding substitute providers may be relatively easy as compared with finding, and maintaining patient-provider relationship with facilities offering the specialized treatment associated with adolescent gender dysphoria—this estimate may have a tendency toward understatement of the proposed rule's cost to patients for switching providers.

In Table 3, we estimate the costs and transfers associated with the proposed requirement over 10 years. Overall, we expect that this proposed rule would result in approximately $53.5 million in savings for payors due to some patients ending SRPs, with a cost of $44 million to patients who continue treatment at new providers for finding a new provider and for patients who would have paid to avoid the experience of being unable to switch providers. We also expect a change in transfers of $53.5 million from hospitals to other provider types as patients seek alternative sources of care. The effect attributable to this proposed rule might be lower in magnitude than the aggregate presented here if other actions, such as the HHS/CMS proposal titled ''Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children'' are finalized before finalization of *this* proposal.

TABLE 3—COSTS AND TRANSFERS FOR CHANGING PATIENT BEHAVIOR RELATED TO SEX-REJECTING PROCEDURES

Year	Costs		Transfers ($)
	Ending sex-rejection procedures ($)	Switching providers (probably tending toward cost under-estimation) ($)	
1	−5,347,077	7,035,970	5,347,077
2	−5,347,077	6,156,474	5,347,077
3	−5,347,077	5,276,978	5,347,077
4	−5,347,077	4,397,481	5,347,077
5	−5,347,077	3,517,985	5,347,077
6	−5,347,077	3,517,985	5,347,077
7	−5,347,077	3,517,985	5,347,077
8	−5,347,077	3,517,985	5,347,077
9	−5,347,077	3,517,985	5,347,077
10	−5,347,077	3,517,985	5,347,077
10 Year Total	−53,470,770	43,974,813	53,470,770

In developing our estimate, we acknowledge that this quantitative approach may fail to capture a societal cost pattern that may be somewhat concentrated in *upfront* transition activity—for example, the potential establishment of free-standing clinics to provide SRPs that would newly be prohibited at hospitals participating in Medicare.[98] There may also be costs for clinicians who provide SRPs for children at hospitals who would incur costs to move to other provider types where these procedures are allowed. We also acknowledge that some patients may choose new forms of treatment such as psychotherapy. Given these various uncertainties, we request comment on how to refine the estimation of regulatory costs.

2. Benefits

As we have noted throughout the proposed rule in Sections I and II, the proposed requirement is designed to ensure the health and safety of children by limiting SRPs given recent research that questions its efficacy and safety. Although we do not have quantitative financial data on the impact of the proposed rule's provision, we estimate the number of children who this proposed rule would positively affect using the same strategy used when estimating the rule's collection of information costs. Specifically, we expect that due to factors such as difficulty in identifying in-network providers that have available space and longer commute times to these providers [99] [100], half of the 8,570 (or 4,285) children who are receiving SRPs in hospitals would stop receiving these procedures leading to the avoidance of unnecessary health complications. As noted in the collection of information section, we assumed this percentage in the absence of quantitative data showing the number of children who will no longer seek SRPs. We seek comments on additional benefits that could emerge from these proposed requirements and sources of data to provide a quantitative estimate of the proposed rule's benefits. We also seek comments on sources of data to more accurately estimate the

[97] The latter portion of the estimate persists in any year when SRPs are estimated to occur at a reduced level due to the proposed rule. By contrast, the former effect is assumed to decline over the first several years of the analytic time horizon, as provider-switching patients age out of childhood.

[98] The cost of setting up separate specialty facilities (a process encompassing managerial, legal, and physical tasks) would exceed the cost of achieving only physical separation—estimated previously by the Department to be at least $20,000 to $40,000 per entity undertaking such actions. Please see *Compliance With Statutory Program Integrity Requirements,* 84 FR 7714, *https://www.federalregister.gov/d/2019-03461/* page-7782.

[99] Borah, Luca et al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA* vol. 330,4 (2023): 375–378. doi:10.1001/jama.2023.11299.

[100] Gridley, Samantha J et al. ''Youth and Caregiver Perspectives on Barriers to Gender-Affirming Health Care for Transgender Youth.'' *The Journal of Adolescent Health,* vol. 59,3 (2016): 254–261. doi: 10.1016/j.jadohealth.2016.03.017.

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number of children who will stop receiving SRPs.

C. Alternatives Considered

As we detailed earlier in this proposed rule, the growth in SRPs in children is a growing concern given recent research that questions its efficacy and safety. We believe that the changes we are proposing are necessary to ensure the health and safety of children throughout the United States and align with the best available scientific evidence. We acknowledge, however, that there are different standards that we could have used in developing these proposed requirements.

In developing this proposed rule, we considered aligning our requirements with those States that already have restrictions on SRPs but with a variety of exceptions they provide as outlined in Section 1.B of this proposed rule. For example, we could have allowed those currently receiving these procedures to continue receiving them. Ultimately, however, we have decided to adopt the proposed provisions with fewer exceptions than are allowed in these States to maximize health and safety for all children. We seek comments, however, on whether we should adopt one or more of the additional State exceptions related to SRPs.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the proposed rule when finalized, we assume that all hospitals will review this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is also possible that other individuals and providers will review this proposed rule. For these reasons we thought that doubling the number of Medicare or Medicaid certified hospitals (n = 4,832) would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 75 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this proposed rule is $132.44 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately ([9,500 words/250 words per minute] × 75 percent) 28.5 minutes for the staff to review 75 percent of this proposed rule. For each entity that reviews the rule, the estimated cost is $62.91 (0.475 hours × $132.44). Therefore, we estimate that the total cost of reviewing this regulation is $607,962 ($[62.91] × [9,664]).

E. Accounting Statement

As required by OMB Circular A–4 (available online at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 4 showing classification of the costs and benefits associated with the provisions of this proposed rule. This includes the total costs for hospitals providing notices to children and their parents that they are no longer providing SRPs as identified in Table 1, the cost for hospitals to update their policies and procedures in Table 2, the reduction in costs due to the ending of SRPs for some patients as well as an increase in cost for patients who seek new providers in Table 3, as well as the regulatory review costs. There are also transfer costs for patients seeking care at other providers as outlined in Table 3. There are $0 benefit estimates in the statement. This statement provides our best estimate for the Medicare and Medicaid provisions of this proposed rule.

TABLE 4—ACCOUNTING STATEMENT

Category	Estimate	Units		
		Year dollar	Discount rate (%)	Period covered
Annualized Monetized Costs ($million/year)	0.32–0.04	2024	7 or 3	2026–2035
Annualized Monetized Transfers ($million/year)	5.3	2024	7 or 3	2026–2035

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals (NAICS 6221) are considered small businesses either by the Small Business Administration's size standards with total revenues of $47.0 million or less in any single year or by the hospital's not for profit status. According to the 2022 Economic Census,[101] general medical and surgical hospitals (NAICS 6221) have revenues of $1.27 trillion.

Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. With estimated annual costs and reduction in transfers resulting in the loss of approximately $11.4 million in annual revenues for hospitals, which is approximately 0.0008 percent of revenues, this proposed rule would not have a significant economic impact as measured on a substantial number of small businesses or other small entities as measured by a change in revenue of 3 to 5 percent. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the statute requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the statute, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. With total requirement costs and the loss of transfers reducing hospital revenues by approximately $11.4 million annually for all 4,832 hospitals, or $2,194 per hospital, we expect that

[101] U.S. Census Bureau. ''All Sectors: Summary Statistics for the U.S., States, and Selected Geographies: 2022.'' *Economic Census, United States Census Bureau,* 2022, *data.census.gov/table/EC2200BASIC?q=EC2200BASIC.* Accessed 15 Dec. 2025.

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this proposed rule would have a negligible impact on small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This proposed rule does not mandate any spending requirements for State, local, or tribal governments, or for the private sector.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, pre-empts State law, or otherwise has federalism implications. This proposed rule would pre-empt State laws that prohibit SRPs for children that include exceptions for reasons beyond those exceptions provided in this proposed rule, including for children who are already undergoing these procedures. It would also pre-empt State laws requiring hospitals to provide SRPs.

Consistent with the Executive Order, we find that State and local laws that provide exceptions from the prohibition beyond those listed in this proposed rule, as well as State and local laws that require hospitals to provide SRPs for children, directly conflict with this exercise of CMS' statutory health and safety authority to prohibit providers subject to this proposed rule from providing these procedures.

Similarly, to the extent that State-run hospitals that receive Medicare and Medicaid funding are required by State or local law to provide SRPs for children except in those cases covered by our exceptions, there is direct conflict between the provisions of this proposed rule (prohibiting such procedures) and the State or local law (allowing them).

As is relevant here, this proposed rule preempts the applicability of any State or local law providing for SRPs to the extent such law provides broader grounds for these procedures than provided for by Federal law and are inconsistent with this proposed rule. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this proposed rule preempts State and local laws to the extent the State and local laws conflict with this proposed rule. The agency has considered other alternatives (for example, relying entirely on State laws prohibiting SRPs) and has concluded that the requirements established by this proposed rule are the minimum regulatory action necessary to achieve the objectives of the statute.

Given the growth in SRPs among children in recent years, we believe that the prohibition of these procedures for children is necessary to promote and protect patient health and safety. The agency has examined research on SRPs for children and concludes that it can cause permanent harm with uncertain benefits. We are inviting State and local comments on the substance as well as legal issues presented by this proposed rule, and its impact on them.

I. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' We followed the implementation guidance from OMB–M–25–20 (*https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf*) when estimating the proposed rule's impact related to the executive order. Specifically, we used a 7 percent discount rate when estimating the cost for the purposes of Executive Order 14192. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 17, 2025.

List of Subjects in 42 CFR Part 482

Grant programs health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 2. Section 482.46 is added to subpart C to read as follows:

§ 482.46 Condition of participation: Sex-rejecting procedures.

The hospital must not perform sex-rejecting procedures on any child.

(a) *Definitions.* As used in this section:

(1) ''Child'' means any individual younger than 18 years of age.

(2) ''Female'' means an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

(3) ''Male'' means an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

(4) ''Sex'' means an individual's immutable biological classification as either male or female.

(5) ''Sex-rejecting procedure'' means any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex either by:

(i) Intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits; or

(ii) Intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.

(b) Exceptions. The definition at paragraph (a)(5) of this section does not include procedures:

(1) To treat an individual with a medically verifiable disorder of sexual development;

(2) For purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex; or

(3) To treat complications, including any infection, injury, disease, or disorder that has been caused by or

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exacerbated by the performance of a sex-rejecting procedure.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23465 Filed 12–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 84

RIN 0945–AA27

Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department) issues this Notice of Proposed Rulemaking (NPRM) to revise 45 CFR 84.4(g) in the regulation implementing section 504 of the Rehabilitation Act of 1973 (section 504) as it applies to recipients of HHS funding (entitled ''Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance,'' 89 FR 40066 (''2024 Final Rule'')), published on May 9, 2024. This rule clarifies that the Department interprets the statutory exclusion of ''gender identity disorders not resulting from physical impairments'' from the definitions of ''individual with a disability'' and ''disability'' set forth at 29 U.S.C. 705(9) & (20)(F)(i), 42 U.S.C. 12211(b), to encompass ''gender dysphoria not resulting from a physical impairment'' for purposes of part 84. This clarification is necessary to resolve ambiguity introduced in the preamble to the 2024 Final Rule and to ensure compliance with the best reading of the plain language of the governing statute.

DATES: *Comments:* Submit comments on or before January 20, 2026.

ADDRESSES: You may submit comments to this proposed rule, identified by RIN Number 0945–AA27, by any of the following methods. Please do not submit duplicate comments.

Federal eRulemaking Portal: You may submit electronic comments at *https://regulations.gov* by searching for the Docket ID number XXXXX. Follow the instructions for submitting electronic comments. If you are submitting comments electronically, the department strongly encourages you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), the Department strongly encourages you to convert the PDF to ''print-to-PDF'' format, or to use some other commonly used searchable text format. Please do not submit the PDF in scanned format. Using a print-to-PDF allows the Department to electronically search and copy certain portions of your submissions to assist in the rulemaking process.

Regular, Express, or Overnight Mail: You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Disability NPRM, RIN 0945–AA27, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

All comments received by the methods and due date specified above, or officially post marked by the due date above, will be posted without change to content to *https://www.regulations.gov,* including any personal information provided, and such posting may occur after the closing of the comment period.

However, the Department may redact certain non-substantive content from comments before posting, including threats, hate speech, profanity, graphic images, or individually identifiable information about an individual third-party other than the commenter. In addition, comments or material designated as confidential or not to be disclosed to the public will not be accepted. Comments may be redacted or rejected as described above without notice to the commenter, and the Department will not consider in rulemaking any redacted or rejected content that would not be made available to the public as part of the administrative record. Because of the large number of public comments normally received on **Federal Register** documents, the Office for Civil Rights is not able to provide individual acknowledgements of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays.

Please note that comments submitted by fax or email and those submitted or postmarked after the comment period will not be accepted.

Docket: For a plain language summary of the proposed rule and complete access to background documents or posted comments, go to *https://www.regulations.gov* and search for Docket ID number XXXXX.

FOR FURTHER INFORMATION CONTACT: John Thompson, Office for Civil Rights, Department of Health and Human Services at (202) 545–4884 or (800) 537–7697 (TDD), or via email at *504@hhs.gov.*

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Background

Statutory Framework

Section 504 of the Rehabilitation Act of 1973, codified at 29 U.S.C. 794, prohibits discrimination on the basis of disability in federally assisted and federally conducted programs and activities. Specifically, 29 U.S.C. 794(a) provides: ''No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency[.]'' The HHS Office for Civil Rights (OCR) enforces section 504 as well as other statutes that prohibit discrimination on the basis of disability. Although the Rehabilitation Act predates the Americans with Disabilities Act of 1990 (ADA), Congress subsequently amended the Rehabilitation Act, through the Rehabilitation Act Amendments of 1992 (Pub. L. 102–569, sec. 102, 106 Stat 4344), to align key definitions in the Rehabilitation Act with key definitions in the ADA. Under these amendments, the term ''individual with a disability'' ''does not include an individual on the basis of . . . transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender

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STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL

STEVE MARSHALL
ATTORNEY GENERAL

501 WASHINGTON AVENUE
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February 17, 2026

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

Submitted electronically via http://www.regulations.gov

Re: Comments on proposed rulemakings: (1) "Medicare and Medicaid Programs: Hospital Condition of Participation: Prohibiting Sex Rejecting Procedures for Children" (Docket No. CMS-2025-1822-0001), and (2)"Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children" (Docket No. CMS-2025-1823-0001).

Dear Secretary Kennedy:

On behalf of the States of Alabama, XX, and XX, we write to comment on two proposed rules to restrict federal funding from subsidizing sex-change procedures for minors. Because those procedures have not been shown to be safe or effective for treating gender dysphoria in minors—and, in fact, have been shown to carry a great risk of harm—we agree that the federal government should stop paying for them. It should also stop subsidizing hospitals that provide the treatments. We support the proposed rules.

We write to provide additional information regarding the purported "standards of care" used by some providers to justify providing sex-change procedures to minors. As the proposed rules note, the organization that authors the primary treatment guideline is the World Professional Association for Transgender Health (WPATH). *See* 90 Fed. Reg. 59441, 59444-45. And as the proposed rules also note, those guidelines "are not trustworthy according to accepted standards for evaluating guideline quality," *id.* at 59445—or, frankly, any other standard.

Many of our States have learned this firsthand through litigating to defend our laws prohibiting the provision of sex-change procedures to minors. For instance, in 2022, shortly after the Alabama legislature passed a law prohibiting pediatric sex-change procedures, plaintiffs there sought a preliminary injunction

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based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[1] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[2] Its evidence-review team "found little to no evidence about children and adolescents."[3] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[4] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged. This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[6]

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[1] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[2] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10. Throughout this letter, the undersigned will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

[3] Ex.173(Doc.560-23):22.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186 (Doc.700-15):32.

[6] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; Leor Sapir, *"We're All Just Winging It": What The Gender Doctors Say in Private*, THE FREE PRESS (Dec. 3, 2025), https://www.thefp.com/p/were-all-just-winging-it-what-the; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

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The Services should have this additional information as it considers finalizing the proposed rules.

* * *

WPATH published Standards of Care 8 (SOC-8) in September 2022.[7] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[8] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[9] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[10] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[11] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[12] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[13]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[14]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[15] Dr. Bouman noted the oddity:

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[7] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.

[8] *Id.* at S248-49.

[9] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[10] Ex.18(Doc.564-8):121:7-11.

[11] Ex.21(Doc.700-3):158:17-25.

[12] Ex.184(Doc.700-13):24.

[13] Ex.184(Doc.700-13):15.

[14] Ex.182(Doc.700-11):152.

[15] Ex.4(Doc.557-4):vi.

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"The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[16] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[17]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[18]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[19] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens of lawsuits in the US right now";[20] "I cannot overstate the importance of SOC 8 getting this right at this important time."[21] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[22]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[23] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[24]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[25]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in

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[16] Ex.182(Doc.700-11):151.

[17] Ex.184(Doc.700-13):14.

[18] SOC-8, *supra* note 12, at S177.

[19] Ex.180(Doc.700-9):11.

[20] *Id.* at 64.

[21] Ex.181(Doc.700-10):43.

[22] *Id.* at 75.

[23] SOC-8, *supra* note 12, at S18.

[24] *Id.*

[25] Ex.181(Doc.700-10):36 (second closed parenthesis added).

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adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[26] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[27] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[28] all while authors and WPATH leaders raised such concerns internally.[29]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[30] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[31]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[32] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[33] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[34]

After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18,

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[26] SOC-8, *supra* note 12, at S45-46.

[27] Ex.174(Doc.560-24):1-2.

[28] Ex.184(Doc.700-13):55.

[29] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[30] Ex.184(Doc.700-13):54.

[31] *See* Ex.187(Doc.700-16):4-5.

[32] Ex.170(Doc.700-4):61-64.

[33] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[34] Ex.170(Doc.700-4):143.

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will result in devastating legislation for trans care."[35] WPATH leaders met with Levine to discuss the age recommendations.[36] Levine's solution was simple: "She asked us to remove them."[37]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[38]

- "I'm also curious how the group feels about us making changes based on current US politics.... I agree about listening to Levine."[39]

- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[40]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[41] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[42]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[43] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[44]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[45] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines ... have a very weak methodology, written by few friends who think the same."[46] But the political reality soon set in: AAP was

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[35] Ex.186 (Doc.700-15):28.
[36] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[37] Ex.186 (Doc.700-15):11.
[38] *Id.* at 32.
[39] *Id.*
[40] *Id.* at 33.
[41] *Id.* at 17.
[42] *Id.* at 57.
[43] *Id.* at 17.
[44] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.
[45] Ex.187(Doc.700-16):13-14, 109.
[46] *Id.* at 100.

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"a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[47] WPATH thus "remove[d] the ages."[48]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[49]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[50] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[51] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[52]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[53] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[54] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[55]

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[47] *Id.* at 191.
[48] *Id.* at 338.
[49] Ex.21(Doc.700-3):293:25–295:16.
[50] Ex.188(Doc.700-17):152.
[51] Ex.177(Doc.700-6):124.
[52] *Id.* at 119.
[53] Ex.188(Doc.700-17):113.
[54] *Id.*
[55] Ex.177(Doc.700-6):102.

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C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[56] Among other things, it boasts that WPATH managed conflicts of interest and engaged an evidence-review team to conduct systematic literature reviews.[57] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[58] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[59]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[60] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[61]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[62] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[63]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[64] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-

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[56] *See* SOC-8, *supra* note 12, at S247-51.

[57] *Id.*

[58] *Id.* at S247.

[59] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[60] Institute of Medicine, *supra* note 64, at 83.

[61] *Id.* (emphasis added).

[62] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[63] Ex.18(Doc.564-8):121:7-11.

[64] Institute of Medicine, *supra* note 64, at 78.

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8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[65] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[66]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or non-financial conflicts of interest."[67] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[68] Dr. Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[69] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[70] "Unfortunately," she lamented, "this was not done here."[71] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[72]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[73]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[74] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[75]

Chapter authors were then to grade the recommendation statements based on the evidence.[76] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of

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[65] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[66] SOC-8, *supra* note 12, at S177.
[67] Ex.21(Doc.700-3):230:17-23.
[68] Ex.174(Doc.560-24):7.
[69] Ex.166(Doc.560-16):1.
[70] *Id.* (emphasis added).
[71] *Id.*
[72] SOC-8, *supra* note 12, at S177.
[73] Ex.21(Doc.700-3):232:13-15.
[74] SOC-8, *supra* note 12, at S250.
[75] *Id.* at S249-50.
[76] *Id.* at S250.

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certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[77] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[78] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[79]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[80] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[81]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[82] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[83]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[84]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly

[77] *Id.*
[78] *Id.*
[79] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.
[80] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.
[81] Ex.39(Doc.592-39):66:2–67:5.
[82] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.
[83] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.
[84] SOC-8, *supra* note 12, at S48.

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"not possible."[85] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[86]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[87] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[88] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[89] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[90] She reported: "[W]e found little to no evidence about children and adolescents."[91]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[92] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[93] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[94] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of

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[85] *Id.* at S46-47.

[86] *Id.* at S111.

[87] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.

[88] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[89] Ex.173 (Doc.560-23):22-25.

[90] *Id.* at 24.

[91] *Id.* at 22.

[92] *Id.*

[93] Ex.167(Doc.560-17):86-88.

[94] *Id.* at 37-38, 75-81.

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the transgender community in the design, drafting of the article, and the *final approval* of the article."[95] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[96]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[97] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[98]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[99]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[100]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[101] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[102] That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[103]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[104] And other SOC-8 authors criticized the

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[95] *Id.* at 37 (emphasis added).

[96] *Id.* at 38.

[97] *Id.* at 91.

[98] *Id.* at 38.

[99] *Cf.* Ex.167(Doc.560-17):91.

[100] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).

[101] SOC-8, *supra* note 12, at S88.

[102] *Id.* at S88-89.

[103] Ex.21(Doc.700-3):172:19–173:25.

[104] *Id.*

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chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[105] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[106] No matter: The guideline that Plaintiffs rely on to ask this Court to reverse the trial court's factual findings recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[107] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[108] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[109] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[110] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[111]

Despite all this, advocates regularly promise that the WPATH Standards were developed using well-accepted processes and similar to other treatment guidelines. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[112]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[113] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal

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[105] Ex.182(Doc.700-11):96.

[106] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

[107] SOC-8, *supra* note 12, at S88.

[108] *Id.*

[109] *Id.*

[110] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[111] *Id.*

[112] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

[113] Ex.190(Doc.700-18):5 (capitalization altered).

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in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[114]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[115] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[116] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[117]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[118] The AAP, Dr. Coleman said, rejected WPATH's request.[119] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[120] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[121]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[122] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[123] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from

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[114] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[115] Ex.190(Doc.700-18):5-6.

[116] *Id.*

[117] *Id.* at 6 (spelling corrected).

[118] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[119] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.

[120] Ex.189(Doc.560-39):15.

[121] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[122] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

[123] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

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publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[124] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[125] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[126] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[127] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[128] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[129]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[130]

* * *

Much more could be said about how untrustworthy WPATH is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare

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[124] And online: https://adc.bmj.com/pages/gender-identity-service-series.

[125] *See generally* Ex.16(Doc.557-16).

[126] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[127] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[128] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[129] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[130] Ex.176(Doc.700-5):152.

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has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.... My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.... It occurred to me that how could anyone truly know how important sexual function was to a relationship, to happiness? It isn't an easy question to answer....[131]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[132]

We thus commend the Services work in this area and support the proposed rules that would stop subsidizing sex-change procedures for minors.

Respectfully submitted,

Steve Marshall

Steve Marshall
Attorney General of Alabama

[131] Ex.176(Doc.700-5):68.
[132] Ex.180(Doc.700-9):59.

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From:	Powell, Anthony J.
To:	Desch, Nikki
Subject:	FW: Join 2/17 3pm CT - HHS letter re: sex-change procedures
Date:	Monday, February 16, 2026 1:40:00 PM
Attachments:	2026.02.13 - Alabama et al Comment Letter DRAFT.docx 2025-23464.pdf 2025-23465.pdf 2025.10.20 - Alabama et al. Amicus Br. iso Ohio FILED.pdf

Joined.

From: Bowdre, Barrett <Barrett.Bowdre@AlabamaAG.gov>
Sent: Friday, February 13, 2026 9:55 AM
To: jenna.lorence@alaska.gov; cori.mills@alaska.gov; jessie.alloway@alaska.gov; ninia.dizon@alaska.gov; Autumn.Patterson@arkansasag.gov; solicitorgeneral.amicus@myfloridalegal.com; jeffrey.desousa@myfloridalegal.com; christopher.baum@myfloridalegal.com; Nathan.Forrester@myfloridalegal.com; David.Dewhirst@myfloridalegal.com; jason.muehlhoff@myfloridalegal.com; rbergethon@law.ga.gov; jhthompson@law.ga.gov; Kimi.White@ag.idaho.gov; isaac.considine@ag.idaho.gov; alan.hurst@ag.idaho.gov; Jack.Corkery@ag.idaho.gov; James.Barta@atg.in.gov; Lori.Torres@atg.in.gov; cory.voight@atg.in.gov; john.lowrey@atg.in.gov; Blake.Lanning@atg.in.gov; Eric.Wessan@ag.iowa.gov; Patrick.Valencia@ag.iowa.gov; Powell, Anthony J. <Anthony.Powell@ag.ks.gov>; Rodriguez, Jay <Jay.Rodriguez@ag.ks.gov>; Steinhilber, Adam <Adam.Steinhilber@ag.ks.gov>; Carswell, Dwight <Dwight.Carswell@ag.ks.gov>; Sciarrotta, Joe <Joe.Sciarrotta@ag.ks.gov>; matt.kuhn@ky.gov; Christopher.Thacker@ky.gov; RobertM.Duncan@ky.gov; JustinD.Clark@ky.gov; Jack.Heyburn@ky.gov; FriemanL@ag.louisiana.gov; ShortT@ag.louisiana.gov; AguinagaJ@ag.louisiana.gov; BrungardM@ag.louisiana.gov; Scott.Stewart@ago.ms.gov; Justin.Matheny@ago.ms.gov; Anthony.Shults@ago.ms.gov; Daniel.Kim@ago.ms.gov; Doug.Miracle@ago.ms.gov; MissouriSG@ago.mo.gov; Louis.Capozzi@ago.mo.gov; Christian.Corrigan@mt.gov; tanner.baird@mt.gov; casey.crowley@mt.gov; cody.barnett@nebraska.gov; Zachary.viglianco@nebraska.gov; zachary.pohlman@nebraska.gov; Anthony.J.Galdieri@doj.nh.gov; christopher.g.bond@doj.nh.gov; masagsve@nd.gov; pjaxt@nd.gov; Joshua.Richardson@OhioAGO.gov; Michael.Hendershot@OhioAGO.gov; Mathura.Sridharan@OhioAGO.gov; Amicus@OhioAGO.gov; zach.west@oag.ok.gov; garry.gaskins@oag.ok.gov; jennifer.lewis@oag.ok.gov; kbowser@attorneygeneral.gov; kking@attorneygeneral.gov; sraiola@attorneygeneral.gov; hjackson@attorneygeneral.gov; Esmith@scag.gov; Bcook@scag.gov; ThomasHydrick@scag.gov; josephspate@scag.gov; Paul.Swedlund@state.sd.us; grant.flynn@state.sd.us; Matt.Rice@ag.tn.gov; Alicia.Gilbert@ag.tn.gov; Chris.Tutor@ag.tn.gov; brent.webster@oag.texas.gov; ralph.molina@oag.texas.gov; ryan.walters@oag.texas.gov; christina.cella@oag.texas.gov; beth.boulton@oag.texas.gov; william.peterson@oag.texas.gov; aaron.barnes@oag.texas.gov; Spurser@agutah.gov; danburton@agutah.gov; Michael.R.Williams@wvago.gov; hwilson@wvago.gov; ryan.schelhaas@wyo.gov
Cc: Robertson, Katherine <Katherine.Robertson@AlabamaAG.gov>
Subject: Join 2/17 3pm CT - HHS letter re: sex-change procedures

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CAUTION: This email originated from outside of the Office of The Attorney General of

Kansas organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi friends,

Alabama invites you to join a comment letter supporting two proposed regulations by the Centers for Medicare & Medicaid Services at HHS. The first would require States to ensure that their Medicaid and State CHIP plans do not fund sex-change procedures for minors. The second would prohibit hospitals from performing sex-change procedures on minors in order to be participate in Medicare and Medicaid programs.

The bad news is that **joins are due by Tuesday, February 17, at 3pm CT**. The good news is that you have seen 95% of the letter before. Because both proposed rules explain why they are departing from the purported "standards of care" recommended by American medical interest groups, we thought it could be helpful to shore up the administrative record with a bit more evidence about why the WPATH Standards cannot be trusted. So, our letter is basically a version of our well-worn WPATH brief. We filed a version of this brief in support of Ohio in October and were joined there by Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming.

I have attached our draft comment letter, the two regulations, and the Ohio brief. Please let me know if you have any questions or would like to join (and send along your AG's signature).

Again, **we can take joins until 3pm CT on Tuesday, February 17.**

Thanks,
Barrett

Barrett Bowdre
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From: Powell, Anthony J.
To: Desch, Nikki
Subject: FW: Join 2/17 3pm CT - HHS letter re: sex-change procedures
Date: Monday, February 16, 2026 1:40:00 PM
Attachments: [redacted]

Joined.

From: Bowdre, Barrett <Barrett.Bowdre@AlabamaAG.gov>
Sent: Friday, February 13, 2026 9:55 AM
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Subject: Join 2/17 3pm CT - HHS letter re: sex-change procedures

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CAUTION: This email originated from outside of the Office of The Attorney General of

Kansas organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi friends,

Alabama invites you to join a comment letter supporting two proposed regulations by the Centers for Medicare & Medicaid Services at HHS. The first would require States to ensure that their Medicaid and State CHIP plans do not fund sex-change procedures for minors. The second would prohibit hospitals from performing sex-change procedures on minors in order to be participate in Medicare and Medicaid programs.

The bad news is that **joins are due by Tuesday, February 17, at 3pm CT**. The good news is that you have seen 95% of the letter before. Because both proposed rules explain why they are departing from the purported "standards of care" recommended by American medical interest groups, we thought it could be helpful to shore up the administrative record with a bit more evidence about why the WPATH Standards cannot be trusted. So, our letter is basically a version of our well-worn WPATH brief. We filed a version of this brief in support of Ohio in October and were joined there by Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming.

I have attached our draft comment letter, the two regulations, and the Ohio brief. Please let me know if you have any questions or would like to join (and send along your AG's signature).

Again, **we can take joins until 3pm CT on Tuesday, February 17.**

Thanks,
Barrett

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In the
Supreme Court of Ohio

MADELINE MOE, *et al.*,	)	Case No. 2025-0472
	)	
Plaintiffs-Appellees,	)	On Appeal from the Franklin County Court of Appeals,
	)	
v.	)	Tenth Appellate District
	)	
DAVE YOST, *et al.*,	)	Court of Appeals
	)	Case No. 24AO-483
Defendants-Appellants.	)	

BRIEF OF *AMICI CURIAE* STATE OF ALABAMA AND 24 OTHER STATES IN SUPPORT OF APPELLANTS AND REVERSAL

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INTRODUCTION

By its own account, the Tenth District's reasoning rises or falls with WPATH—the World Professional Association for Transgender Health. Based on its cherrypicked reading of amicus briefs since rejected by the U.S. Supreme Court in *United States v. Skrmetti*, 145 S. Ct. 1815 (2025), the Tenth District concluded that, along with the Endocrine Society, WPATH is one of the "standard-bearers in gender-affirming care" and that its guidelines "are the current prevailing standards of care for the treatment of individuals with gender dysphoria." *See Moe v. Yost*, 2025-Ohio-941 (10th Dist. Mar. 18, 2025) ("Op."), ¶¶14, 19; *see also* ¶¶13 & n.8, 70 & n.32 (discussing *Skrmetti* amicus briefs supporting WPATH). The court's legal analysis was based on this factual finding. As it wrote, the court "consider[ed] the constitutional issues in this case by accepting the Guidelines as the prevailing standards of care." Op. ¶20.

For all the reasons the Ohio Attorney General explains in his brief, it is doubtful that the Ohio Constitution outsources the State's regulation of medicine to the very interest groups whose members are being regulated. So the Tenth District's starting premise is almost certainly wrong. If the General Assembly wished to regulate the prescription of opioids, for instance, it could do so in the face of conflicting "guidelines" by the American Pain Society. So, too, could it restrict children's access to opioids—again, even if the American Pain Society, and even if the child's parents, thought differently. So it is here.

Yet even if the Tenth District's reasoning were sound, reversal would still be warranted because the WPATH guidelines are simply not trustworthy. Even Plaintiffs now tacitly acknowledge that fact. Though they built their case on the promise that "[t]he medical profession's generally accepted guidelines for treating gender dysphoria are issued by the Endocrine Society

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and the World Professional Association for Transgender Health (WPATH),"[1] Plaintiffs now say that only "[t]he Endocrine Society Guideline is the standard of care widely accepted by the medical community across our country." *See* Appellees' Mem. in Response to Jurisdiction at 2. What happened?

What happened is court-ordered discovery. In 2022, shortly after the Alabama legislature passed a law prohibiting pediatric sex-change procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[2] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[3] Its evidence-review team "found little to no evidence

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[1] Br. of Appellants, No. 24AP-483 (10th Dist.), at 11 (emphasis added).

[2] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[3] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10.

Throughout this brief, *amici* will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

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about children and adolescents."[4] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[5] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[6] WPATH obliged.

This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[7] And Plaintiffs' counsel are well aware of this evidence, having been involved in other cases where it has been discussed. *See, e.g.*, *Skrmetti*, 145 S. Ct. at 1847-49 (Thomas, J., concurring) (noting "[r]ecent revelations [that] suggest that WPATH, long considered a standard bearer in treating pediatric gender dysphoria, bases its guidance on insufficient evidence and allows politics to influence its medical conclusions" (citation omitted)). One of their expert witnesses—Dr. Antommaria—even served as an expert witness in Alabama's case and thus had direct access to the discovery there.

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[4] Ex.173(Doc.560-23):22.

[5] Ex.174(Doc.560-24):1-2.

[6] Ex.186 (Doc.700-15):32.

[7] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

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No wonder Plaintiffs are running away from WPATH. But running to the Endocrine Society guideline is no answer because WPATH helped write it, too. As the Cass Review for England's National Health Service explained, the "two guidelines" are "closely interlinked, with WPATH adopting Endocrine Society recommendations, and acting as a co-sponsor and providing input to drafts of the Endocrine Society guideline."[8] Indeed, not only did WPATH sponsor both the 2009 and 2017 Endocrine Society guidelines, but the 2017 Endocrine Society guideline and WPATH's SOC-8 were also "closely linked through overlapping authors."[9] And the groups' guidelines "influenced nearly all the other guidelines" by other organizations, so there is simply no escaping WPATH's fingerprints in any of the pro-affirming guidelines.[10] As the Cass Review concluded, "[t]he circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[11]

Plaintiffs thus cannot outrun WPATH. And they cannot escape the fact that they built their case on a faulty cornerstone. This Court should reverse.

INTEREST OF *AMICI CURIAE*

Like Ohio, *amici* States determined that sex-change procedures should not be made available to kids. That determination should not be controversial. *Amici* have always regulated healthcare. *See Dent v. West Virginia*, 129 U.S. 114, 121-24 (1889). And until a few years ago, the

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[8] *The Cass Review: Independent Review of Gender Identity Services for Children and Young People* 130 (Apr. 2024), https://perma.cc/3QVZ-9Y52; *see also* Jo Taylor et al., *Clinical Guidelines for Children and Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review of Guideline Quality (Part 1)*, ARCH. DIS. CHILD. S71 (2024), https://perma.cc/F3HW-FJAS ("These two guidelines are themselves linked through cosponsorship and like other guidelines lack a robust and transparent approach to their development.").

[9] Dep't of Health and Human Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* 133 (May 1, 2025), https://perma.cc/F236-84DW.

[10] *Cass Review*, *supra* note 8, at 130.

[11] *Id.*

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notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized. *Amici* write to share a little about how we got here.

STATEMENT

I. The WPATH Guidelines Are Not Reliable.

WPATH published Standards of Care 8 (SOC-8) in September 2022.[12] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[13] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[14] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[15] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen

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[12] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.
[13] *Id.* at S248-49.
[14] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.
[15] Ex.18(Doc.564-8):121:7-11.

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[their] position in court."[16] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[17] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[18]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[19]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[20] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[21] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[22]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[23]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[24] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens

[16] Ex.21(Doc.700-3):158:17-25.
[17] Ex.184(Doc.700-13):24.
[18] Ex.184(Doc.700-13):15.
[19] Ex.182(Doc.700-11):152.
[20] Ex.4(Doc.557-4):vi.
[21] Ex.182(Doc.700-11):151.
[22] Ex.184(Doc.700-13):14.
[23] SOC-8, *supra* note 12, at S177.
[24] Ex.180(Doc.700-9):11.

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of lawsuits in the US right now";[25] "I cannot overstate the importance of SOC 8 getting this right at this important time."[26] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[27]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[28] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[29]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[30]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter,

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[25] *Id.* at 64.
[26] Ex.181(Doc.700-10):43.
[27] *Id.* at 75.
[28] SOC-8, *supra* note 12, at S18.
[29] *Id.*
[30] Ex.181(Doc.700-10):36 (second closed parenthesis added).

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for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[31] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[32] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[33] all while authors and WPATH leaders raised such concerns internally.[34]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[35] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[36]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the

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[31] SOC-8, *supra* note 12, at S45-46.

[32] Ex.174(Doc.560-24):1-2.

[33] Ex.184(Doc.700-13):55.

[34] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[35] Ex.184(Doc.700-13):54.

[36] *See* Ex.187(Doc.700-16):4-5.

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publisher for proofreading and typesetting.[37] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[38] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[39]

After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[40] WPATH leaders met with Levine to discuss the age recommendations.[41] Levine's solution was simple: "She asked us to remove them."[42]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[43]

- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[44]

[37] Ex.170(Doc.700-4):61-64.
[38] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.
[39] Ex.170(Doc.700-4):143.
[40] Ex.186 (Doc.700-15):28.
[41] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[42] Ex.186 (Doc.700-15):11.
[43] *Id.* at 32.
[44] *Id.*

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- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[45]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[46] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[47]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[48] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[49]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[50] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same."[51] But the political reality soon set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[52] WPATH thus "remove[d] the ages."[53]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical

[45] *Id.* at 33.
[46] *Id.* at 17.
[47] *Id.* at 57.
[48] *Id.* at 17.
[49] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.
[50] Ex.187(Doc.700-16):13-14, 109.
[51] *Id.* at 100.
[52] *Id.* at 191.
[53] *Id.* at 338.

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guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[54]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[55] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[56] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[57]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[58] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[59] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[60]

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[54] Ex.21(Doc.700-3):293:25–295:16.
[55] Ex.188(Doc.700-17):152.
[56] Ex.177(Doc.700-6):124.
[57] *Id.* at 119.
[58] Ex.188(Doc.700-17):113.
[59] *Id.*
[60] Ex.177(Doc.700-6):102.

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C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[61] Among other things, it boasts that WPATH managed conflicts of interest and engaged an evidence-review team to conduct systematic literature reviews.[62] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[63] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[64]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[65] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[66]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were

[61] *See* SOC-8, *supra* note 12, at S247-51.
[62] *Id.*
[63] *Id.* at S247.
[64] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).
[65] Institute of Medicine, *supra* note 64, at 83.
[66] *Id.* (emphasis added).

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already enthusiastic about transitioning treatments.[67] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[68]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[69] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[70] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[71]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[72] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[73] Dr.

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[67] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.
[68] Ex.18(Doc.564-8):121:7-11.
[69] Institute of Medicine, *supra* note 64, at 78.
[70] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[71] SOC-8, *supra* note 12, at S177.
[72] Ex.21(Doc.700-3):230:17-23.
[73] Ex.174(Doc.560-24):7.

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Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[74] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[75] "Unfortunately," she lamented, "this was not done here."[76] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[77]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[78]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[79] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[80]

Chapter authors were then to grade the recommendation statements based on the evidence.[81] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved,"

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[74] Ex.166(Doc.560-16):1.
[75] *Id.* (emphasis added).
[76] *Id.*
[77] SOC-8, *supra* note 12, at S177.
[78] Ex.21(Doc.700-3):232:13-15.
[79] SOC-8, *supra* note 12, at S250.
[80] *Id.* at S249-50.
[81] *Id.* at S250.

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"few downsides," and "a high degree of acceptance among providers."[82] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[83] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[84]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[85] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[86]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[87] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[88]

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[82] *Id.*
[83] *Id.*
[84] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.
[85] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.
[86] Ex.39(Doc.592-39):66:2–67:5.
[87] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.
[88] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

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At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[89]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[90] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[91]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[92] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[93] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

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[89] SOC-8, *supra* note 12, at S48.
[90] *Id.* at S46-47.
[91] *Id.* at S111.
[92] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.
[93] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

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E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[94] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[95] She reported: "[W]e found little to no evidence about children and adolescents."[96]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[97] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[98] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[99] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[100] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[101]

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[94] Ex.173 (Doc.560-23):22-25.
[95] *Id.* at 24.
[96] *Id.* at 22.
[97] *Id.*
[98] Ex.167(Doc.560-17):86-88.
[99] *Id.* at 37-38, 75-81.
[100] *Id.* at 37 (emphasis added).
[101] *Id.* at 38.

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This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[102] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[103]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[104]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[105]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[106] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[107] That's not an exaggeration. When asked at his

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[102] *Id.* at 91.
[103] *Id.* at 38.
[104] *Cf.* Ex.167(Doc.560-17):91.
[105] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).
[106] SOC-8, *supra* note 12, at S88.
[107] *Id.* at S88-89.

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deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[108]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[109] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[110] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[111] No matter: The guideline that Plaintiffs rely on to ask this Court to reverse the trial court's factual findings recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[112] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[113] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[114] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[115] "The fictional pornography" "includes themes such as Nazi doctors

[108] Ex.21(Doc.700-3):172:19–173:25.
[109] *Id.*
[110] Ex.182(Doc.700-11):96.
[111] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.
[112] SOC-8, *supra* note 12, at S88.
[113] *Id.*
[114] *Id.*
[115] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

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castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[116]

Despite all this, Plaintiffs told the court below that the WPATH guideline was developed "using well-accepted processes" and is "comparable to treatment guidelines used in many other areas of medicine." Br. of Appellants, No. 24AP-483 (Tenth Appellate District), at 11-12. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[117]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[118] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[119]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He

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[116] *Id.*
[117] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.
[118] Ex.190(Doc.700-18):5 (capitalization altered).
[119] *Id.*; *see* Ex.16(Doc.557-16):¶103.

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noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[120] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[121] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[122]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[123] The AAP, Dr. Coleman said, rejected WPATH's request.[124] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[125] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[126]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[127] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the

[120] Ex.190(Doc.700-18):5-6.
[121] *Id.*
[122] *Id.* at 6 (spelling corrected).
[123] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.
[124] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.
[125] Ex.189(Doc.560-39):15.
[126] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.
[127] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

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Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[128] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[129] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[130] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[131] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from

[128] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.
[129] And online: https://adc.bmj.com/pages/gender-identity-service-series.
[130] *See generally* Ex.16(Doc.557-16).
[131] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

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gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[132] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[133] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[134]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[135]

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Much more could be said about how untrustworthy Plaintiffs' once-favorite medical organization is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough…. It occurred to me that how could anyone truly know

[132] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[133] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[134] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[135] Ex.176(Doc.700-5):152.

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> how important sexual function was to a relationship, to happiness? It isn't an easy question to answer….[136]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[137]

II. The General Assembly Rejects The WPATH Model Of "Care," Which The Tenth District Rules It Cannot Do.

In January 2024, the Ohio General Assembly enacted the "Saving Ohio Adolescents from Experimentation" Act to prohibit doctors from administering puberty blockers, cross-sex hormones, and sex-change surgeries to minors for the purpose of gender transition. *See* R.C. 3129.02(A)(1), (2). In doing so, the State definitively rejected the WPATH model of "care."

Following a five-day trial, the trial court upheld the State's law against challenge. Com. Pl. Op. 12 (Aug. 6, 2024). The Tenth District reversed on two grounds, both premised on the reliability of the WPATH Standards of Care. *See* Op.¶20 ("[W]e find support for our decision to consider the constitutional issues presented in this case by accepting the Guidelines as the prevailing standards of care for gender dysphoria.").

First, the court held that the Healthcare Freedom Amendment restricted the General Assembly's authority to regulate medicine to instances where the regulation is "in accordance with the prevailing standards of care." Op.¶73. Because the Act's prohibitions on sex-change procedures for minors were *not* in accordance with the WPATH Standards, the court held, the Act violated the Healthcare Freedom Amendment.

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[136] Ex.176(Doc.700-5):68.
[137] Ex.180(Doc.700-9):59.

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Second, the Tenth District held that the Act violates the Due Course of Law Clause because it interferes with "a parent's fundamental right to direct the medical care of their child" in accordance with "medically accepted standards." Op.¶87. Here again, the court reasoned, because WPATH set the "standard," and Ohio departed from WPATH, the Act was unconstitutional.

This appeal followed. This Court stayed the Tenth District's order and accepted jurisdiction and agreed to review the judgment below. *See Moe v. Yost*, 2025-Ohio-1483; *Moe v. Yost*, 2025-Ohio-2537.

ARGUMENT

This case presents a question of fundamental importance to self-governance: whether the people's representatives in the Ohio General Assembly are bound by guidelines promulgated by interest groups like WPATH or, instead, interest groups like WPATH are bound by medical regulations enacted by the General Assembly. Who regulates whom?

The answer to that question matters in this case because children deserve so much better than the WPATH Standards. After spending years conducting a comprehensive review for the National Health Service in England, Dr. Hilary Cass summed up her findings: "I can't think of another area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[138] No wonder countries in Europe are restricting minors' access to the "treatments." *See* Lavietes, *Britain Bans Puberty Blockers for Transgender Minors*, NBC NEWS (Dec. 11, 2024), https://perma.cc/3Q4SNV8E; Ghorayshi, *Scotland Pauses Gender Medications for Minors*, N.Y. TIMES (Apr. 18, 2024), https://perma.cc/4YV6- FCX5 (noting Scotland became "the sixth country in Europe to limit" access).

[138] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024), https://perma.cc/KUM3-XL2S.

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The co-chair of the adolescent chapter of WPATH's SOC-8, Annelou de Vries, does not even seem to disagree with Dr. Cass's assessment. Dr. de Vries is a seminal researcher in the field, having co-authored the original "Dutch studies" on which everything else has been built. In a recent essay, she tacitly admitted the truth of "the critique that there is insufficient evidence," and wrote to "question" the "normative assumption" that pediatric sex-change procedures "must necessarily result in 'effective' outcomes in order to be considered legitimate and essential care."[139] She suggested instead that sex-changes for kids be "provided and justified on the basis of personal desire and autonomy," that "effectiveness" be measured by how well the procedures "help individuals achieve their embodiment goals," and that any "experience of regret" be welcomed as "inherent to all lives."[140]

This case asks whether the Ohio General Assembly is powerless to disagree.

State Appellants' Proposition of Law No. 1:

> *The Due Course of Law Clause does not create a parental right to obtain drug-based "gender transitions" for a child.*

The Tenth District reasoned that Ohio's Due Course of Law Clause is coextensive with the Fourteenth Amendment's Due Process Clause, including its purported right to substantive due process. But there is no right for parents to obtain sex-change procedures for their children that is deeply rooted in our Nation's history and tradition, and the general recognition that parents can direct the medical care of their children does not afford them the ability to subject every restricted treatment to strict scrutiny (and make judges de facto medical regulators in the process). Were it

[139] Oosthoek, de Vries, et al., *Gender-affirming Medical Treatment for Adolescents*, 25 BMC MEDICAL ETHICS 154 (2024), https://perma.cc/8W4R-CEG7.
[140] *Id.*

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otherwise, parents could unlock access to vaccines before FDA approval and to euthanasia drugs that a State prohibits.

Nor does the Tenth District's restriction to "accepted standards" help matters. Op.¶103. It simply raises another problem: accepted by whom? Not the General Assembly or other government regulators, the Tenth District says, but WPATH. But our nation's "history and tradition" is that governments regulate medical providers, not the other way around. *E.g.*, *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 302 (2022) ("The Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion."). "This country does not have a custom of permitting parents to obtain banned medical treatments for their children and to override contrary legislative policy judgments in the process." *L.W. v. Skrmetti*, 83 F.4th 460, 475 (6th Cir. 2023). Indeed, "[i]f parents could veto legislative and regulatory policies about drugs and surgeries permitted for children, every such regulation—there must be thousands—would come with a springing easement: It would be good law until one parent in the country opposed it," at which point "either the parent would take charge of the regulation or the courts would." *Id.*

State Appellants' Proposition of Law No. 2:

> *The Health Care Freedom Amendment does not create a parental right to obtain drug-based "gender transitions" for a child.*

The Tenth District also wrongly deferred to WPATH when interpreting the Health Care Freedom Amendment. By its express terms, the Amendment "does not … affect any laws calculated to deter fraud or punish wrongdoing in the health care industry." Ohio Const. art. I, §21(d). The Act here does both by rejecting the fraudulent WPATH model of care and protecting minors from unproven, high-risk procedures that are justified by their primary proponents on grounds that

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children have the right to experience "regret."[141] The Health Care Freedom Amendment, enacted to prevent an individual mandate to compel insurance coverage, does nothing to the General Assembly's traditional power to regulate medicine—even when doing so departs from the wishes of the interest groups whose members are being regulated.

CONCLUSION

The Court should reverse the Tenth District's judgment.

Dated: October 20, 2025

Respectfully submitted,

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[141] Oosthoek, *supra* note 139.

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through the Local Notice to Mariners, Broadcast Notice to Mariners, Marine Safety Information Bulletins, or Coast Guard Advisory Notices.

(b) *Definitions.* As used in this section, *Designated Representative* means a Coast Guard coxswain, petty officer, or other officer or a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the security zone.

Foreign Naval Vessel means any naval vessel of a foreign state, which is not required to be licensed for entry into the U.S. for visit purposes under 22 CFR 126.6, provided it is not undergoing repair or overhaul.

U.S. Naval Vessel means any vessel owned, operated, chartered, or leased by the U.S. Navy; any pre-commissioned vessel under construction for the U.S. Navy, once launched into the water; and any vessel under the operational control of the U.S. Navy or a Combatant Command.

(c) *Regulations.* (1) Under the general security zone regulations in subpart C of this part, you may not enter the security zones described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's Representative on VHF–FM channel 16 or by telephone at (844) NYC–USCG. Those in a security zone must comply with all lawful orders or directions given to them by the COTP or the COTP representative.

(3) The Coast Guard Northeast District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov.*

Dated: December 16, 2025.

M.E. Platt,

Rear Admiral, U.S. Coast Guard, Commander, Coast Guard Northeast District.

[FR Doc. 2025–23435 Filed 12–18–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 441 and 457

[CMS–2451–P]

RIN 0938–AV73

Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would require that a State Medicaid plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under 18 and prohibit the use of Federal Medicaid dollars to fund sex-rejecting procedures for individuals under the age of 18. In addition, it would require that a separate State Children's Health Insurance Program (CHIP) plan must provide that the CHIP agency will not make payment under the plan for sex-rejecting procedures for children under 19 and prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures for individuals under the age of 19.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–2451–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2451–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2451–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *MedicaidSRPInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background [1]

Title XIX of the Social Security Act (the Act) authorizes Federal grants to the States for Medicaid programs to

[1] This document contains links to non-U.S. Government websites. We are providing these links because they contain additional information relevant to the topics discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are providing these links for reference only; linking to a non-U.S. Government website does not constitute an endorsement by CMS, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by U.S. Government websites do not apply to third-party sites.

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provide medical assistance to persons with limited income and resources and title XXI of the Act authorizes Federal grants to States to provide child health assistance to targeted low-income children under age 19 through a separate CHIP, a Medicaid-expansion program, or a combination of the two. Separate CHIPs are programs under which a State receives Federal funding from its title XXI allotment to provide child health assistance through coverage that meets the requirements of section 2103 of the Act and 42 CFR 457.402. For the purposes of this proposed rule, the term CHIP is used to refer to separate CHIPs. Medicaid and CHIP programs are administered primarily by the States, subject to Federal oversight and approval. Each State establishes its own Medicaid and CHIP eligibility standards, benefits packages, and payment rates in accordance with (and subject to) Federal statutory and regulatory requirements. If States comply with requirements in the Federal Medicaid and CHIP statutes and regulations (such as reflected in the provisions of their Federally-approved State plans), the Federal Government will match their expenditures with Federal funds. Each State Medicaid program and CHIP must be described and administered in accordance with a Federally approved State plan. This comprehensive document describes the nature and scope of the States' Medicaid program and CHIP and provides assurances that they will be administered in conformity with applicable Federal requirements.

Under title XIX, the Federal Government makes matching payments to States for medical assistance expenditures according to the formula described in sections 1903 and 1905(b) of the Act. Under title XXI, the Federal Government makes matching payments to States for child health assistance at the enhanced Federal medical assistance percentage (FMAP) established under section 2105 of the Act. Section 1903 of the Act requires that the Secretary of Health and Human Services (the Secretary) (except as otherwise provided) pay to each State which has a plan approved under title XIX of the Act, for each quarter, an amount equal to the FMAP of the total amount expended by the State during such quarter as medical assistance under the State plan. Section 1905(b) of the Act defines the FMAP. For CHIP, section 2105 requires the Secretary to pay each State with an approved plan under title XXI of the Act, for each quarter, an amount equal to the enhanced FMAP of expenditures in the quarter, paid from the State allotment. The enhanced FMAP, as defined at section 2105(b), for a State for a fiscal year, is equal to the FMAP (as defined in the first sentence of section 1905(b)) for the State increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such FMAP for the State is less than (2) 100 percent; but in no case shall the enhanced FMAP for a State exceed 85 percent.

As relevant to this proposed rule, among the statutory requirements for Medicaid State plans, section 1902(a)(19) of the Act [2] requires that a State plan for medical assistance provide such safeguards as may be necessary to assure that care and services under the plan will be provided in a manner consistent with the best interests of the recipients. Furthermore, under section 1902(a)(30)(A) of the Act,[3] the State plan must provide such methods and procedures relating to payment for care and services as may be necessary to assure that payments are consistent with quality of care. Among the statutory requirements for CHIP State plans, under section 2101(a) of the Act, funds are provided to States to provide health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

Section 1102 of the Act requires the Secretary to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is charged under the Act. In Medicaid, these Secretarial functions would include oversight of Medicaid State programs for consistency with the requirements of sections 1902(a)(19) and 1902(a)(30)(A) of the Act. In CHIP, these Secretarial functions would include oversight of CHIP under section 2101(a), which calls for effective and efficient administration of CHIP and coordination with other health care programs, including Medicaid, and under section 2107(e) of the Act, carrying out the functions required by the Medicaid provisions that apply to title XXI in the same manner as they apply under title XIX.

On January 28, 2025, President Trump issued Executive Order (E.O.) 14187, Protecting Children from Chemical and Surgical Mutilation (E.O. 14187). Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions for specific programs, including Medicaid. The Centers for Medicare & Medicaid Services (CMS) is aware that the U.S. District Court for the Western District of Washington has issued a preliminary injunction that enjoins defendant agencies from enforcing or implementing section 4 of E.O. 14187 within the plaintiff States, as well as sections 3(e) or 3(g) of E.O. 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (E.O. 14168), to condition or withhold Federal funding based on the fact that a health care entity or health professional provides ''gender-affirming care'' within the plaintiff States. *Washington* v. *Trump*, 768 F. Supp. 3d 1239, 1282 (W.D. Wash. 2025). In addition, the U.S. District Court for the District of Maryland has issued a preliminary injunction that enjoins the Federal defendants in that case from conditioning, withholding, or terminating Federal funding under section 3(g) of E.O. 14168 and section 4 of E.O. 14187, based on the fact that a healthcare entity or health professional provides ''gender-affirming care'' to a patient under the age of 19 and required that written notice of this order be given to the aforementioned groups that Defendants may not take any steps to implement, give effect to, or reinstate under a different name the directives in section 3(g) of E.O. 14168 or section 4 of E.O. 14187 that condition or withhold Federal funding based on the fact that a healthcare entity or health professional provides ''gender-affirming medical care'' to a patient under the age of 19. *PFLAG, Inc.* v. *Trump*, 769 F. Supp. 3d 405, 455 (D. Md. 2025). We note that if this proposed rule were to be finalized, it would not conflict with those preliminary injunctions because, among other things, it would be based

[2] Section 1902(a)(19) of the Act states that a State plan for medical assistance must ''provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients.''

[3] Section 1902(a)(30)(A) of the Act states that a State plan for medical assistance must ''provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) of the Act) 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.''

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on independent legal authority and section 5(a) of E.O. 14187 and not the enjoined sections of the executive orders. In any event, any regulatory provisions on this issue would not be effective until the specified effective date of any final rule, and would not be implemented, made effective, or enforced in contravention of any court orders.

As further discussed later in this proposed rule, we propose to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act by adding a new subpart N to 42 CFR part 441 to prohibit the use of Federal Medicaid dollars to fund sex-rejecting procedures, as defined in this proposed rule, for individuals under the age of 18. In addition, we propose to implement section 2103 of the Act by revising subpart D of part 457 of the Act to prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures, as defined in this proposed rule, for individuals under the age of 19. These proposed changes would not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

A. The Rise of Sex-Rejecting Procedures for Treatment of Gender Dysphoria in Minors

Over the past decade, increasing numbers of children and adolescents have been diagnosed with gender dysphoria. The recorded prevalence of gender dysphoria/incongruence increased substantially in children and young people between 2011 and 2021, particularly in recorded females. Levels of anxiety, depression and self-harm were high, indicating an urgent need for better prevention and treatment of mental health difficulties in these patients [with gender dysphoria].[4]

Similar research in Germany showed increasing rates in the diagnosis of gender incongruence.[5] Additionally, research in England explained that ''[r]ecent increases in incidence of gender dysphoria/incongruence have a range of potential explanations, including social factors (for example, . . . increasing use of social media and networking); increasing rates of emotional distress and poor mental health in this age group, particularly for females; and changes in supply and delivery of healthcare.'' [6] The number of children receiving medical interventions for gender dysphoria rose significantly following the publication of the ''Dutch Protocol'' in an article in the *European Journal of Endocrinology in* 2006.[7] Over the past decade, increasing numbers of children have received diagnoses of gender dysphoria and received sex-rejecting procedures as recommended by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (ES).[8] [9] The WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC–8) noted that the creation of a chapter on adolescents was due in part to the ''exponential growth in adolescent referral rates.'' [10] Surveys measuring ''transgender'' identity find prevalence of 1.2 percent among adolescents and ''gender diverse'' identities as high as 9 percent.[11] WPATH also noted that female adolescents were seeking such procedures at twice to seven times the rate of males.[12]

Included in SOC–8 is the recommendation that care providers ''undertake a comprehensive biopsychosocial assessment of adolescents'' who seek medical transition [13] and ''involve relevant disciplines, including mental health and medical professionals,'' as well as parents, ''unless their involvement is determined to be harmful.'' [14]

The number of pediatric patients seeking sex-rejecting procedures can only be roughly estimated. In recent years, ''the United States—characterized by its decentralized and privatized healthcare system—saw the emergence of many new specialty gender clinics, along with a proliferation of independently practicing clinicians. According to a recent conservative estimate, as of March 2023 there were 271 clinics offering [pediatric medical transition] in the U.S., though 70 were inactive due to legislative restrictions.'' [15]

An approach for gender dysphoria, referred to in this proposed rule as sex-rejecting procedures,[16] can involve the use of puberty suppressing drugs to prevent the onset of puberty; cross-sex hormones to spur the secondary sex characteristics of the opposite sex; and surgeries including mastectomy and (in rare cases) vaginoplasty. ''Thousands of American children and adolescents have received these interventions.'' [17]

A study published in 2023 estimated that between 2016 and 2020, nearly 3,700 children between the ages of 12 and 18 diagnosed with gender dysphoria underwent surgical procedures, including over 3,200 children who had breast or chest surgery, and over 400 children who had genital surgery.[18] Another analysis found that between 2017 and 2021, more than 120,000 children ages 6 to 17 were diagnosed with gender dysphoria and, of that group, more than 4,700 started taking puberty blockers and more than 14,000 started hormonal therapy.[19] However, as discussed later in this proposed rule, current medical evidence does not support a favorable

[4] Stuart William Jarviset al., ''Epidemiology of gender dysphoria and gender incongruence in children and young people attending primary care practices in England: retrospective cohort study,'' *Archives of Disease in Childhood* 110 (2025): 612, doi:10.1136/archdischild-2024–327992.

[5] Christian J. Bachmann et al., ''Gender identity disorders among young people in Germany: Prevalence and trends, 2013–2022. An analysis of nationwide routine insurance data,'' *Deutsches Ärzteblatt International* 121 (2024): 370–371, doi:10.3238/arztebl.m2024.0098. ''Gender incongruence'' as defined by ICD–11 is ''characterized by a marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' See ''International Classification of Diseases 11th Revision (ICD–11),'' World Health Organization, accessed September 9, 2025, *https://icd.who.int/en/*.

[6] Jarvis et al., ''Epidemiology of gender dysphoria,'' 619.

[7] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, ''Clinical management of gender identity disorder in adolescents: A protocol on psychological and pediatric endocrinology aspects,'' *European Journal of Endocrinology* 155, Supp 1 (2006): S131–S137, *https://doi.org/10.1530/eje.1.02231*.

[8] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,'' *International Journal of Transgender Health* 23, Supp 1 (2022): S1–S258, *https://doi.org/10.1080/26895269.2022.2100644*.

[9] Wylie C. Hembree et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658*.

[10] E. Coleman et al., ''Standards of Care,'' S43.

[11] E. Coleman et al., ''Standards of Care,'' S43.

[12] E. Coleman et al., ''Standards of Care,'' S43.

[13] Medical transition refers to the provision of hormonal or surgical interventions, as adapted from the Department of Health and Human Services, ''Treatment for Pediatric Gender Dysphoria Review of Evidence and Best Practices,'' (November 19, 2025): 29, *https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf* [hereinafter ''HHS Review''].

[14] Jennifer Block, ''US transgender health guidelines leave age of treatment initiation open to clinical judgment,'' *BMJ* 378 (2022), *https://doi.org/10.1136/bmj.o2303*. See also E. Coleman et al., ''Standards of Care,'' S50, S56, S58.

[15] HHS Review, 57–58. See Luca Borah et al., ''State restrictions and geographic access to gender-affirming care for transgender youth,'' *JAMA* 330, no. 4 (2023): 375–378, doi:10.1001/jama.2023.11299.

[16] In this proposed rule, we have sought to use the term ''sex-rejecting procedures'' to refer to the set of procedures encompassed in the proposed definition.

[17] HHS Review, 9.

[18] Jason D. Wright et al., ''National Estimates of Gender-Affirming Surgery in the US,'' *Jama Network Open* 6, no. 8 (2023), doi:10.1001/jamanetworkopen.2023.30348.

[19] Robin Respaut and Chad Terhune, ''Putting numbers on the rise in children seeking gender care,'' *Reuters,* October 6, 2022, *https://www.reuters.com/investigates/special-report/usa-transyouth-data/*.

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risk/benefit profile for the use of chemical or surgical procedures in children to treat gender dysphoria.

B. Medical Evidence Regarding Sex-Rejecting Procedures for Minors

The existing guidelines to support the care of children and adolescents experiencing gender dysphoria around the world vary in their methodological rigor and quality.

On May 1, 2025, the United States Department of Health and Human Services (HHS) released a comprehensive review of the evidence and best practices for promoting the health of children and adolescents diagnosed with gender dysphoria.[20] On November 19, 2025, HHS published a final version of the review following conclusion of the peer review process (HHS Review).[21] The HHS Review, informed by an evidence-based medicine approach, indicated serious concerns about outcomes associated with certain medical interventions, such as puberty blockers, cross-sex hormones, and surgeries, that attempt to transition children and adolescents away from their sex.[22] The HHS Review highlights evidence pointing to significant risks associated with the use of these procedures, including irreversible harms such as infertility, and finds extremely weak evidence of benefit. Significantly, the HHS Review finds that the evidence base does not support conclusions about the effectiveness of medical and surgical interventions in improving mental health or reducing gender dysphoria symptoms, stating that ''[a]nalysis of the biological plausibility of harms is necessary, and suggests that some short- and long-term harms are likely (in some cases expected) sequalae of treatment.'' [23] Likewise, the data considered in the HHS Review indicate that the risk/benefit profile of medical and surgical interventions for children and adolescents diagnosed with gender dysphoria is unfavorable. While the HHS Review itself does not make clinical, policy, or legislative recommendations, it provides critical insights that should inform policymakers as they make decisions to promote health and safety, especially for vulnerable populations such as minors.

Specifically, the HHS Review conducted an overview of systematic reviews—also known as an ''umbrella review''—to evaluate the evidence regarding the benefits and harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria. Existing systematic reviews of evidence, including several that have informed health authorities in Europe, were assessed for methodological quality. The umbrella review found that the overall quality of evidence concerning the effects of sex-rejecting procedures on psychological outcomes, quality of life, regret, or long-term health, is very low.

Although the HHS Review acknowledges that systematic reviews offer limited evidence regarding the harms of sex-rejecting procedures in minors, it also provides plausible explanations for why evidence of harms may not have been sought, detected or reported. This may be due to several factors: the relatively recent adoption of hormonal and surgical treatment approaches, shortcomings in existing studies in consistently monitoring and reporting adverse effects, and publication bias. Even in the absence of strong evidence from large-scale population studies, the HHS Review notes, based on what is known about human physiology and the effects and mechanisms of the pharmacological agents used, there are known and plausible risks of significant harms from puberty blockers, cross-sex hormones, and surgeries. These include ''infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, psychiatric disorders, surgical complications, and regret.'' [24]

The HHS Review documents the weak evidence and growing international retreat from the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors [25] and the ''risk of significant harms.'' [26] The HHS Review explains that ''many treatments (*e.g.* surgery, hormone therapy) can lead to relatively common and potentially serious long-term adverse effects.'' [27] The HHS Review includes a methodologically rigorous assessment of evidence underpinning the use of surgical or endocrine interventions, including puberty blockers and cross-sex hormones, while also drawing on international practice evaluations such as the United Kingdom's Cass Review, described in more detail below. The HHS Review documents serious concerns regarding the lack of reliable evidence of benefits, and risks of significant harms for this model of care that have mounted in recent years, and points to psychotherapy (talk therapy) as a noninvasive alternative. The HHS Review makes clear that ''the evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain.'' [28] The HHS Review cites widely accepted principles of medical ethics to conclude that when ''medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients.'' [29]

We are aware that approximately 17 State Medicaid programs cover sex-rejecting procedures for children, citing guidelines from several major U.S. medical professional associations (American Medical Association, the American Academy of Pediatrics, and the American Psychological Association) who have issued statements deeming sex-rejecting procedures, which they refer to as ''gender-affirming care,'' safe and effective.[30] [31] [32] [33] These medical society endorsements further supported adoption of sex-rejecting procedures by clinicians across the U.S. The HHS Review explains why such guidelines, including the WPATH Standards of Care for the Health of Transgender and

[20] HHS Review, 1. ''HHS Releases Comprehensive Review of Medical Interventions for Children and Adolescents with Gender Dysphoria,'' U.S. Department of Health and Human Services, released May 1, 2025, *https://www.hhs.gov/press-room/gender-dysphoria-report-release.html.*

[21] ''HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures,'' U.S. Department of Health and Human Services, released November 19, 2025, *https://www.hhs.gov/press-room/hhs-releases-peer-reviewed-report-discrediting-pediatric-sex-rejecting-procedures.html.*

[22] See ''Information Quality Guidelines,'' Office of the Assistant Secretary for Planning and Evaluation (ASPE), accessed August 11, 2025, *https://aspe.hhs.gov/topics/data/information-quality-guidelines;* ''HHS Information Quality Peer Review,'' ASPE, accessed August 11, 2025, *https://aspe.hhs.gov/hhs-information-quality-peer-review.*

[23] HHS Review, 134.

[24] HHS Review, 10.

[25] HHS Review, 63–65.

[26] HHS Review, 10.

[27] HHS Review, 230.

[28] HHS Review, 15.

[29] HHS Review, 15.

[30] Stacy Weiner, ''States are banning gender-affirming care for minors. What does that mean for patients and providers?,'' *AAMCNews,* February 20, 2024, *https://www.aamc.org/news/states-are-banning-gender-affirming-care-minors-what-does-mean-patients-and-providers.*

[31] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' American Psychological Association, released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[32] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* January 6, 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[33] ''Criminalizing Gender Affirmative Care with Minors,'' American Psychological Association, accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

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Gender Diverse People, Version 8 (SOC–8), are not trustworthy according to accepted standards for evaluating guideline quality. As the HHS Review documents in detail, the creation of SOC–8 marked a ''clear departure from the principles of unbiased, evidence-driven clinical guideline development.'' [34] In the context of developing its recommendations, WPATH suppressed systematic reviews of evidence, failed to manage conflicts of interest, and relied on legal and political considerations rather than clinical ones.[35] A recent systematic review of international guideline quality concluded that ''[h]ealthcare professionals should consider the lack of quality and independence of available guidance when utilizing this [WPATH and Endocrine Society international guidelines] for practice.'' [36]

1. European Approaches for the Treatment of Pediatric Gender Dysphoria

The HHS Review's current findings are aligned with conclusions reached by multiple European countries. Sweden, Finland, and the United Kingdom conducted independent systematic reviews of evidence commissioned by their public health authorities. ''All three concluded that the risks of medicalization [37] may outweigh the benefits for children and adolescents with gender dysphoria at the population level, and subsequently sharply restricted access to medical gender transition interventions for minors.'' [38] These three countries now recommend exploratory psychotherapy as the first line of treatment. Sweden and Finland reserve hormonal interventions only for exceptional cases, recognizing their experimental status.[39] [40] [41]

In particular, the most influential effort to date has been the United Kingdom's Cass Review—a 4-year independent evaluation of pediatric gender medicine that was published in April 2024.[42] The findings of the Cass Review led to the closure of the United Kingdom's Gender Identity Development Service (GIDS), which had been given a rating of ''inadequate'' by the Care Quality Commission in 2021. The Cass Review recommended a restructuring of the care delivery model—away from the centralized ''gender clinic'' model of care toward a more holistic framework centering on psychosocial support, to be delivered through regional hubs. The Cass Review's findings also led the United Kingdom to ban the use of puberty blockers outside of clinical trials, and to significantly restrict cross-sex hormones. While cross-sex hormones are still officially an available treatment, the National Health Service (NHS) recently revealed that since the Cass Review was published, no minor has been found eligible to receive cross-sex hormones according to the updated policy. In the United Kingdom, minors have never received gender dysphoria-related surgery through the NHS.

In 2022, Sweden's National Board of Health and Welfare (NBHW) reviewed and updated its guidelines for minors under the age of 18. Sweden's NBHW determined that the risks of puberty suppressing treatment with GnRH-analogues (injectable drugs that prevent the ovaries and testicles from producing sex hormones) and gender-affirming hormonal treatment likely outweigh the possible benefits.[43] Specifically, Sweden's NBHW outlined that the first line of treatment should be mental health support and exploratory psychological care. Hormonal interventions can be a last resort measure for some youth. Sweden has made the decision to no longer offer gender transition [sex-rejecting procedures] to minors outside of research settings, and restricted eligibility to the early childhood-onset of gender dysphoria.

In 2020, Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued guidelines that called for psychosocial support as the first line treatment, hormone therapy on a case-by-case basis after careful consideration, and no surgical treatment for minors. Finland has restricted eligibility for hormone therapy to minors with early childhood-onset of gender dysphoria and no mental health comorbidities.[44]

In Denmark, more than 1300 minors with gender incongruence were ''referred to the national service between 2016 and 2022 with increasing referral numbers over time,'' of which females constituted 70 percent.[45] The

[34] HHS Review, 181.

[35] HHS Review, 182.

[36] Jo Taylor et al., ''Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),'' *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65-s72, doi:10.1136/archdischild-2023–326499.

[37] ''Medicalization'' means ''the act of considering something to be a medical problem, or representing it as a medical problem.'' Cambridge Dictionary, accessed August 8, 2025, *https://dictionary.cambridge.org/us/dictionary/english/medicalization*. This definition is based on a plain meaning approach and note that the authors of the study did not otherwise supply a specific definition for the term.

[38] HHS Review, 255. See Jonas F. Ludvigsson et al., ''A systematic review of hormone treatment for children with gender dysphoria and recommendations for research,'' *Acta Paediatrica* 112, no. 11 (2023): 2279–2292, *https://doi.org/10.1111/apa.16791;* National Institute for Health and Care Excellence (NICE), ''Evidence Review: Gender Affirming Hormones for Children and Adolescents with Gender Dysphoria,'' (2020), *https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf;* National Institute for Health and Care Excellence (NICE), ''Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria,'' (2020), *https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf;* I. Pasternack et al., ''Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa: Systemaattinen katsaus [Medical approaches to treating gender dysphoria: A systematic review],'' Summaryx Oy (2019); Jo Taylor et al., ''Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review,'' *Archives of Disease in Childhood* 109, Supp 2 (2024): s33–s47, doi:10.1136/archdischild-2023–326669; Jo Taylor et al., ''Masculinising and feminising hormone interventions for adolescents experiencing gender dysphoria or incongruence: A systematic review,'' *Archives of Disease in Childhood* 109, Supp 2 (2024): s48–s56, doi:10.1136/archdischild-2023–326670.

[39] ''Children and young people's gender services: implementing the Cass Review recommendations,'' NHS England, last updated August 29, 2024, *https://www.england.nhs.uk/long-read/children-and-young-peoples-gender-services-implementing-the-cass-review-recommendations/*.

[40] ''Care of children and adolescents with gender dysphoria-summary of national guidelines,'' The Swedish National Board of Health and Welfare (Socialstyrelsen), December 2022, *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf*.

[41] ''One Year Since Finland Broke with WPATH 'Standards of Care','' Society for Evidence Based Gender Medicine, July 2, 2021, *https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors*.

[42] Hilary Cass, ''Independent review of gender identity services for children and young people: Final report,'' (2024), *https://cass.independent-review.uk/home/publications/final-report/*.

[43] ''Care of children and adolescents with gender dysphoria-summary of national guidelines,'' The Swedish National Board of Health and Welfare (Socialstyrelsen), December 2022, *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf*. See also the Swedish National Board of Health and Welfare (Socialstyrelsen), ''Care of children and young people with gender Dysphoria—national knowledge support with recommendations for the profession and decision makers,'' (2022), *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf*.

[44] Council for Choices in Healthcare in Finland, ''Summary of a recommendation by COHERE Finland,'' June 16, 2020, *https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474*.

[45] Nanna Ravnborg et al., ''Gender Incongruence in Danish Youth (GenDa): A Protocol for a Retrospective Cohort Study of Danish Children and Adolescents Referred to a National Gender Identity Service,'' *Journal of Clinical Medicine* 13 (2024), *https://doi.org/10.3390/jcm13226658*.

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increase in the number of referrals for these procedures and reports of regret or reversal of hormone-induced changes to the body led Denmark to take an approach that focuses on assessment and psychosocial support for minors, and postpones decisions on hormone therapy, including puberty blockers and cross-sex hormones, in circumstances ''when gender incongruence has been brief,'' such as ''when there are concerns about the stability of the experienced gender identity.''[46]

In Norway, the Norwegian Commission for the Investigation of Health Care Services (UKOM), an independent State-owned agency, made recommendations in 2023 on the treatment offered to children and young people with gender incongruence.[47] The recommendations consisted of: defining puberty blockers and surgical treatment for children as experimental, revising national guidelines based on a systematic knowledge summary, and consideration for a national registry to improve quality and reduce variation in patient treatment. Norway's public health authority has signaled an intention to respond to UKOM's concerns by considering whether the current treatment guidelines need to be adjusted.[48]

Other countries which have restricted various approaches to treatment for minors (or have contemplated restrictions) include: New Zealand,[49] Italy,[50] Brazil,[51] and Australia.[52]

In sum, there is growing international concern about the use of hormonal and surgical interventions for pediatric gender dysphoria. We are aware that some medical associations have endorsed sex-rejecting procedures, but as the HHS Review makes clear, their endorsement is not based on sound principles of evidence-based medicine. In addition to other issues, we solicit comment of any published findings that measure the effects of similar restrictions as proposed on insurers, providers, and patients in these countries.

2. Medical Professional Societies Supporting Sex-Rejecting Procedures

We are aware that numerous organizations[53] (including the American Medical Association (AMA),[54] the American Academy of Pediatrics (AAP),[55] and the American Psychological Association[56][57]) have issued statements supporting access to sex-rejecting procedures, including for minors. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the U.S. are the WPATH and the ES clinical practice guidelines and the AAP guidance document. We reviewed each of these documents and agree with the conclusions of a recent systematic review of international guideline quality by researchers at the University of York (the York appraisal) that found all three documents as very low quality and should not be implemented.[58]

As the HHS Review notes regarding the role of medical organizations in the treatment of pediatric gender medicine:

U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition (PMT). This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.[59]

The Endocrine Society (ES) issued clinical practice guidelines in 2017 entitled ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.''[60] As the HHS Review notes:

In WPATH and ES guidelines, the principal goal of CSH administration [cross sex hormone] is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations. Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.[61]

The HHS Review states:

The ES 2017 guideline, which used the GRADE [Grading of Recommendations Assessment, Development and Evaluation] framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base. Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents. The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a ''satisfactory physical appearance'' while putting the lowest value on avoiding physical harms. The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower

[46] Ravnborg et al., ''Gender Incongruence in Danish Youth (GenDa).''

[47] Norwegian Healthcare Investigation Board (Ukom), ''Pasientsikkerhet for barn og unge med kjønnsinkongruens [Patient safety for children and adolescents with gender incongruence],'' March 2023, *https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag.*

[48] Jennifer Block, ''Norway's guidance on paediatric gender treatment is unsafe, says review,'' *BMJ* 380 (2023), doi:10.1136/bmj.p697.

[49] Eva Corlett, ''New Zealand bans puberty blockers for young transgender people,'' *The Guardian,* November 19, 2025, *https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.*

[50] Alvise Armellini, ''Italy moves to tighten controls on gender-affirming medical care for minors,'' *Reuters,* August 5, 2025, *https://www.reuters.com/business/healthcare-pharmaceuticals/italy-moves-tighten-controls-gender-affirming-medical-care-minors-2025-08-05/.*

[51] AFP, ''Brazil prohibits hormone therapy for transgender minors,'' *MSN News,* April 20, 2025, *https://www.msn.com/en-in/news/other/brazil-prohibits-hormone-therapyfor-transgender-minors/ar-AA1D66l7.*

[52] Australian Associated Press, ''Queensland halts prescription of puberty blockers and hormones for children with gender dysphoria,'' *The Guardian,* January 28, 2025, *https://www.theguardian.com/australia-news/2025/jan/28/queensland-halts-prescription-of-puberty-blockers-and-hormones-for-children-with-gender-dysphoria.*

[53] ''Medical Organization Statements,'' Advocates For Trans Equality's Trans Health Project, accessed November 20, 2025, *https://transhealthproject.org/resources/medical-organization-statements/.*

[54] ''Clarification of Evidence-Based Gender-Affirming Care H–185.927,'' American Medical Association, last modified 2024, *https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml.*

[55] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* January 6, 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[56] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' American Psychological Association, released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[57] ''Criminalizing Gender Affirmative Care with Minors,'' American Psychological Association, accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

[58] HHS Review, 141.

[59] HHS Review, 15.

[60] Wylie C. Hembree et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658.*

[61] HHS Review, 124.

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value on avoiding harm from potentially prolonged pubertal suppression.[62]

As explained in Chapter 9 of HHS Review, the guidelines issued by the World Professional Association for Transgender Health (WPATH) ''have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines.'' [63] As the HHS Review points out: ''Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH Standards of Care guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.'' [64] In 2022, WPATH issued guidelines entitled ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8'' (SOC–8).[65] These guidelines relaxed eligibility criteria for children to access sex-rejecting procedures, and ultimately recommend that adolescents wishing to undergo sex-rejecting procedures receive them. Besides the problems identified in systematic reviews of international guidelines, as the HHS Review states, ''in the process of developing SOC–8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC–8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.'' [66]

The HHS Review goes on to explain: ''The recommendations are couched in cautious-sounding language, stating that GD should be 'sustained over time,' particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase 'several years, leaving critical decisions open to broad and subjective interpretation.' '' [67]

Regarding the WPATH guidelines, the HHS review states:

On the surface, WPATH SOC–8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a ''comprehensive biopsychosocial assessment'' prior to initiating medical interventions in order ''to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care.'' At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases (ICD–11) diagnosis of ''Gender Incongruence of Adolescence and Adulthood,'' which, unlike the DSM–5 diagnosis of ''Gender Dysphoria,'' requires only ''marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' Because SOC–8 defines transgender in a similar way (''people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth'') and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC–8 effectively recognizes transgender identification as a medical condition justifying medical interventions.[68]

The HHS Review also argues: ''Although WPATH's guidelines do not necessarily discourage mental healthcare, they likewise do not require it as a precondition for PMT [pediatric medical transition]. Some guideline authors opposed even minimal requirements for mental health support, arguing that such provisions were analogous to ''conversion therapy.'' SOC–8's only formal recommendation is for a ''comprehensive biopsychosocial assessment,'' although WPATH emphasizes that its guideline is ''flexible,'' thereby leaving room for considerable variation in clinical practice.'' [69]

While AMA and the AAP have not issued their own treatment guidelines, they support the ES and WPATH guidelines, as discussed previously in this proposed rule. AAP issued a policy statement in 2018 supporting the use of puberty blockers, cross-sex hormones, and surgeries for minors.[70] In support of sex-rejecting surgeries, AAP stated that while ''current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.'' The AAP reaffirmed its policy statement in 2023, but also stated that it was conducting its own review of the evidence and guideline development—which still have not been released.[71] Regarding the AAP policy statement, the HHS Review states:

The AAP 2018 policy statement is not technically a CPG [clinical practice guideline] but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD. Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs [puberty blockers], CSH, and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7. As noted in Chapter 2, the AAP's policy statement's use of ''gender diverse'' casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.[72]

In addition to other issues, we solicit comment of any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients in international settings as well as the U.S.

C. United States' State Bans of and Coverage of Sex-Rejecting Procedures

State lawmakers have adopted policy positions reflecting the emerging evidence of sex-rejecting procedures administered to youth. There are 27 States and one Territory that have enacted laws restricting sex-rejecting procedures.[73] These include Alabama,

[62] HHS Review, 147.

[63] HHS Review, 157.

[64] HHS Review, 157.

[65] E. Coleman et al., ''Standards of Care.''

[66] HHS Review, 14.

[67] HHS Review, 165.

[68] HHS Review, 194–195.

[69] HHS Review, 196.

[70] Jason Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, ''Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents,'' *Pediatrics* 142, no. 4 (2018), *doi.org/10.1542/peds.2018-2162*.

[71] Alyson Sulaski Wyckoff, ''AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update,'' *AAP News,* August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy.*

[72] HHS Review, 148–149.

[73] See ''Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions,'' KFF,

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Arkansas, Arizona, Florida, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Carolina, New Hampshire,[74] North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. As of August 8, 2025, some of these States have ongoing litigation proceedings impacting whether the State laws are partially or fully enjoined by a court.

There are a mix of age ranges for these bans. Of the 28 States and Territories with enacted laws/policies (in effect or not), 25 States prohibit some sex-rejecting procedures to young people under the age of 18, two States prohibit them for those under the age of 19, and Puerto Rico prohibits them for those under the age of 21.

Of the 24 States and one Territory with restriction statutes in effect as of August 8, 2025, 21 States and one Territory prohibit *both* the prescribing of at least one type of sex-rejecting medication *and* surgeries.[75] No State bans only medications without also banning surgeries. However, all the States and the Territory with restrictions provide exceptions to the law/policies. The most common exceptions include procedures to treat:

- A medically verifiable disorder of sexual development. This allows treatment for children who are born with medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other medical factors that can be medically verified.
- Any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of gender transition procedures.
- A physical disorder, physical injury, or physical illness that would otherwise place the minor in danger of death or impairment of bodily function.

We note that 12 States provide tapering off periods for patients who started puberty blockers or hormones before enactment of the State restriction, with some specifying specific dates (for example, in South Carolina services cannot go beyond January 31, 2025) and others specifying a period of time from the time of enactment (ranging between 6 months and 1 year). Ten States have grandfather clauses primarily allowing minors who were already receiving treatment to continue receiving it indefinitely. However, we note that many of these States do not provide such exceptions or grandfather clauses for purposes of prohibitions on State funding, including for State funding under the Medicaid program and CHIP, for sex-rejecting procedures.

Conversely, 14 States and the District of Columbia have shield laws protecting some or all sex-rejecting procedures, and three States have executive orders (State EOs) protecting these procedures. These States are Arizona,[76] California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. Shield laws and State E.O.s often describe various types of sex-rejecting procedures broadly, including medications and surgeries, and include these under broader definitions of protected health care activities. These laws and State E.O.s generally attempt to shield providers and recipients (of all ages) against laws in other States that restrict these services. They also often protect providers from adverse action by medical malpractice insurers and licensure boards and allow for their address to remain confidential. One State, Maine, has a shield law specific to minors that allows minors 16 and over to receive hormone therapy when the guardian has refused sex-rejecting procedures. Four States explicitly provide child abuse and child custody protections for parents who supported their children in receiving sex-rejecting procedures. Four States have requirements for sex-rejecting procedures to be covered under health plans. Arizona requires coverage for State employee health plans. Illinois, Oregon, and Vermont require some level of coverage of sex-rejecting procedures by all health insurance providers. Vermont includes an exception for services that do not comply with Federal law.

Some States may experience negative financial impacts as a result of having built their Medicaid programs and CHIPs, including policies and operations, on the understanding that we would make Federal Medicaid and CHIP payments to States for services that this proposed rule would define as sex-rejecting procedures. We believe protecting children enrolled in Medicaid and CHIP from the harms of sex-rejecting procedures, including possible long-term and irreversible harms, outweighs the possible financial costs some States may experience if they begin to pay with State funds the full cost of sex-rejecting procedures for children enrolled in Medicaid and CHIP.

Providers in these States may be concerned that this proposed regulation would interfere with the physician-patient relationship. This proposed regulation would only prohibit Federal Medicaid and CHIP payment for certain services and does not require providers to communicate certain advice or information to patients. Federal Medicaid and CHIP payments will still be available for mental health counseling and psychotherapy for gender dysphoria. We believe a prohibition on Federal Medicaid and CHIP payments for sex-rejecting procedures is needed to avoid the possibility of minors receiving irreversible or risky pharmaceutical or surgical interventions, particularly in circumstances where the minor may be of an age to not have the capacity to understand the irreversible or long-term risks of these procedures or have the capacity to continue to communicate with providers their preferences regarding treatment after treatment has already begun.

Certain medical providers may also be relying on continued Federal funding for sex-rejecting procedures. These providers may face financial harm by the loss of the revenue from the proposed limitations on Federal payment for these procedures; however, these providers have other avenues to continue to receive compensation for providing medical care. Providers may continue to receive payment for pharmaceutical or surgical interventions for purposes of aligning a child's physical appearance or body with an asserted identity that differs from the child's sex from sources other than Medicaid or CHIP. Providers may also receive payment for these services when

last updated June 18, 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker;* ''Equality Maps: Bans on Best Practice Medical Care for Transgender Youth,'' Movement Advancement Project, accessed August 11, 2025, *https://www.lgbtmap.org/equality-maps/healthcare/youth_medical_care_bans.*

[74] New Hampshire's laws go into effect January 1, 2026 under NH HB712 and NH HB377.

[75] Arizona and New Hampshire currently do not prohibit sex-rejecting procedures using medications; however, New Hampshire has a new policy (NH HB377) taking effect January 1, 2026, that would restrict sex-rejecting procedures using medications for minors. Nebraska currently restricts, but does not fully ban, access to sex-rejecting procedures using medications, so it was not included in this count.

[76] Arizona banned pediatric sex-rejecting surgeries in 2022. However, in 2023 the governor issued an executive order which removes the exclusion of coverage for sex-rejecting surgery under the state's healthcare plan for state employees and prohibits investigative assistance to impose criminal or civil liability or professional sanctions on persons or entities for providing, assisting, seeking, or obtaining gender affirming care.

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providing these procedures for the exempted purposes as outlined in the proposed rule. Lastly, providers may be paid through Medicaid and CHIP for providing other types of care for individuals diagnosed with gender dysphoria, such as psychotherapy.

We also recognize that Medicaid and CHIP beneficiaries and their families would be impacted by this proposed rule. Families of these beneficiaries may look to obtain other health insurance or privately pay for these services. Medicaid and CHIP beneficiaries who are unable to find alternative means to pay for these services may either have to rely on other methods of intervention such as psychotherapy or mental health counseling, or never begin receiving these services because of this proposed rule, if finalized. We are concerned about the difficulties that these minors may experience and encourage other, less invasive, ways to support these individuals, such as encouraging psychotherapy as a first line of treatment.

This proposed rule would help to protect these children from the risks of adverse effects of sex-rejecting procedures. CMS carefully considered the scope of its limitation on Federal Medicaid and CHIP payments and permits coverage of other procedures, such as psychotherapy, which does not carry the same concerns of pharmaceutical or surgical interventions included in the definition of sex-rejecting procedures. Moreover, CMS does not believe Federal Medicaid and CHIP payment for these sex-rejecting procedures is consistent with quality of care given the state of the research into the effectiveness of these procedures for the purposes included in our proposed definition of this term, namely as treatments for gender dysphoria. In light of the HHS Review, CMS believes State reliance on certain medical organizations and the SOC–8 to justify covering sex-rejecting procedures is misplaced.

In addition to other issues, we solicit comment on any published studies or findings that measure the effects of similar restrictions as proposed (or laws protecting these procedures) on insurers, providers, and patients in these States.

Recently, the U.S. Supreme Court in United States v. Skrmetti, 605 U.S. 495 (2025), upheld Tennessee's law restricting certain surgical and chemical interventions for minors diagnosed with gender dysphoria (and similar conditions), referred to as Senate Bill 1 or ''SB1'' in litigation challenging that law under the Equal Protection Clause of the U.S. Constitution. SB1 prohibits a healthcare provider from performing medical procedures, including surgery, and prescribing puberty blockers, for a minor for the purpose of enabling the minor to identify with a purported identity inconsistent with the minor's sex. At the same time, SB1 allows healthcare providers to perform medical procedures for minors if the procedure is to treat a minor's congenital defect, precocious puberty, disease, or physical injury. On June 18, 2025, the Court found that SB1's prohibition of certain medical procedures for minors diagnosed with gender dysphoria incorporates classifications based on age and medical use—not the minor's sex. Because the classifications turned on age and medical use rather than sex, the Court held that SB1 was not subject to heightened scrutiny under the Equal Protection Clause of the Fourteenth Amendment and went on to find the law satisfied rational basis review. As discussed in more detail later in this proposed rule, like the law at issue in *Skrmetti,* this proposed rule would not discriminate on the basis of sex and it is not based on an invidious discriminatory purpose. The proposed rule is animated by significant child safety concerns when sex-rejecting procedures are used for certain medical uses–that is to align a child's physical appearance or body with an asserted identity that differs from the child's sex.

D. Psychotherapy as the First Line Treatment for Children Diagnosed With Gender Dysphoria

Since 2010, there has been a significant increase in mental health conditions among teens and young adults.[77] Current research has not revealed a simple explanation for this rise in the need for youth mental health services. The etiology of gender dysphoria remains understudied.[78] However, patients presenting to pediatric gender medicine clinics have a high rate of comorbid mental health conditions.[79]

We believe interested parties supporting the use of sex-rejecting procedures to treat gender dysphoria in children may state that limiting access to these treatments (which prohibiting Federal Medicaid and CHIP funding for them could do) will exacerbate these comorbidities and lead to adverse mental health outcomes and increase suicide risks. As noted previously, the Cass Review emphasized the lack of robust evidence regarding the effectiveness of interventions such as puberty blockers and cross-sex hormones to treat gender dysphoria and incongruence in children and adolescents.[80] Taylor et al. recently conducted a review of 23 international, national, and regional clinical guidelines that contained recommendations about the management of children/adolescents experiencing gender dysphoria. They found that the majority of these guidelines were developed without an independent or evidence-based approach and raised questions about the credibility of available guidance.[81] As Sweden's national health authority has recommended, ''[p]sychosocial support that helps adolescents deal with natal puberty without medication needs to be the first option when choosing care measures.'' [82]

While evidence on the benefits of medical and surgical interventions to improve mental health or reduce symptoms of gender dysphoria is lacking, psychotherapy has been proven to be an effective intervention for many of the neurodevelopmental disorders and mental health conditions that are highly prevalent in children and adolescents, including those frequently co-occurring in patients diagnosed with gender dysphoria.[83] Psychotherapy and mental health counseling are non-invasive interventions that would remain available to youth under Medicaid's mandatory Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions in section 1905(r) of the Act. EPSDT requires the provision of screening, vision, dental, and hearing services, and such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects and physical and mental illness and conditions discovered by the screening services, whether or not such services are covered under the State plan. Most children enrolled in Medicaid are entitled to coverage of robust and comprehensive psychotherapy services under EPSDT . We note that under a State's EPSDT program, States may only include tentative limits on services and must take into account the individual needs of the child. Thus, EPSDT is key

[77] Patrick McGorry et al., ''The Lancet Psychiatry Commission on youth mental health,'' Lancet Psychiatry 11, no. 9 (September 2024): 731–774, doi:10.1016/S2215–0366(24)00163–9.

[78] HHS Review, 257.

[79] HHS Review, 68.

[80] Cass, ''Cass Review.''

[81] Jo Taylor et al., ''Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),'' *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65-s72, doi:10.1136/archdischild–2023–326499.

[82] HHS Review, 256.

[83] HHS Review, 257–260.

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to ensuring that children receive appropriate mental health screenings and treatments. Furthermore, we have developed numerous resources to provide information regarding services and good practices for children and youth with mental health conditions.[84] While EPSDT is not a required CHIP benefit for States that have separate CHIPs, many States with such programs have opted to provide EPSDT services that mirror the Medicaid standards set out at section 1905(r) of the Act to children enrolled in CHIP. In addition, section 2103(c)(7) of the Act requires States to provide mental health services in CHIP that are applied in the same manner as required under section 2726(a) of the Public Health Service Act [([42 U.S.C. 300gg–26(a)])] for group health plans under such section.

E. States' Duty To Ensure Medicaid and CHIP Services for Children Are Consistent With Quality of Care and the Best Interests of Beneficiaries

Under section 1902(a)(19) of the Act, State Medicaid agencies are required to ensure that Medicaid-covered services are in the best interests of beneficiaries; as relevant to this proposed rule, children under age 18. Additionally, States are required, under section 1902(a)(30)(A) of the Act, to ensure that Medicaid payments for Medicaid covered services are consistent, in relevant part, with quality of care. Under section 2101(a) of the Act, CHIP programs are required to provide health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children, including State Medicaid programs. The research described previously in this proposed rule indicates that sex-rejecting procedures lack the necessary outcomes data to reasonably rely on for evidence of long-term effectiveness.

On April 11, 2025, we issued a letter to State Medicaid Directors to ensure Medicaid agencies were aware of growing utilization of certain interventions offered to children to treat gender dysphoria, and to remind States of their statutory responsibilities to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interests of recipients.[85] In the letter, we also stated that due to the underdeveloped body of evidence, the use of sex-rejecting procedures to treat gender dysphoria lacks reliable evidence of long-term benefits for minors and are now known to cause long-term and irreparable harm for some children.[86] A second letter, issued on May 28, 2025, was sent to a number of hospitals to address significant issues concerning quality standards and specific procedures affecting children diagnosed with gender dysphoria. The letter requested hospitals to provide information on their policies and procedures related to the adequacy of informed consent protocols for children diagnosed with gender dysphoria, including how children are deemed capable of making these potentially life changing decisions and when parental consent is required; changes to clinical practice guidelines and protocols that the institution plans to enact in light of the recent comprehensive review and guidance released by the Department; medical evidence and any adverse events related to these procedures, particularly children who later look to detransition; and complete financial data for all pediatric sex-rejecting procedures performed at the institution and paid, in whole or in part, by the Federal Government.[87]

As outlined previously in this proposed rule, we take very seriously the absence of rigorous scientific data demonstrating the effectiveness of sex-rejecting procedures and the considerable evidence regarding the risks. Given the potential risks and lack of clear benefits associated with sex-rejecting procedures, we believe that covering them with Federal Medicaid or CHIP funding would be, for Medicaid beneficiaries, inconsistent with their best interests and with quality of care; and, for CHIP beneficiaries, inconsistent with the provision of health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. In this section, we describe how this proposed rule would intersect with existing statutory and regulatory provisions.

1. Intersection With Nondiscrimination (Section 1557 of the Patient Protection and Affordable Care Act)

This proposed rule is not a form of sex discrimination in violation of section 1557 of the Patient Protection and Affordable Care Act (Affordable Care Act).[88] Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities, any part of which is receiving Federal financial assistance.

A Federal court recently considered the question of whether the prohibition on sex discrimination found in section 1557 of the Affordable Care Act includes discrimination on the basis of gender identity. On October 22, 2025, in *State of Tennessee et al* v. *Kennedy et al,*[89] the district court declared that ''HHS exceeded its statutory authority when (1) it interpreted Title IX, as incorporated into Section 1557, to prohibit discrimination on the basis of gender identity, and (2) when it implemented Section 1557 regulations concerning gender identity and 'gender affirming care.' '' Accordingly, the Court vacated the following regulations to the extent that they expand Title IX's definition of sex discrimination to include gender-identity discrimination: 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(b)(3), and 460.112(a), and 45 CFR 92.101(a)(2)(iv), 92.206(b)(1)–(4), § 92.207(b)(3) through(5), 92.8(b)(1), 92.10(a)(1)(i), and 92.208.[90]

[84] ''Children and Youth,'' Medicaid, accessed June 12, 2025, *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/children-and-youth.*

[85] CMS, ''Puberty Blockers, Cross-sex Hormones, and Surgery Related to Gender Dysphoria,'' April 11, 2025, *https://www.cms.gov/files/document/letter-stm.pdf.*

[86] CMS, ''Puberty Blockers.''

[87] Department of Health & Human Services, Centers for Medicare and Medicaid Services, Urgent Review of Quality Standards and Gender Transition Procedures, May 28, 2025, *www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.*

[88] The Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1049), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA''.

[89] *Tennessee* v. *Kennedy*, ---F. Supp. 3d---,1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025).

[90] As part of a 2024 rulemaking implementing section 1557 of the Affordable Care Act, HHS amended 42 CFR 440.262, 438.3(d) and 438.206(c)(2) to specifically include discrimination based on ''gender identity'' as a form of ''sex discrimination,'' and amended 42 CFR 457.495 to cross-reference amended 440.262. The amendments to sections 438.3(d) and 438.206(c)(2) also apply to CHIP managed care through cross references in §§ 457.1201(d) and 457.1230(a) that predated the section 1557 rulemaking. These amendments to the Medicaid and CHIP rules were based on sections 1902(a)(4), 1902(a)(19), and 2101(a) of the Act. See Nondiscrimination in Health Programs and Activities, 89 FR 37522 (May 6, 2024). In *Tennessee* v. *Kennedy,* ---F. Supp. 3d---, 1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025), the court vacated 42 CFR 440.262, 438.3(d)(4), and 438.206(c)(2) (among others) ''to the extent that they expand Title IX's definition of sex discrimination

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Notwithstanding the outcome of this litigation, the Court's holding in *Skrmetti,* as explained previously in this proposed rule and expounded upon below, supports our position that this proposed rule would not discriminate on the basis of sex. In 2023, Tennessee enacted a State law,[91] SB1, which, in relevant part, prohibits a healthcare provider from performing certain medical procedures, including surgery, and from prescribing puberty blockers, for a minor for the purpose of enabling the minor to identify with a purported identity inconsistent with the minor's sex.[92] SB1 does not prohibit healthcare providers from providing those procedures if done to treat a minor's congenital defect, precocious puberty, disease, or physical injury. The U.S. Supreme Court analyzed SB1 under the Equal Protection Clause of the Fourteenth Amendment and held that SB1 does not turn on sex-based classifications, noting ''the law does not prohibit conduct for one sex that it permits for the other.'' [93]

Like SB1, this proposed rule would apply uniformly to all children regardless of the child's sex. This proposed rule would treat all children the same when it would prohibit a State Medicaid or CHIP agency from covering, as part of its Federally funded Medicaid program and CHIP, the procedures that the proposed rule would define as sex-rejecting procedures. At the same time, this proposed rule would permit State Medicaid and CHIP agencies to continue to so cover procedures when the child has a medically verifiable disorder of sexual development, needs the procedure for a purpose other than attempting to align the child's physical appearance or body with an asserted identity that differs from the child's sex, or has complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Further, this proposed rule would be neither arbitrary nor based on an invidious discriminatory purpose. Rather, based on the review of current research and the reasoning for similar conclusions reached and actions taken by multiple European countries discussed previously in this proposed rule, we believe that Medicaid and CHIP coverage and payment of sex-rejecting procedures are not in the best interests of minors and not consistent with quality of care or the effective and efficient standard required under section 2101(a) of the Act. Therefore, we are proposing to prohibit Federal funding for these procedures in Medicaid and CHIP. This proposal is based on careful consideration of the facts as described in detail in section I.B. of this proposed rule and on our determination that the risks of sex-rejecting procedures for children outweigh the benefits. We continue to support Medicaid and CHIP coverage of services for children that research shows may be helpful for treating gender dysphoria in children without the risks of harm. Further, while State laws may differ, State Medicaid agencies are not currently specifically prohibited under Federal law from covering sex-rejecting procedures for Medicaid beneficiaries who are 18 years of age and older.

2. Intersection With Sufficiency of Amount, Duration, and Scope (§ 440.230(c))

This proposed rule would also be consistent with 42 CFR 440.230, which provides that a Medicaid State plan must specify the amount, duration, and scope of covered services. CMS has long afforded State Medicaid agencies considerable flexibility under § 440.230 to establish the amount, duration, and scope of covered Medicaid services, and to develop State-specific medical necessity criteria and utilization control procedures for covered services. State-specific limits on amount, duration, and scope are frequently applied based on an assessment of a beneficiary's specific circumstances, rather than being blanket limitations. In addition to specifying the amount, duration, and scope of covered services, historically, States have determined whether, and how, to cover services and we make Federal Medicaid payments to States if the services otherwise complied with Federal law and regulation. Within CHIP, under § 457.402(x), States have the ability to add coverage of additional services if recognized by State law.

Some States may be using the authorities under sections 1905 and 2110 of the Act, such as sections 1905(a)(6) and 2110(a)(24) of the Act,[94] to cover sex-rejecting procedures as services that are recognized under State law.

However, this flexibility under § 440.230 is not absolute. Section 440.230 requires State Medicaid agencies to comply with certain guidelines when determining the amount, duration, and scope of covered services. States must detail their proposed coverage of services in a State plan amendment and submit the State plan amendment to CMS for approval. We review the State plan amendment to ensure that States meet these guidelines. For example, under § 440.230(b), State Medicaid agencies must ensure that any covered service is sufficient in amount, duration, and scope to reasonably achieve its purpose. If a state limits the amount, duration or scope of a service without exception for medical necessity, the State must explain to us the reasoning and evidence to support the limitation prior to CMS approving the State's submission. Similarly in CHIP, the flexibility under § 457.402(x) is not absolute. Section 457.60 requires States to submit a State plan amendment when a State is making a change in policy or operation of the program that affects the benefits provided. Like in Medicaid, States must detail their proposed coverage of services in a State plan amendment and submit the State plan amendment to CMS for approval. We review the State plan amendment to ensure that States meet these guidelines.

For this proposed rule, we have considered the risk/benefit profile of sex-rejecting procedures for the purposes included in our proposed definition and the alternative treatments available, before determining that a national response prohibiting Federal Medicaid funding for sex-rejecting procedures for children under age 18 enrolled in Medicaid and under age 19 enrolled in CHIP is warranted. This prohibition includes circumstances in which a provider may determine that a sex-rejecting procedure is medically necessary for a child diagnosed with gender dysphoria.

to include gender identity discrimination'' and declared HHS had ''exceeded its statutory authority when (1) it interpreted Title IX, as incorporated into Section 1557, to prohibit discrimination on the basis of gender identity, and (2) when it implemented Section 1557 regulations concerning gender identity and 'gender affirming care.'" See also Texas v. Becerra, No. 6:24–CV–211–JDK (E.D. Tex. Aug. 30, 2024), in which the court entered a nationwide stay of certain regulations of the final rule, including 42 CFR 440.262, 438.3(d)(4), and 438.206(c)(2). Given *Skrmetti's* holding, we believe that the outcome of this litigation will not affect the proposed rule. As a result, CMS does not further discuss 42 CFR 440.262, 438.3, and 438.206 in this proposed rule.

[91] Tenn. Code Ann. § 68–33–101 *et seq.*

[92] As defined by SB1, ''minor'' means an individual under eighteen (18) years of age. Tenn. Code Ann. § 68–33–102.

[93] *United States* v. *Skrmetti,* 145 S. Ct. 1816 (2025).

[94] Section 1905(a)(6) of the Act states ''medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law'' and section 2110(a)(24) of the Act defines ''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 . . . (24) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services . . . if recognized by State law . . .''

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Lastly, this proposed rule is consistent with § 440.230(c), which prohibits State Medicaid agencies from arbitrarily denying or reducing the amount, duration, or scope of a covered service to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition. This proposed rule reflects the agency's efforts to address significant concerns about the risk/benefit profile of sex-rejecting procedures for the uses included in our proposed definition of that term, due to the safety concerns, risks of irreversible harm, long-term health outcomes, and unestablished effectiveness associated with those uses, as explained previously. This proposed rule takes into account the different risk/benefit profiles of different uses of these procedures, which is why it focuses on purposes that might be associated with a particular diagnosis, type of illness or condition. Our proposed definition of sex-rejecting procedures would exclude from the definition certain uses of these procedures for which the risk/benefit profile creates less significant concerns. Additionally, other treatments, such as mental health treatment, would remain Federally funded for children diagnosed with gender dysphoria.

As discussed previously in this proposed rule, we have considered the concerns of States, providers, and beneficiaries who have relied on CMS making Federal Medicaid and CHIP payment for these services. Notwithstanding the potential financial burden to States, providers, and individuals, and the psychological and physical impact on beneficiaries who wish to receive these services, a nationwide prohibition on Federal Medicaid and CHIP payments for these services is warranted. We believe that the concerns of States, providers and beneficiaries described previously in this proposed rule are outweighed by the potential harm of sex-rejecting procedures for minors, including potential long-term harm, especially when the possible benefits of these services are unproven and the procedures are irreversible. More data is needed on how the procedures that the proposed rule would define as sex-rejecting procedures in children under age 18 in Medicaid and under age 19 in CHIP affect the long-term health of such individuals, including any impact on fertility, and whether these procedures result in, or increase the risk of, sexual dysfunction, impaired boned density, adverse cognitive impacts and other health deviations, as mentioned previously.

3. Intersection With Early and Periodic Screening, Diagnostic and Treatment (EPSDT)

This proposed rule also would be consistent with States' obligations under the EPSDT requirement, even though it would limit States' longstanding flexibility to develop State-specific processes for determining when a service is medically necessary for an EPSDT-eligible beneficiary under section 1905(r)(5) of the Act. Under EPSDT, States must cover medically necessary services described in section 1905(a) of the Act for most Medicaid eligible children under the age of 21. Children eligible for EPSDT generally include beneficiaries under the age of 21 enrolled: in Medicaid through a categorically needy group; in Medicaid through a medically needy group in a State that has elected to include EPSDT in the medically needy benefit package; in a Medicaid-expansion CHIP program; or in a separate CHIP program that has elected to cover EPSDT. This includes beneficiaries with an institutional level of care who are eligible for Medicaid by virtue of their enrollment in a home and community-based services (HCBS) waiver under section 1915(c) of the Act. EPSDT is not available to beneficiaries without satisfactory immigration status who are eligible only for treatment of an emergency medical condition and other groups of individuals under age 21 who are eligible only for limited services as part of their Medicaid eligibility, such as, for example, family planning services.

Under this proposed rule, sex-rejecting procedures for the uses included in our proposed definition would no longer be Federally funded as Medicaid-covered services for individuals under the age of 18 or as CHIP-covered services for individuals under the age of 19, because such services may pose a risk of harm to children, including long-term irreversible harm, and result in adverse outcomes on their health including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, and psychiatric disorders. We are not endorsing or requiring any particular treatment modality for gender dysphoria.

In our prior EPSDT coverage guidance,[95] [96]we discuss how States should approach their determination of whether a service is medically necessary. In this prior guidance, we emphasize that States (or their delegated entity) must take into account the particular needs of the child. We explain that States should consider the child's long-term needs, not just what is required to address the immediate situation. The State should consider all aspects of a child's needs, including nutrition, social development, and mental health and substance use disorders. Accordingly, while sex-rejecting procedures have been covered by some State Medicaid programs to address gender dysphoria to alleviate its symptoms, these procedures can involve use of puberty suppressing drugs to prevent the onset of puberty and cross-sex hormones to spur the secondary sex characteristics of the opposite sex. For children under 18 (or under 19 in CHIP) who have undergone the suppression of puberty, these procedures may pose a significant risk of harm, including possible long-term harm to a child's health, including the risk of infertility and bone density loss, as discussed previously.

As discussed previously in this proposed rule, some State Medicaid programs and CHIPs have relied upon clinical guidelines that have failed to meet the principles of unbiased, evidence-driven clinical guideline development. As a result of this reliance, State Medicaid programs and CHIPs have developed coverage criteria which may not have considered the full effects of all aspects of a child's needs (including long-term needs) as required under EPSDT.

F. Prohibition on Federal Funding and Coverage in a Separate CHIP

Title XXI of the Act allows States to implement CHIP as a separate CHIP, a Medicaid-expansion program, or a combination of the two. Title XXI-funded Medicaid expansion programs generally follow Medicaid rules. This section relates to separate CHIPs.

States with separate CHIPs receive Federal funding from the title XXI allotment to provide child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act and regulations at § 457.402. Section 2101(a) of the Act calls for the provision of CHIP in a manner that is effective and efficient and coordinated with other sources of

[95] CMS, ''EPSDT–A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,'' June 2014, *https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf.*

[96] CMS, State Health Official Letter #24–005, ''Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements,'' September 26, 2024, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf.*

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health benefits coverage for children, notwithstanding section 2110(a)(24) of the Act that allows States to cover additional services that are recognized by State law. While CMS recognizes the considerable State flexibility provided to States under section 2110(a)(24) of the Act, CMS has concluded that it is in the best interest of children under age 19 enrolled in CHIP to no longer permit Federal funding for coverage of procedures when utilized for purposes of sex-rejecting procedures because such services may result in adverse outcomes on their health including infertility/sterility, sexual dysfunction, impaired bone density accrual, diverse cognitive, cardiovascular disease and metabolic disorders, and psychiatric disorders. Therefore, CMS has concluded it is most efficient and effective, and in the best interests of children, for CHIP to align and coordinate with the Medicaid program.

Section 2103 of the Act and § 457.410 allow States to choose any of the following four types of health benefits coverage for separate CHIPs: (1) Benchmark coverage in accordance with § 457.420; (2) Benchmark-equivalent coverage in accordance with § 457.430; (3) Existing comprehensive State-based coverage in accordance with § 457.440; and (4) Secretary-approved coverage in accordance with § 457.450. Regardless of the type of health coverage selected by a State, States are required to provide all services identified at § 457.410(b) to children enrolled in CHIP. In addition to these services, States have the flexibility to cover additional services at § 457.402, which lists the services included in ''child health assistance.'' In addition to the specified services, § 457.402(x) permits states to select additional services and treatments that it will cover. The majority of separate CHIP States have elected Secretary-approved coverage. Under Secretary-approved coverage at § 457.450, the Secretary currently has the discretion to determine whether the coverage provided by a State is appropriate coverage for the population of targeted low-income children covered under the program. Recently, there have also been changes to allowable procedures under the benchmark coverage options for CHIP under § 457.420 as described later in this proposed rule.

On June 20, 2025, we issued the ''Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability,'' final rule (90 FR 27074) (referred to hereafter as the ''2025 Marketplace final rule''), which prohibits issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to the essential health benefit (EHB) requirements—from providing coverage for ''specified sex-trait modification procedures'' as an EHB beginning with Plan Year 2026. This prohibition was proposed and finalized because section 1302(b)(2)(A) of the ACA requires that the scope of the EHB be equal to the scope of benefits provided under a typical employer plan, and coverage of such procedures is not typically included in employer-sponsored plans.[97] In addition, on January 31, 2025, the U.S. Office of Personnel Management issued letter 2025–01A, which prohibited coverage of certain surgeries and hormone treatments for covered individuals in Federal Employees Health Benefits (FEHB) and Postal Service Health Benefits (PSHB) Programs under age 19. That letter was amended by letter 2015–01B, issued on August 15, 2025, which eliminated the age limit and advised that for Plan Year 2026, chemical and surgical modification of an individual's sex traits through medical interventions (to include ''gender transition'' services) will no longer be covered under the FEHB or PSHB Programs. Specifically, it excludes hormone treatments that pertain to chemical and surgical modification of an individual's sex traits (including as part of ''gender transition'' services) and clarifies that carriers should not exclude coverage for entire classes of pharmaceuticals. For example, GnRH agonists may be prescribed during in vitro fertilization (IVF), for reduction of endometriosis or fibroids, and for cancer treatment or prostate cancer/tumor growth prevention.[98]

As previously noted, section 2101(a) of the Act provides 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. As outlined previously in this proposed rule, while the prohibitions on coverage are not identical, they will effectively result in prohibition of coverage of sex-rejecting procedures in both the FEHB Program and as an EHB beginning with Plan Year 2026. Therefore, we are proposing to add a new section § 457.476 to prohibit Federal financial participation for sex-rejecting procedures under CHIP, to align CHIP with Medicaid, the FEHB Program, and EHBs. Although title XXI of the Act does not apply EHB rules under a separate CHIP, the services which must be covered under title XXI also are EHBs. We note that similar to Medicaid, this proposed change in CHIP would not prohibit Federal payment for procedures undertaken to treat a child with a medically verifiable disorder of sexual development; for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

We also note that section 2107(e) of the Act applies numerous provisions in Medicaid in the same manner to title XXI as would be the case under this proposed rule.

We take very seriously the weak evidence base supporting the safety or effectiveness of sex-rejecting procedures in minors, and the plausible evidence of harm, for the purposes included in our proposed definition. Based on these factors, we propose to prohibit Federal CHIP funds for sex-rejecting procedures for the purposes included in our proposed definition. It is also important to reiterate that these regulatory changes would not prohibit the use of Federal CHIP dollars for mental health treatments for conditions such as gender dysphoria.

II. Provisions of the Proposed Regulations

A. General Discussion

We propose to exercise our separate authorities under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to add a new subpart N to part 441 to prohibit Federal Financial Participation (FFP) in Medicaid for sex-rejecting procedures for the purposes included in our proposed definition for individuals under the age of 18, as this is the age of majority in most States. For CHIP, we

[97] Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 FR 27152 (June 25, 2025). While portions of the ''Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability,'' final rule (90 FR 27074), have been challenged, the requirement that issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to the essential health benefit (EHB) requirements—cannot provide coverage for ''specified sex-trait modifications'' as an EHB will begin with Plan Year 2026.

[98] U.S. Office of Personnel Management (OPM) FEHB Program Carrier Letter, Letter Number 2025–01A, ''Addendum to Call Letter for Plan Year 2026,'' January 31, 2025, *https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-1a.pdf.* Amended by OPM FEHB Programs Carrier Letter, Letter Number 2025–01B, ''Subject: Chemical and Surgical Sex-Trait Modification Services for Plan Year 2026 Proposals,'' August 15, 2025, *https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-01b.pdf.*

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propose to exercise our authority under section 2103(c) of the Act to revise subpart D of 42 CFR part 457 to prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures for the purposes included in our proposed definition for individuals under the age of 19, as this age aligns with the statutory definition of ''child'' at 2110(c)(1) of the Act. While this proposal aligns with section 5(a) of E.O. 14187, we are also proposing this change based on current evidence, which does not conclusively support the use of sex-rejecting procedures to treat gender dysphoria in children. It is important to emphasize that these proposed regulatory changes would not prohibit the use of Federal Medicaid or CHIP dollars for mental health treatments for conditions such as gender dysphoria. Nor would these proposed changes prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP. We note that this proposed rule also does not prohibit Federal reimbursement of procedures undertaken (i) to treat a child with a medically verifiable disorder of sexual development; (ii) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (iii) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

B. Prohibition on Medicaid Payment for Sex-Rejecting Procedures (§ 441.800)

We propose to add a new subpart N to 42 CFR part 441 to protect Medicaid beneficiaries and ensure Medicaid payments are consistent with quality of care by prohibiting Federal Medicaid payments to States for sex-rejecting procedures provided to children under the age of 18. The basis and purpose of proposed subpart N (as described previously in this proposed rule) is reflected in proposed § 441.800.

Within new subpart N, we propose at § 441.802(a) that State Medicaid plans must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18. Per 42 CFR 430.10, the State plan is the vehicle through which States assure that their Medicaid programs will be administered in conformity with title XIX of the Act (including sections 1902(a)(19) and 1902(a)(30)(A) of the Act) and CMS' implementing regulations, and the State plan must also contain all information necessary for CMS to determine whether the plan can serve as a basis for FFP. Proposed § 441.802(a) would not preclude States from covering sex-rejecting procedures with State-only funding outside of their Federally-matched Medicaid programs. We propose at § 441.802(b) that FFP would not be available in State expenditures for sex-rejecting procedures for children under the age of 18.

Proposed § 441.801 would define sex-rejecting procedures as any pharmaceutical or surgical intervention that attempts to align a child's physical appearance or body with an asserted identity that differs from the child's sex either by: (1) intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or (2) intentionally altering a child's physical appearance or body, including amputating, minimizing, or destroying primary or secondary sex-based traits such as the sexual and reproductive organs. However, our proposed definition also provides that the term sex-rejecting procedures would not include procedures undertaken: (i) to treat a child with a medically verifiable disorder of sexual development; (ii) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (iii) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Given States' obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to assure care and services are provided consistent with the best interests of Medicaid recipients and that payments are consistent with quality of care, respectively, we believe that our proposed prohibition of FFP in State expenditures for sex-rejecting procedures for children under age 18 is necessary given the lack of an adequate evidence base for the effectiveness of these treatments for the purposes that would be included in our proposed definition and the significant potential for negative and irreversible side effects.

We note that CMS has imposed age limitations on the availability of Federal funding for certain procedures in the Medicaid program before. CMS has long prohibited, at § 441.253, Federal funding for permanent sterilizations furnished to individuals under age 21, motivated by concerns about potential coercion, informed consent, and patient regret that were based on data specifically related to permanent sterilizations (see preamble discussion at 43 FR 52146, 52151 through 52153). In this context, our concerns about the effectiveness of sex-rejecting procedures and the plausible evidence of harm motivate our proposal to prohibit Federal funding for sex-rejecting procedures for children under the age of 18. Specifically, this proposed rule recognizes that the more cautious approach of psychosocial support to treat individuals diagnosed with gender dysphoria prior to age 18—the legal age of majority in nearly all U.S. States and Territories [99] [100]—better protects children and youth from adverse effects of any such procedures.

Three states have a different, higher age of majority. Alabama and Nebraska's age of majority is 19 and Mississippi has the highest age of majority at 21.[101] This rule would not conflict with the age of majority in Alabama, Nebraska and Mississippi because these States recognize higher ages of majority than this proposed rule. Under this proposed rule, sex-rejecting procedures would be available for Medicaid coverage at age 18, which is a lower age than the age of majority in these States. Additionally, nothing in this proposed rule preempts State authority to regulate the age of majority in their State, nor does it interfere with a State's ability to fund these services with State-only funds. Further, it is clear that in making policy choices for the administration of a Federal program, State law is not controlling. This proposed rule would make age 18 the floor of Federal coverage for sex-rejecting procedures under the Medicaid program, should a State include such procedures in their program.

We originally considered establishing the prohibition on Federal reimbursement of sex-rejecting procedures to individuals under age 19 as we are now proposing for CHIP.

[99] CMS is aware that 3 States—Alabama, Nebraska, and Mississippi—recognize higher ages as the age of majority. See ''Age of Majority by State 2025,'' World Population Review, accessed August 11, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.* CMS is proposing to prohibit FFP in State expenditures within the Medicaid program for sex-rejecting procedures for children under the age of 18 to correspond to the legal age of majority used by the overwhelming majority of States and Territories. Because section 2110(c)(1) of the Act defines ''child'' for purposes of CHIP as an individual under age 19, CMS is proposing to prohibit FFP in State expenditures within CHIP for sex-rejecting procedures for children under age 19.

[100] ''Age of Majority by State 2025,'' World Population Review, accessed September 9, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.*

[101] ''Age of Majority by State 2025,'' World Population Review, accessed September 9, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.*

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However, age 19 has no specific meaning for the Medicaid program and, as stated, is a year older than the legal age of majority in nearly all U.S. States and Territories. By comparison, this is not true under CHIP, as the statutory definition of a child in CHIP under section 2110(c)(1) of the Act is an individual under 19 years of age. In addition to other issues, we solicit comment on the operational feasibility of States in implementing the under age 18 prohibition in Medicaid and the under age 19 prohibition in CHIP.

As discussed previously, States have obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to ensure that Medicaid-covered care and services are provided in a manner consistent with the best interests of beneficiaries and to assure that payments for Medicaid-covered care and services are consistent with quality of care. For the reasons discussed in this proposed rule, CMS believes prohibiting Federal Medicaid funding for sex-rejecting procedures for children under the age of 18 is warranted to help ensure that States meet these statutory obligations.

We believe that the proposed definition of sex-rejecting procedures provides an appropriate degree of clarity and certainty regarding which sex-rejecting procedures would and would not be subject to the prohibitions at proposed § 441.802. We believe the proposed definition is narrowly tailored and appropriate to exclude only treatments CMS has determined to lack sufficient evidence of safety for their intended purposes. Examples such as procedures to treat precocious puberty, therapy subsequent to a traumatic injury, or the use of hormone replacement therapy to treat a growth hormone deficiency would not fall under the proposed definition of sex-rejecting procedures, and Federal Medicaid payment for such procedures would therefore not be prohibited for individuals under the age of 18, when medically necessary. As the HHS Review explains, central precocious puberty and gender dysphoria are distinct clinical entities. In addition, because the proposed definition is narrowly tailored in this way, we believe that States will be able to administer Medicaid coverage for drugs in a manner that is consistent with both the proposed rule and the requirements in section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, if manufacturers enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act, payment is available for the CODs covered under that NDRA for medically accepted indications.[102] As defined in section 1927(k)(6) of the Act, ''medically accepted indications'' mean use for a COD approved under the Federal Food, Drug, and Cosmetic Act or approved for inclusion in any of the compendia described in subsection 1927(g)(1)(B)(i) of the Act. 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. In addition, we note that this proposed rule only applies to pharmaceuticals that are used in the proposed definition and would not apply to other pharmaceuticals that are prescribed to a child.

As noted previously, the proposed definition of sex-rejecting procedures categorically would exclude procedures undertaken (1) to treat a child with a medically verifiable disorder of sexual development; (2) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (3) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s). We reiterate that these proposed regulatory changes would not prohibit the use of Federal Medicaid dollars for mental health treatments for conditions such as gender dysphoria.

In addition, to further explain the meaning of terms used in the proposed sex-rejecting procedures definition, we also propose definitions at new § 441.801 that would apply to subpart N of part 441. We propose to define FFP for purposes of subpart N of part 441 as Federal financial participation, recognizing the longstanding term used in the Medicaid program to describe the Federal Government's matching arrangement with States and Territories. We also propose to define ''female'' as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We propose to define ''male'' as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. We propose to define ''sex'' as a person's immutable biological classification as either male or female.

A landmark study of and model for anisogamy established that differences in gamete size, and the associated differences in gamete production time, lead to stable sexual dimorphism and the establishment of two biological sexes: ovum producers (females) and sperm producers (males).[103] Additionally, more recent literature acknowledges differences in sex roles but maintains that such differences can still be traced to the concept of anisogamy and the resultant sexual dimorphism that remain the root cause of sex specific selection, the sex roles, and the determination of biological sex.[104] We believe our proposed definitions of female, male, and sex are appropriately rooted in this concept and biological reality. In addition to other issues, we solicit comments on whether these proposed definitions of ''sex'', ''male'', and ''female'' could pose challenges to States in operationalizing this proposed prohibition on Federal reimbursement of sex-rejecting procedures or other aspects of the Medicaid program or CHIP.

Given the weak evidence base underlying sex-rejecting procedures for children and the potential risk of harm, including long-term harm, we believe this proposed rule appropriately implements the directives to States under sections 1902(a)(19) and 1902(a)(30)(A) of the Act that care and treatment provided under Medicaid must be in the best interests of recipients, and that payment for services must be consistent with quality of care.

C. Prohibition on CHIP Payment for Sex-Rejecting Procedures

We propose to revise subpart D in 42 CFR part 457 to prohibit Federal CHIP payments to States for sex-rejecting procedures provided to children. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with section 2101(a) of the Act by prohibiting Federal financial participation in payments by

[102] The NDRA does not have a specific OMB number, however the OMB package that contains all of the information a manufacturer has to report once entering into an NDRA is included in CMS 367a–367e.

[103] G.A. Parker et al., ''The origin and evolution of gamete dimorphism and the male-female phenomenon,'' *Journal of Theoretical Biology* 36, no. 3 (1972): 529–553, *https://doi.org/10.1016/0022-5193(72)90007-0.*

[104] Lukas Schärer et al., ''Anisogamy, chance and the evolution of sex roles,'' *Trends in Ecology & Evolution* 27, no. 5 (2012): 260–264, *https://doi.org/10.1016/j.tree.2011.12.006.*

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States for sex-rejecting procedures for a child under the age of 19. This would create consistency between CHIP coverage and Medicaid.

The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. The definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

We believe that our proposed prohibition of Federal CHIP payment for sex-rejecting procedures is necessary given the need to align CHIP coverage with coverage of these services in Medicaid, the lack of scientific evidence regarding the effectiveness of these treatments, and the significant potential for negative and often irreversible side effects when used for the purposes included in our proposed definition in children.

For each of these provisions outlined previously in this proposed rule, we anticipate stopping the Federal reimbursement of sex-rejecting procedures immediately upon the effective date of the rule finalizing these provisions, for both Medicaid and CHIP.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule (CMS–2451–F, RIN 0938–AV73), if this proposed rule is finalized.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Statistics for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialist	13–1000	43.76	43.76	87.52
General and Operations Manager	11–1021	64.00	64.00	128.00

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Definitions (§ 441.801)

We anticipate that the proposed definitions (adding and defining ''female'', ''male'', ''sex'', and ''sex-rejecting procedure'') may result in the need for some States to amend existing policy/manual documents where those items are inconsistent with the parameters of this proposed rule. However, we do not anticipate that this would impact any active claims/billing forms or their instructions.

We estimate a potential of 56 Medicaid respondents and 56 CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. Based on research discussed in section I.1.C. (United States' State Bans of and Coverage of Sex-Rejecting Procedures) of this proposed rule, approximately 27 States and one Territory have laws enacted restricting some or all of the *sex*-rejecting *procedures* that would be covered by this proposed rule. For these States and Territories, we do not anticipate State staff will need to conduct a review of policy documents for Medicaid or CHIP as these procedures are currently banned (or will be banned).

For the remainder of States and Territories, we assume that State staff will conduct a review for both Medicaid policy documents and CHIP policy documents. As a result, we estimate 28 States and Territories that would need to amend their existing policy documents consistent with these definitions. We estimate it will take 3 hours at $87.52/hr for a Business Operations Specialist to review existing State policy documents to ensure consistency with the proposed definitions and 1 hour at $128.00/hr for a General and Operations Manager to review and approve the necessary State policy document changes.

In aggregate we estimate a one-time State burden of 112 hours (28 States × 4 hr/response) at a cost of $10,936 [(3 hr × $87.52/hr × 28 States) + (1 hr × $128.00/hr × 28 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of $5,468 ($10,936 * 0.5). We assumed all services meeting the proposed definition would no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

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2. ICRs Regarding the Prohibition on Payment for Sex-Rejecting Procedures (§ 441.802)

If this proposed rule is finalized, the following changes and associated SPA template will be made available for public review/comment under control number CMS–10398 #97, OMB 0938–1148) via the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, the following scores the potential impact for preparing and submitting the SPA. We will revisit these preliminary estimates during the standard PRA process and revise if needed.

Under the proposed provision, States and Territories would be required to submit SPAs specifically indicating adherence to the prohibition on claiming Federal funding of sex-rejecting procedures for individuals under the age of 18 for Medicaid and for individuals under the age of 19 for CHIP. The content of the SPA would be a simple recitation of the prohibition. As indicated above, the template will be made available for public review and comment if this proposed rule is finalized. We intend to require all States and Territories to submit this template for approval as part of their State plan.

We estimate a potential of 56 Medicaid and CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. We estimate it will take 2 hours at $87.52/hr for a Business Operations Specialist to prepare an initial SPA and 1 hour at $128.00/hr for a General and Operations Manager to review and approve the SPA for submission to CMS.

In aggregate, we estimate a one-time State burden of 168 hours (56 States × 3 hr/response) at a cost of $16,970 [(2 hr × $87.52/hr × 56 States) + (1 hr × $128.00/hr × 56 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of $8,485 ($16,970 * 0.5). We assumed all services meeting the proposed definition would no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

C. Summary of Proposed Requirements and Burden Estimates

TABLE 2—PROPOSED REQUIREMENTS/BURDEN ESTIMATES

Regulation section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Respondents	Responses (per State)	Total responses	Time per response (hr)	Total time (hr)	Labor costs ($/hr)	Total cost ($)	State cost ($)
§ 441.801	N/A	28 States and Territories	1	28	4	112	Varies	10,936	5,468
§ 441.802	CMS–10398 #97, OMB 0938–1148.	56 States and Territories	1	56	3	168	Varies	16,970	8,485
Total		56	2	84	Varies	280	Varies	27,906	13,953

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the proposed rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the proposed rule (CMS–2451–P, RIN 0938–AV73), the ICR's CFR citation, and the OMB control number.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Statement of Need

Throughout the U.S., thousands of children are receiving sex-rejecting procedures for the purpose of attempting to align their bodies with an asserted identity that differs from their sex. As outlined in this proposed rule, however, the current medical evidence does not support conclusively these interventions and indicates that they might lack clear benefits while posing a health and safety risk to children. To help ensure that Medicaid services are provided in a manner consistent with the best interests of the recipients and that Medicaid payments are consistent with quality of care, we are proposing a prohibition on State Medicaid Agencies from providing payment under the plan for sex-rejecting procedures for children under the age of 18 and proposing a prohibition on State CHIPs from providing payment under the plan for sex-rejecting procedures for children under the age of 19.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan

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programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Impacts on Federal Expenditures and Other Transfers

We estimate that this proposal would reduce Federal Medicaid spending by about $188 million from fiscal year 2027 through fiscal year 2036 (in real 2027 dollars). To estimate the impact of this proposal, we analyzed data from T–MSIS TAF v8.0 for 2023. We selected all claims with a gender dysphoria diagnosis and in the following claims categories: inpatient hospital with surgical procedure; outpatient hospital with surgical procedure; and professional services and prescription drugs with hormone therapy. We included fee-for-service and managed care encounter data. We also analyzed this data by beneficiary age group and counted only spending for individuals ages 17 and younger. We note that the proposed policy would not prohibit payment by a State Medicaid agency for these services for those age 18, and those individuals and costs are not included as part of the estimates. This data also includes CHIP expenditures for these services.

For 2023, we identified about $31 million in total computable Medicaid and CHIP spending for these services and individuals. States that had not banned gender dysphoria treatments for children as of 2023 accounted for 76 percent of spending, including 92 percent of inpatient treatment with surgery and 87 percent of outpatient treatment with surgery.

TABLE 3—MEDICAID EXPENDITURES ON GENDER DYSPHORIA TREATMENT BY CATEGORY OF SERVICE AND AGE GROUP, 2023

	Age 6–12	Age 13–14	Age 15–18	Total
Inpatient hospital with surgery	$0	$0	$180,553	$180,553
Outpatient hospital with surgery	15,526	23,534	2,145,082	2,184,142
Professional services hormone therapy	482,924	1,180,610	3,089,948	4,753,482
Prescription drug hormone therapy	2,566,749	6,130,955	14,779,884	23,477,588
Total	3,065,198	7,335,099	20,195,468	30,595,765

Source: Analysis of T–MSIS TAF v8.0.
Note: The T–MSIS data includes enrollment and spending by age groups, which includes ages 15–18 as one group. The policy in this proposed rule would only affect Medicaid enrollees under age 18 (ages 15–17), but the table above includes spending for individuals age 18. We note that we have adjusted for this when developing the estimates in the RIA.

We projected this spending forward from 2023 through 2035 using projected growth in Medicaid and CHIP spending on children from the Mid-Session Review of the President's fiscal year 2026 Budget. We assumed all services would no longer be covered by Medicaid or CHIP, and thus not eligible for Federal matching funds. We solicit comment on whether states that currently cover services would continue to cover these services absent FFP as described in this proposed rulemaking.

States that currently cover these services under Medicaid would see the largest reductions in Medicaid spending. We also assumed about 3 percent of spending would be delayed until individuals reach age 18, reflecting 50 percent of the surgical procedures being paid by Medicaid and CHIP in the future. Absent data or analysis on the impact of prohibitions on these procedures, we assumed some individuals would ultimately receive these services once eligible and believe 50 percent is reasonable (considering that some individuals would no longer be eligible for Medicaid in the future and some individuals may find other sources of coverage).

Table 4 shows the annual impact of the proposal on total and Federal Medicaid and CHIP spending in millions of dollars. These estimates assume the policies in the proposed rule would be effective as of October 1, 2026. Total Medicaid and CHIP spending would be reduced by $318 million over 10 years, Federal spending would be reduced by $188 million, and State spending would be reduced by $130 million (in real 2027 dollars). Actual impacts may vary from these estimates. We have relied on the most recently available program data for this analysis and projections of future enrollment and spending. Actual future costs may vary if enrollment and spending are higher or lower than projected.

TABLE 4—PROJECTED IMPACTS OF PROHIBITING COVERAGE OF SEX-REJECTING PROCEDURES FOR INDIVIDUALS UNDER 18 ON MEDICAID SPENDING

[In millions of real 2027 dollars]

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027–2036
Total	−30	−30	−30	−31	−32	−32	−32	−33	−34	−34	−318
Federal	−18	−18	−18	−18	−19	−19	−19	−19	−20	−20	−188
State	−12	−12	−12	−13	−13	−13	−13	−14	−14	−14	−130

We have made reasonable assumptions about how individuals may use these services in the future. A greater or lesser number of individuals may still receive coverage for these services upon reaching age 18 than we have assumed. In addition, it is possible some individuals may find alternative coverage for these services (for example,

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States covering services without Federal funding, or private insurance). We have also not estimated if there would be any other impacts on Federal expenditures (for example, increases in other healthcare services related to gender dysphoria).

2. Costs

In addition, the proposed rule may result in several costs. States would need to update State plans or waivers to comply with the proposed changes to covered benefits. Those impacts are described in section III. of this proposed rule. In addition, the changes in this proposed rule may prevent or delay individuals from receiving these healthcare services.

3. Alternatives

As an alternative to this proposed rule, we considered taking no action to require that a State Medicaid or CHIP plan must provide that the Medicaid or CHIP agency will not make payment under the plan for sex-rejecting procedures for children in Medicaid under the age of 18 and children in CHIP under the age of 19 and to prohibit the use of Federal Medicaid or CHIP dollars to fund sex-rejecting procedures for these individuals. On January 28, 2025, President Trump issued E.O. 14187, Protecting Children from Chemical and Surgical Mutilation. Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children including regulatory and sub-regulatory actions for specific programs, including Medicaid. In alignment with the Executive Order and the evidence outlined in section I.B. of this proposed rule, CMS decided to pursue this proposed policy. These proposed changes would not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

D. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant economic impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all hospitals and other healthcare providers are small entities as that term is used in the RFA (including small businesses, small nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other healthcare providers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, approximately 96 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards. According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards,* the health care industries impacted fall in the North American Industrial Classification System (NAICS) 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; and 622110 General Medical and Surgical Hospitals. Table 5 shows the industry size standards for each of these health care industries.

TABLE 5—HEALTH CARE INDUSTRY SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/ small entity threshold (million)	Total small businesses
446110	Pharmacies and Drug Stores	$37.5	18,461
621111	Offices of Physicians (except Mental Health Specialists)	16.0	129,117
621112	Offices of Physicians, Mental Health Specialists	13.5	12,325
621493	Freestanding Ambulatory Surgical and Emergency Centers	19.0	5,569
621498	All Other Outpatient Care Centers	25.5	9,801
622110	General Medical and Surgical Hospitals	47.0	1,169

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html*.

Tables 6 through 11 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These tables aim to provide an understanding of the disproportionate impacts among firms, between small and large firms.

TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES

[$37.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	18,461	100	$3,930,615.08
<$100K	560	3	50,953.57
$100K–$499K	1,733	9	292,525.68
$500–$999K	1,764	10	753,448.41
$1M–$2.499M	4,810	26	1,760,637.01
$2.5M–$4.999M	5,159	28	3,606,681.53
$5M–$7.499M	2,137	12	6,079,067.38
$7.5M–$9.999M	869	5	8,624,350.98
$10M–$14.999M	762	4	11,934,971.13
$15M–$19.999M	318	2	16,805,396.23
$20M–$24.999M	146	1	21,375,342.47
$25M–$29.999M	98	1	26,077,561.22
$30M–$34.999M	64	0	27,529,546.88
$35M–$39.999M	41	0	30,746,414.63

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TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES—Continued

[$37.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
LARGE FIRMS			
Receipts>$40M	396	N/A	672,827,431.82

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 7—NAICS 621111 OFFICES OF PHYSICIANS (EXCEPT MENTAL HEALTH SPECIALISTS)

[$16.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	129,117	100	$1,463,302.41
<$100K	11,119	9	51,195.79
$100K–$499K	44,138	34	296,376.77
$500–$999K	30,224	23	712,231.21
$1M–$2.499M	24,522	19	1,559,970.11
$2.5M–$4.999M	10,388	8	3,475,423.18
$5M–$7.499M	3,799	3	6,048,868.65
$7.5M–$9.999M	1,945	2	8,498,150.64
$10M–$14.999M	2,003	2	11,844,361.46
$15M–19.999M	979	1	16,517,796.73
LARGE FIRMS			
Receipts >$20M	3,782	N/A	116,848,659.18

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 8—NAICS 621112 OFFICES OF PHYSICIANS, MENTAL HEALTH SPECIALISTS

[$13.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	12,325	100	$634,311.40
<$100K	2,125	17	52,448.00
$100K–$499K	6,341	51	261,018.29
$500–$999K	2,092	17	686,686.90
$1M–$2.499M	1,206	10	1,496,716.42
$2.5M–$4.999M	338	3	3,331,017.75
$5M–$7.499M	111	1	5,735,522.52
$7.5M–$9.999M	52	0	8,039,461.54
$10M–$14.999M	60	0	10,485,850.00
LARGE FIRMS			
Receipts >$15M	212	N/A	14,421,103.77

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 9—NAICS 621493 FREESTANDING AMBULATORY SURGICAL AND EMERGENCY CENTERS

[$19.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	5,569	100	$2,713,466.15
<$100K	353	6	48,246.46
$100K–$499K	1,249	22	287,140.11
$500–$999K	867	16	724,727.80
$1M–$2.499M	1,265	23	1,648,132.81
$2.5M–$4.999M	845	15	3,602,647.34
$5M–$7.499M	413	7	5,999,140.44
$7.5M–$9.999M	223	4	8,392,170.40
$10M–$14.999M	241	4	11,472,634.85
$15M–19.999M	113	2	16,496,955.75
LARGE FIRMS			
Receipts >$20M	610	N/A	46,366,978.69

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

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TABLE 10—NAICS 621498 ALL OTHER OUTPATIENT CARE CENTERS

[$25.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	9,801	100	$2,124,005.00
<$100K	1,079	11	48,916.59
$100K–$499K	2,925	30	283,037.26
$500–$999K	1,832	19	719,524.02
$1M–$2.499M	1,990	20	1,545,938.69
$2.5M–$4.999M	790	8	3,409,083.54
$5M–$7.499M	289	3	5,739,238.75
$7.5M–$9.999M	193	2	7,644,943.01
$10M–$14.999M	292	3	10,567,616.44
$15M–$19.999M	184	2	13,609,652.17
$20M–$24.999M	137	1	16,169,890.51
$25M–$29.999M	90	1	21,218,188.89
LARGE FIRMS	.....	.....	.....
Receipts >$30M	1,008	N/A	55,938,203.37

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 11—NAICS 622110 GENERAL MEDICAL AND SURGICAL HOSPITALS

[$47.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	1,169	100	$17,598,603.93
<$100K	59	5	49,491.53
$100K–$499K	150	13	270,466.67
$500–$999K	54	5	696,814.81
$1M–$2.499M	28	2	1,522,000.00
$2.5M–$4.999M	28	2	3,739,428.57
$5M–$7.499M	35	3	6,512,657.14
$7.5M–$9.999M	51	4	8,550,588.24
$10M–$14.999M	124	11	11,777,798.39
$15M–$19.999M	132	11	16,993,166.67
$20M–$24.999M	121	10	22,389,727.27
$25M–$29.999M	100	9	26,686,900.00
$30M–$34.999M	99	8	31,329,858.59
$35M–$39.999M	66	6	35,617,636.36
$40M–44.999M	122	10	42,184,385.25
$45M–$49.999M	1,169	5	17,598,603.93
LARGE FIRMS	.....	.....	.....
Receipts >$50M	1,404	N/A	884,790,689.46

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

Individuals and States are not included in the definition of a small entity.

As shown in Table 12, all the industries combined, according to the 2022 Economic Census, earned approximately $2,364,153,884,000, while the small firms for all the industries combined earned approximately $325,819,624,000. Table 13 in section V.E. estimates a $31.6 million reduction in total annualized monetized transfers from the Federal Government and States to health care providers. This total estimated reduction represents less than 1 percent of the total revenues of the health care industries impacted and the total revenues of the small firms in the health care industries impacted. It also represents less than 1 percent of the total revenues of each health care industry impacted and the total revenues of the small firms in each health care industry impacted. As a result, this proposed rule if finalized would result in a change in revenue of less than 1 percent for the impacted health care industries.

TABLE 12—TOTAL REVENUES, ALL FIRMS AND SMALL FIRMS, BY NAICS CLASSIFICATION

NAICS	Total revenues (all firms)	Revenue test* (%)	Total revenues (small firms)	Revenue test* (%)
446110 Pharmacies and Drug Stores	$339,002,748,000.00	0.01	$72,563,085,000.00	0.04
621111 Offices of Physicians (except Mental Health Specialists)	630,858,846,000.00	0.00	188,937,217,000.00	0.02
621112 Offices of Physicians, Mental Health Specialists	10,875,162,000.00	0.29	7,817,888,000.00	0.40
621493 Freestanding Ambulatory Surgical and Emergency Centers	43,395,150,000.00	0.07	15,111,293,000.00	0.21
621498 All Other Outpatient Care Centers	77,203,082,000.00	0.04	20,817,373,000.00	0.15

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TABLE 12—TOTAL REVENUES, ALL FIRMS AND SMALL FIRMS, BY NAICS CLASSIFICATION—Continued

NAICS	Total revenues (all firms)	Revenue test* (%)	Total revenues (small firms)	Revenue test* (%)
622110 General Medical and Surgical Hospitals	1,262,818,896,000.00	0.00	20,572,768,000.00	0.15
Total	2,364,153,884,000.00	0.00	325,819,624,000.00	0.01

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html*.
*Calculated using an estimated reduction in total annualized monetized transfers of $31.6 million (as shown in Table 13) as a percentage of total revenues.

As its measure of significant economic impact on a substantial number of small entities,

HHS uses a change in revenue of more than 3 to 5 percent. According to Table 12, we do not believe that the 3 to 5 percent threshold will be reached by the proposed requirements in this rule for NAICS 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; or 622110 General Medical and Surgical Hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities in these industries.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. The proposed rule would not mandate significant spending costs on State, local, or Tribal governments in the aggregate, or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. This proposed rule will have a substantial direct effect on the ability of States to receive Federal Medicaid funds for sex-rejecting procedures furnished to children under age 18 and on the ability of States to receive Federal CHIP funds for sex-rejecting procedures furnished to children under age 19.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 13 showing the classification of the impact associated with the provisions of this proposed rule.[105]

TABLE 13—ACCOUNTING STATEMENT

Transfers	Estimate (million)	Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($/year)	$18.7	2027	7	2027–2036
	18.7	2027	3	2027–2036
Quantitative: • Estimated reduction in transfers from Federal Government to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				
Annualized Monetized ($/year)	12.9	2026	7	2027–2036
	12.9	2026	3	2027–2036
Quantitative: • Estimated reduction in transfers from States to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				

Table 13 shows the annualized monetized transfer values required under OMB Circular A–4. At a discount rate of 7 percent, the annualized monetized transfers are $18.7 million to the Federal government and $12.9 million to the States, reflecting a reduction in payment for these services to healthcare providers. At a discount rate of 3 percent, the annualized monetized transfers are also $18.7 million to the Federal government and $12.9 million to the States.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid

[105] The effects attributable to this proposed rule might be lower in magnitude than the aggregates presented here if other actions, such as the HHS/CMS proposal titled ''Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures on Children,'' are finalized before finalization of this proposal.

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Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

Grant programs—health, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 1. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Part 441 is amended by adding subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.
441.800 Basis and purpose.
441.801 Definitions.
441.802 General rules.

§ 441.800 Basis and purpose.

Basis and purpose. The purpose of this section is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

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

(1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat a child with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or.

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) A State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 457.476 is added to subpart D to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) Basis and purpose. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23464 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Medicare and Medicaid certified hospitals must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of children and reflect HHS' review of recent information on the safety and efficacy of sex-rejecting procedures (SRPs) on children. The revisions to the requirements would prohibit hospitals from performing sex-rejecting procedures on children.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3481–P.

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Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

Grant programs—health, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 1. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Part 441 is amended by adding subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.
441.800 Basis and purpose.
441.801 Definitions.
441.802 General rules.

§ 441.800 Basis and purpose.

Basis and purpose. The purpose of this section is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

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

(1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat a child with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or.

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) A State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 457.476 is added to subpart D to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) Basis and purpose. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23464 Filed 12–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Medicare and Medicaid certified hospitals must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of children and reflect HHS' review of recent information on the safety and efficacy of sex-rejecting procedures (SRPs) on children. The revisions to the requirements would prohibit hospitals from performing sex-rejecting procedures on children.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3481–P.

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Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3481–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3481–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: CMS Office of Communications, Department of Health and Human Services; email *press@cms.hhs.gov.*

For technical inquiries: CMS Center for Clinical Standards and Quality. Department of Health and Human Services. *HospitalSRPInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background

On January 28, 2025, President Trump signed Executive Order (E.O.) 14187 ''Protecting Children from Chemical and Surgical Mutilation.'' [1] In particular, Section 5(a) of the order directs the Secretary of HHS consistent with applicable law to ''take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and subregulatory actions, which may involve [. . .]: Medicare or Medicaid conditions of participation or conditions for coverage.'' CMS has developed this proposed rule in compliance with this E.O. As further discussed in this proposed rule, we describe CMS' statutory authority related to patient health and safety standards (known as Medicare ''Conditions of Participation'' (CoPs), ''Conditions for Coverage'' (CfCs), or simply ''Requirements''), summarize data on the rise of sex-rejecting procedures (SRPs) on children, review the latest information on SRPs in children as described in the HHS Review (the Review), provide an overview of State laws, as well as prior CMS actions on this topic. We propose to add a new section to 42 CFR part 482, subpart C that would prohibit Medicare-participating hospitals from performing sex-rejecting procedures (SRPs) on any child (§ 482.46(a)).

A. Statutory Authority

CMS has broad statutory authority under the Social Security Act (the Act) to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of children. Section 1861(e)(9) of the Act, applicable to hospitals that participate in the Medicare program, explicitly gives CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in a hospital, while section 1871 of the Act gives CMS the authority to prescribe regulations as necessary to carry out the administration of the program. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, entitled ''Conditions of Participation'' for Hospitals. Section 1905(a) of the statute provides that Medicaid payments from States may be applied to hospital services. Under regulations at §§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii), hospitals that provide inpatient and outpatient services, respectively, to Medicaid enrollees are required to meet the Medicare CoPs to also participate in Medicaid. In this way, the CoPs regulate the safety of all patients in a facility that is subject to 42 CFR part 482, regardless of payor (for example, Medicare, Medicaid, private insurance, and self-pay).

The CoPs for hospitals include specific, process-oriented requirements for certain hospital services or departments. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals.

B. Sex-Rejecting Procedures for Children With Gender Dysphoria

1. The Rise of Chemical and Surgical Interventions for Children as Part of Sex-Rejecting Procedures for Gender Dysphoria

Gender dysphoria is a condition defined by the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM–5–TR) as a ''marked incongruence between one's experienced/expressed gender and assigned gender'' that ''must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.'' [2] [3] Over the past decade, increasing numbers of children have been diagnosed with gender dysphoria and been treated with SRPs.[4] [5] SRPs can encompass a range of hormonal and surgical interventions: pharmacological interventions including puberty blocking medications to delay the onset of puberty, cross-sex hormone therapy to promote secondary sexual

[1] ''Protecting Children from Chemical and Surgical Mutilation.'' *The White House,* 28 Jan. 2025, *https://www.whitehouse.gov/presidential-actions/2025/01/protecting-children-from-chemical-and-surgical-mutilation/.*

[2] Coleman, E., et al. ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online,* doi:10.1080/26895269.2022.2100644.

[3] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders.* 5th ed. Edition, Text Revision, American Psychiatric Publishing,2022, *https://doi.org/10.1176/appi.books.9780890425787.*

[4] Coleman Eli, et. al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022 pp. S1–S259. *Taylor & Francis Online, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.*

[5] Hembree, Wylie C., et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.'' *The Journal of Clinical Endocrinology & Metabolism,* vol. 102, no. 11 (13 September 2017, pp. 3869–3903, *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

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characteristics associated with the opposite biological sex, and surgical procedures (such as chest/breast and genital surgery).[6] [7]

The recorded prevalence of SRPs for children with gender dysphoria varies across sources. A study published in 2023 estimated that between 2016 and 2020, nearly 3,700 children aged 12 to 18 years old diagnosed with gender dysphoria underwent SRPs (2.50 per 100,000),[8] including an estimated 3,200 chest/breast procedures (2.17 per 100,000) [9] and 400 genital surgeries (0.27 per 100,000).[10] [11] Another study documented that almost 0.2 percent (or almost 2 in every 1,000) of 17-year-olds [12] with private insurance received SRP hormone treatment between 2018 through 2022.[13] [14]

While Medicare does not pay for a significant number of SRP procedures for children, we conclude that, based on the previously cited data, hospitals that participate in Medicare perform a considerable number of these procedures every year. We further note that the Medicare hospital CoPs apply to hospitals providing services to patients receiving Medicaid covered services ((§§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii)). Approximately half of U.S. children receive health care through Medicaid.

2. Medical Evidence Regarding Sex-Rejecting Procedures in Children

The rising numbers of children seeking and receiving SRPs in recent years [15] has spurred ongoing debates regarding the safety and efficacy of these interventions.

a. The HHS Review

In compliance with Executive Order (E.O.) 14187, ''Protecting Children from Chemical and Surgical Mutilation'' [16] signed on January 28, 2025 (as discussed previously in this proposed rule), HHS released a preliminary comprehensive review of the evidence and best practices for treating pediatric gender dysphoria on May 1, 2025.[17] On November 19, 2025, HHS published a final version following the conclusion of a peer review process.[18] the Review provides an overview of systematic reviews—also known as an ''umbrella review''—to evaluate the evidence of the benefits and harms of SRPs in children. Several existing systematic reviews of evidence that have informed health authorities in Europe were assessed for methodological quality.

The Review itself does not provide clinical or policy recommendations. Instead, it analyzes evidence and best practices for children experiencing gender dysphoria. The Review also contains an ethics review that applies widely accepted principles of medical ethics to the practice of SRPs in children.[19] Accordingly, the Review states:

''As demonstrated throughout this Review, the presuppositions that guide [pediatric medical transition (PMT)] have not been shown to be valid; the nature, probability and magnitude of risks associated with PMT have not been distinguished with sufficient clarity; PMT proponents' estimates of the probability of harm and benefit have not been shown to be reasonable, as judged by known facts and available studies; and the risks of serious impairment that PMT involves have not been shown to be justified. For these reasons, administering PMT to adolescents, even in a research context, is in tension with well-established ethical norms for human subjects research.'' [20]

The Review (as further discussed in Section I.B.c. of this proposed rule) provides evidence of the clinical realities of SRPs in the United States, documenting the abandonment of medical guardrails. For example, the Review highlights how a protocol establishing SRPs in minors originated in the Netherlands and quickly spread to other Western countries without rigorous testing, and was codified in medical guidelines, which later did away with some of their already contested safeguards.[21] The Endocrine Society (ES) incorporated puberty blockers and hormones into their 2009 and 2017 clinical practice guidelines, recommending hormonal interventions for certain pediatric patients with gender dysphoria while also acknowledging the lack of reliable evidence for these treatments.[22] ES justified this recommendation in a ''values and preferences'' statement that places a higher priority on ''avoiding a[n] unsatisfactory physical outcome when secondary sex characteristics have

[6] Coleman, Eli, et al. ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[7] Hembree, Wylie C., et. al. ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.'' *The Journal of Clinical Endocrinology & Metabolism.* vol. 102, no. 11, 1 November 2017, *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

[8] CMS calculation: The annual number of overall SRPs (Breast/chest surgery, genital surgery, and other cosmetic procedures) on children aged 12 to 18 years is 740. The annual estimated number of children aged 12 to 18 according to U.S, Census Bureau data is 29,600,770. This results in annual estimate of 2.17 chest/breast procedures per 100,000 children aged 12 to 18 ((643/29,600,770) × 100,000 =2.50)). This calculation assumes 1 SRP per person.

[9] CMS calculation: The annual number of breast/chest surgeries on children aged 12 to 18 years is 643. The annual estimated number of children aged 12 to 18 according to U.S, Census Bureau data is 29,600,770. This results in annual estimate of 2.17 breast/chest surgeries per 100,000 children aged 12 to 18 ((643/29,600,770) × 100,000 =2.17)). This calculation assumes 1 breast/chest surgery per person.

[10] CMS calculation: The annual number of genital surgeries on children aged 12 to 18 years is 81. The annual estimated number of children aged 12 to 18 according to U.S. Census Bureau data is 29,600,770. This results in annual estimate of 0.27 genital procedures per 100,000 children aged 12 to 18 ((81/29,600,770) × 100,000 =0.27)). This calculation assumes 1 genital surgery is done per person.

[11] Wright J. D., et al. ''National estimates of gender-affirming surgery in the US.'' *JAMA Network Open,* vol. 6, no. 8, e2330348, 23 Aug. 2023, *http://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707.*

[12] CMS calculation: Per the article, the highest rate of hormone treatment occurs at age 17 with 140 AFAB adolescents (assigned female at birth) receiving testosterone (per 100,000 is 0.14% (140/100,000) ×100=0.14%)) and 82 AMAB adolescents (assigned male at birth) receiving estrogen (per 100,000 is 0.082% (82/100,000) ×100 =0.082%). This results in 222 (82+140= 222) per 100,000 or 0.222 (0.14% + 0.082% = 0.222). This calculation assumes 1 sex rejecting hormone treatment is done per person.

[13] Hughes Landon D., et al., ''Gender-affirming medications among transgender adolescents in the US.'' *JAMA Pediatrics,* 179,3 (2025): 342–344. doi:10.1001/jamapediatrics.2024.6081, *https://pubmed.ncbi.nlm.nih.gov/39761053.*

[14] CMS calculation: 140 + 82 = 222. This results in an estimate of 222 SRP hormone treatment per 100,000 children aged 17, between 2018 through 2022. This calculation assumes 1 SRP hormone treatment is done per person.

[15] Wright, Jason D., et al.. ''National Estimates of Gender-Affirming Surgery in the US.'' *JAMA Network Open,* vol. 6, no. 8, 23 Aug. 2023, doi:10.1001/jamanetworkopen.2023.30348, *http://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707.*

[16] 90 FR 8771 (February 3, 2025).

[17] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office Of Population Affairs,* 1 May 2025. *https://opa.hhs.gov/gender-dysphoria-report.*

[18] U.S. Department of Health and Human Services (HHS), ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,*19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report.*

[19] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 218–246.

[20] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg., 246.

[21] Biggs, M. (2023b). The Dutch Protocol for juvenile transsexuals: Origins and evidence. *Journal of Sex & Marital Therapy, 49*(4), 348–368.

[22] Hembree, Wylie C., et al. ''Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline.'' *Journal of Clinical Endocrinology & Metabolism,* vol. 94, 9, 2009: 3132–52/doi:10.1210/jc.2009–0354.

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become manifest and irreversible'' than on ''avoiding potential harm from early pubertal suppression.'' [23]

The World Professional Association for Transgender Health (WPATH) endorsed a similar approach and most recently recommend these in their Standards of Care, Version 8 (SOC–8).[24] However, as carefully documented in the Review, the creation of SOC–8 marked ''a clear departure from the principles of unbiased, evidence-driven clinical guideline development.'' [25] The HHS Review cites court documents containing internal WPATH communications used when developing SOC–8 that show WPATH suppressed systematic reviews of evidence after learning that these reviews would not support its preferred medical approach. WPATH also failed to manage conflicts of interest and eliminated age minimums for hormones and most surgeries due to political pressures.[26] A recent systematic review of international guidelines did not recommend either the WPATH or ES guidelines for clinical use after determining they ''lack developmental rigour and transparency.'' [27]

b. International Reviews of SRPs in Children

The Review also describes practice reversals in several European countries (Norway, Finland, Sweden, Denmark, United Kingdom) following systematic reviews of evidence.

In 2020, Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued guidelines stating that ''gender reassignment of minors is an experimental practice.'' While not banning SRPs outright, the guidelines state ''based on studies examining gender identity in minors, hormonal interventions [puberty blockers, hormone therapy] may be considered before reaching adulthood in those with firmly established transgender identities, but it must be done with a great deal of caution, and no irreversible treatment should be initiated.'' [28] For children with gender dysphoria prior to and worsening at the onset of puberty, the report recommends that ''puberty suppression treatment [that is, puberty blockers] may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications.'' This is similar to past recommendations, and as before, these treatments would be limited to research settings for payment by the nation's health service. For children with gender dysphoria that have undergone puberty, the guidelines recommend that decisions regarding initiation of hormone treatment that alter sex characteristics be ''based on thorough, case-by-case consideration, [. . .] [and] only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria [. . .] and that no contraindications [that is, mental health conditions] are present.'' Previously, recommendations noted that hormone therapy should not begin before age 16 in this group and that patients under 18 may receive 3 to 6 months of puberty blockers prior to beginning hormone therapy. The current report mentions no age or month specific treatment guidelines. The report continues to recommend that all such interventions be done in a research setting. The report adds that ''[i]nformation about the potential harms of hormone therapies is accumulating slowly and is not systematically reported'' and calls for further rigorous research of the benefits and risks of these treatments. Consistent with past recommendations, the report adds that ''surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors.'' [29]

In 2022, Sweden's National Board of Health and Welfare (NBHW) reviewed and updated its guidelines for treatment of children with gender dysphoria.[30] [31] At the population level, NBHW issued ''weak, negative recommendation as guidance to the healthcare system'' that the risks of hormone treatment (which included gonadotropin releasing hormones (GnRH) also known as puberty blockers) and mastectomy likely outweigh the expected benefits for most adolescents. NBHW concludes that ''existing scientific evidence is insufficient for assessing the effects of puberty suppressing and gender-affirming hormone therapy on gender dysphoria, psychosocial health and quality of life of adolescents with gender dysphoria.'' While not banning access to SRPs, NBHW suggests restricting such treatments to exceptional circumstances or research settings, and adhering to the original ''Dutch protocol'' criteria including ''existence of the incongruence since childhood, the stability of gender identity over time, clear distress caused by the onset of puberty, and the absence of factors that complicate the diagnostic assessment.'' [32] The report did not discuss SRP surgeries aside from mastectomy.

In the United Kingdom, the National Health Service (NHS) commissioned a comprehensive review of the existing literature on SRPs and the prevailing service model. The 4-year independent evaluation of pediatric gender medicine (PGM), known as the ''Cass Review,'' was published by Dr. Hilary Cass in April 2024. The Cass review concluded that the evidence base for SRPs in children is ''remarkably weak'' and recommended restructuring of the service model towards prioritization of psychotherapy.[33]

In terms of research quality, the Cass Review notes that the number of studies on gender dysphoria treatment in children is very low, with small study sizes that have inconsistent metrics, low

[23] Hembree, Wylie C., et al. ''Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. Endocrine Practice,'' 23(12), 2017: 1437–1437.

[24] Coleman, Eli, et al. ''Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7.'' *International Journal of Transgenderism,* 13(4), 165–232.

[25] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,,* p. 181.

[26] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* p. 157–186.

[27] Taylor, Jo, et al. ''Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review.'' *Archives of Disease in Childhood,* vol. 109, Suppl. 2, s33-s47, 30 Oct. 2024, doi:10.1136/archdischild–2023–326669.

[28] Council for Choices in Health Care Finland. ''Finnish 2020 COHERE Guidelines for Minors Finland)'' certified translation. IFTCC Archives, 2020, *https://archive.iftcc.org/finnish-2020-cohere-guidelines-minors-finland-certified-translation.*

[29] Council for Choices in Health Care Finland. ''Finnish 2020 COHERE Guidelines for Minors Finland)'' certified translation. IFTCC Archives, 2020, *https://archive.iftcc.org/finnish-2020-cohere-guidelines-minors-finland-certified-translation.*

[30] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and adolescents with gender dysphoria: Summary of National Guidelines.'' Dec. 2022. *https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330.*

[31] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and young people with gender Dysphoria—National knowledge support with recommendations for the profession and decision makers.'' 16 Dec. 2022. *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf.*

[32] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and adolescents with gender dysphoria-summary of national guidelines.'' Dec 2022, *https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330/.*

[33] Cass, Hilary ''Cass Review Final Report.'' *The National Archives,* Apr. 2024, *https://cass.independent-review.uk/home/publications/final-report.*

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quality methods (uncontrolled observational studies), results of low certainty, and lack of longitudinal data (that is, do not follow youth into adulthood; average duration of hormone treatment is between 1 year and 5.8 years). The Cass Review notes that this weak evidence base makes conclusions regarding the benefits versus risk of gender dysphoria treatment in children extremely difficult to assess. The Cass Review also critiques WPATH guidelines, noting that WPATH's own systemic review acknowledges a high risk of bias in study designs, small sample sizes, and confounding variables.

Regarding guideline development, the Cass Review notes that most current guidelines have not followed the international standards for guideline development, including the WPATH guidelines. As such, the Cass Review only recommends two guidelines: the Finnish guideline (2020) and the Swedish guideline (2022) as discussed above. However, the Cass Review notes that even these guidelines lack clear recommendations regarding certain aspects of practice and ''would be of benefit if they provided more detailed guidance on how to implement recommendations.''

While not banning access to puberty blockers, Dr. Cass concluded in a July 2023 letter that ''because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, [puberty blockers] should only be offered under a research protocol [for treatment of pediatric gender dysphoria].'' NHS England and National Institute for Health and Care Research (NIHR) have enacted this recommendation as of December 2024. Exceptions are permitted for non-gender dysphoria-related medical conditions (*i.e.* precocious puberty) and for those patients already on treatment.[34] For hormone interventions, the Cass Review highlights a lack of high-quality research assessing the (long-term) outcomes of hormone interventions in children with gender dysphoria. Given this weak evidence base, Dr. Cass notes that ''no conclusions can be drawn about the effect [of hormone interventions] on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health.'' the Cass Review ultimately calls for caution, better research (prospective studies with long-term outcome data), honest communication with patients about the limitations of current knowledge, and development of evidence-based guidelines that acknowledge the limitations of current evidence. Of note, in the United Kingdom, children have never received gender dysphoria related surgery as paid by the NHS; Cass therefore did not systemically review evidence for gender dysphoria related surgeries in children.

Norway and Denmark are exploring or have enacted similar restrictions, though neither have issued direct bans of SRPs. In 2023, the Norwegian Commission for the Investigation of Health Care Services (Ukom), an independent State-owned agency, made recommendations on the treatment for youth with gender dysphoria.[35] The recommendations consisted of: defining SRPs (that is, puberty blockers, hormonal therapies, and surgical treatment) as ''experimental treatment,'' revising national guidelines based on a systematic knowledge summary, and consideration for a national registry to improve quality and reduce variation in patient treatment.While not banning access to SRPs, Norway's public health authorityhas signaled an intention torespond to UKOM's concerns with an adjustment to the current treatment guidelines.[36] While also not banning access to SRPs, Denmark has also taken a cautious approach to hormone interventions (that is, puberty blockers and cross-sex hormones) pending more evidence of its beneficial effects becoming available.[37] Notably, Denmark does not offer surgical treatment to children with gender dysphoria before age 18 as paid for by its national health service.[38] Other countries that have considered or restricted various gender dysphoria treatments for children include Italy,[39] Brazil,[40] New Zealand,[41] and Australia.[42]

c. Medical Professional Societies Supporting SRPs

We are aware that major medical organizations [43] (including the American Medical Association (AMA),[44] the American Academy of Pediatrics (AAP),[45] and the American Psychological Association [46] [47]) have issued statements supporting access to SRPs, including for children. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the U.S. are the WPATH and the ES clinical practice guidelines and the AAP guidance document.[48] We reviewed

[34] Department of Health and Social Care. ''Ban on puberty blockers to be made indefinite on experts' advice.''*GOV.UK,* 11 Dec. 2024. *https://www.gov.uk/government/news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice.*

[35] Norwegian Healthcare Investigation Board (Ukom). ''Pasientsikkerhet for barn og unge med kjønnsinkongruens [Patient safety for children and adolescents with gender incongruence].'' March 2023, *https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag.*

[36] Block, Jennifer. ''Norway's guidance on paediatric gender treatment is unsafe, says review,'' *BMJ (Clinical research ed.)* vol. 380 697, 23 Mar. 2023, doi:10.1136/bmj. p697.

[37] Hansen, Mette Vinther et al., ''Sundhedsfaglige tilbud til børn og unge med kønsubehag [Healthcare services for children and adolescents with gender dysphoria],'' *Ugeskrift for Laeger [The Journal of the Danish Medical Association]* 3 July 2023, *https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag.*

[38] Hansen, Mette Vinther et al., ''Sundhedsfaglige tilbud til børn og unge med kønsubehag [Healthcare services for children and adolescents with gender dysphoria],'' *Ugeskrift for Laeger [The Journal of the Danish Medical Association]* 3 July 2023, *https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag.*

[39] Armellini, Alvise. ''Italy moves to tighten controls on gender-affirming medical care for minors.'' *Reuters.* 5 Aug. 2025. *https://www.reuters.com/business/healthcare-pharmaceuticals/italy-moves-tighten-controls-gender-affirming-medical-care-minors-2025-08-05.*

[40] AFP. ''Brazil prohibits hormone therapy for transgender minors.'' *MSN News.* 17 Apr. 2025. *https://www.msn.com/en-in/news/other/brazil-prohibits-hormone-therapyfor-transgender-minors/ar-AA1D66l7.*

[41] Corlett, Eva. ''New Zealand Bans Puberty Blockers for Young Transgender People.'' *The Guardian,* Guardian News and Media, 19 Nov. 2025, *https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.*

[42] Australian Associated Press. ''Queensland halts prescription of puberty blockers and hormones for children with gender dysphoria.'' *The Guardian,* 28 Jan. 2025. *https://www.theguardian.com/australia-news/2025/jan/28/queensland-halts-prescription-of-puberty-blockers-and-hormones-for-children-with-gender-dysphoria.*

[43] Advocates For Trans Equality. ''Medical Organization Statements.'' *A4TE's Trans Health Project, https://transhealthproject.org/resources/medical-organization-statements/.*

[44] ''Clarification of Evidence-Based Gender-Affirming Care H–185.927,'' *American Medical Association Policy Finder,* American Medical Association, 2024, *https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml.*

[45] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* 6 Jan. 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[46] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' *American Psychological Association,* released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[47] ''Criminalizing Gender Affirmative Care with Minors,'' *American Psychological Association,* accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

[48] The American Academy of Pediatrics' (AAP) 2018 Policy Statement was reaffirmed in 2023 (Rafferty et al., 2018); the Endocrine Society's (ES) published in 2017 represents the most recent published version (Hembree et al., 2017); the World Professional Association for Transgender Health's (WPATH) most recent clinical practice guideline is

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each of these documents and agree with the HHS Review that discusses the conclusions of a recent systematic review of international guideline quality by researchers at the University of York (the York Appraisal) that found all three documents are very low quality and should not be implemented.[49]

As the HHS Review notes regarding the role of medical organizations in the treatment of pediatric gender medicine:

''U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition. This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.'' [50]

The Endocrine Society (ES) issued clinical practice guidelines in 2017 entitled ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.'' [51] As the HHS Review notes:

''In WPATH and ES guidelines, the principal goal of CSH administration is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations. Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.'' [52]

The HHS Review states:

''The ES 2017 guideline, which used the GRADE [Grading of Recommendations Assessment, Development and Evaluation] framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base. Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents. The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a ''satisfactory physical appearance'' while putting the lowest value on avoiding physical harms. The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower value on avoiding harm from potentially prolonged pubertal suppression.'' [53]

As explained in Chapter 9 of HHS Review, the guidelines issued by the World Professional Association for Transgender Health (WPATH) ''have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines.'' [54] As the HHS Review points out: ''Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH Standards of Care guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.'' [55] In 2022, WPATH issued guidelines entitled ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8'' (SOC–8).[56] These guidelines relaxed eligibility criteria for children to access sex-rejecting procedures and ultimately recommends that adolescents wishing to undergo sex-rejecting procedures receive them. Besides the problems identified in systematic reviews of international guidelines, as the HHS Review states, ''in the process of developing SOC–8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC–8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.'' [57] The HHS Review goes on to explain: ''The recommendations are couched in cautious-sounding language, stating that GD should be ''sustained over time,'' particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase ''several years'', leaving critical decisions open to broad and subjective interpretation.[58]

Regarding the WPATH guidelines, the HHS review states:

''On the surface, WPATH SOC–8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a ''comprehensive biopsychosocial assessment'' prior to initiating medical interventions in order ''to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care.'' [59]At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases (ICD–11) diagnosis of ''Gender Incongruence of Adolescence and Adulthood,'' which, unlike the DSM–5 diagnosis of ''Gender Dysphoria,'' requires only ''marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' [60] Because SOC–8 defines transgender in a similar way (''people whose gender identities and/or gender expressions are not what is typically

Standards of Care, Version 8 (SOC–8) (Coleman et al., 2022).

[49] HHS Review pg. 141.

[50] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 15.

[51] Wylie C. Hembree et al. ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658.*

[52] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 124.

[53] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 147.

[54] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 157.

[55] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 157.

[56] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[57] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 14.

[58] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 165.

[59] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[60] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 194.

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expected for the sex to which they were assigned at birth'') and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC–8 effectively recognizes transgender identification as a medical condition justifying medical interventions.'' [61]

While AMA and the AAP have not issued their own treatment guidelines, they support the ES and WPATH guidelines, as discussed previously in this proposed rule. AAP issued a policy statement in 2018 supporting the use of puberty blockers, cross-sex hormones, and surgeries for minors.[62] In support of sex-rejecting surgeries, AAP stated that while ''current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.'' The AAP reaffirmed its policy statement in 2023 but also stated that it was conducting its own review of the evidence and guideline development—which still has not been released.[63]

Regarding the AAP policy statement, the HHS Review states:

''The AAP 2018 policy statement is not technically a CPG [clinical practice guideline] but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD [gender dysphoria].[64] Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs [puberty blockers], CSH [cross-sex hormones], and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7. As noted in Chapter 2, the AAP policy statement's use of ''gender diverse'' casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.'' [65]

We solicit comment of any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients in international settings as well as the U.S.

3. U.S. Legal Landscape Regarding Sex-Rejecting Procedures

The United States has seen a high level of activity both at the State level and within the judicial system on this topic in recent years.

a. U.S. State Laws

Several States and territories have adopted laws reflecting their views of the evidence on SRPs for children with 28 restricting and 15 protecting this treatment. As of August 2025, 27 States and one territory have laws limiting or prohibiting some or all SRPs for children.[66] These include Alabama, Arkansas, Arizona, Florida, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Carolina, New Hampshire, North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. Of these, 2 States' laws or policies (Montana and Arkansas) are pending resolution of ongoing legal challenges (as of August 2025).

States with such laws or policies apply them to varying age ranges. Twenty-five States prohibit certain SRPs in individuals under the age of 18. Two States (Nebraska and Alabama) prohibit them for those under the age of 19. Puerto Rico prohibits such procedures for those under the age of 21.

Which SRPs (that is puberty blockers, hormone therapy, and surgery) are banned for children varies by State. As of August 2025, 25 States have laws that prohibit access to puberty blockers, hormone therapies, and gender dysphoria related surgeries for children. Two States (New Hampshire and Arizona) have restrictions on surgery (but permit endocrine SRPs) for this population. No State bans only medications without also banning surgical procedures.[67]

All the States and the territory with restrictions provide exceptions to the law/policies. The most common exceptions include:

- Children born with medically verifiable disorder of sex development. This allows treatment for children who are born with medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other factors that can be medically verified.
- Children who have been diagnosed with a disorder of sexual development by a physician through genetic or biochemical testing.
- Treatment for any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of SPRs.
- Children suffering from physical disorders, physical injuries, or physical illnesses that would otherwise place the children in danger of death or impairment of bodily function.

We note that 12 States provide tapering off periods for patients who started puberty blockers or hormones before enactment of the restriction, with some specifying specific dates (for example, in South Carolina services cannot go beyond January 31, 2025) and others specifying a period of time from the date of enactment (ranging between 6 months and 1 year). Ten States have grandfather clauses primarily allowing children who were already receiving treatment to continue receiving it indefinitely.

Conversely, 14 States and the District of Columbia have shield laws protecting SRPs, and three other States have E.O.s protecting these procedures.[68] These

[61] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 194–195.

[62] Rafferty, Jason, et al. ''Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents.'' *Pediatrics,* vol. 142, no. 4, 1 Oct. 2018, doi:10.1542/peds.2018–2162.

[63] Wyckoff, Alyson Sulaski. ''AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update.'' *AAP News,* August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy.*

[64] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 148.

[65] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 148, 149.

[66] Dawson, L., Kates, J. ''Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions.'' *KFF,* 21 Aug. 2025 [24 Nov. 2025], *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker.*

[67] American Psychological Association. ''Navigating the legal landscape: FAQs on gender affirming care for minors.'' *American Psychological Association,* 28 Jun. 2024, *https://www.apaservices.org/practice/legal/managed/legal-landscape-gender-care-minors.*

[68] ''Equality Maps: Transgender Healthcare 'Shield' Laws.'' *Movement Advancement Project,*

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States are (not including the District of Columbia): Arizona,[69] California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. Shield laws and State E.O.s often describe SRPs broadly, including medications and procedures, and include these under broader definitions of protected healthcare activities. These laws often protect providers from adverse action by medical malpractice insurers and licensure boards and allow for their address to remain confidential. One State (Maine) has a shield law that allows children 16 and over to receive hormone therapy when the guardian has refused SRPs. Four States explicitly provide child abuse and child custody protections for parents who supported their children in receiving specified procedures. Four State shield laws and E.O.s have requirements for SRPs to be covered under health plans. Arizona requires coverage for State employee health plans. Illinois, Oregon, and Vermont require some level of SRPs coverage by all health insurance providers. Vermont includes an exception for services that do not comply with Federal law.

b. United States Supreme Court

Recently, the Supreme Court in *United States* v. *Skrmetti*, 145 S. Ct. 1816 (2025) upheld Tennessee's law (referred to as Senate Bill 1; SB 1) banning certain surgical and chemical interventions for children with gender dysphoria, in litigation challenging that law under the Equal Protection Clause of the U.S. Constitution. SB1 prohibits a healthcare provider from performing medical procedures, including surgery, and prescribing puberty blockers, for a child for the purpose of enabling the child to identify with a purported identity inconsistent with the child's sex. At the same time, SB1 allows healthcare providers to perform medical procedures for children if the procedure is to treat a child's congenital defect, precocious puberty, disease, or physical injury. On June 18, 2025, the Court found that SB1's prohibition of certain medical procedures for children with gender dysphoria incorporates classifications based on age and medical use—not the child's sex. As a result of these classifications based on age and medical use, the Court held that SB1 was not subject to heightened scrutiny under the Equal Protection Clause of the Fourteenth Amendment and the law satisfied so called ''rational basis'' review.

4. CMS Actions

The proposed rule is animated by significant child safety concerns when SRPs are used for certain medical uses—that is to align a child's physical appearance or body with an asserted identity that differs from the child's biological sex. CMS published a formal guidance letter to State Medicaid Directors regarding SRPs on April 11, 2025, reminding States of their responsibility to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interest of recipients.[70] In addition, the Administrator of CMS sent a letter issued on May 28, 2025, to a number of hospitals addressing significant issues concerning quality standards and specific procedures affecting children. The letter requested that the recipient hospitals provide CMS with copies of certain hospital policies and procedures on the adequacy for informed consent protocols for children with gender dysphoria, including how hospitals determine that children are capable of making these potentially life changing decisions and when parental consent is required; describe any changes to clinical practice guidelines and protocols that the institution plans to enact in light of the recent comprehensive review and guidance released by the Department; provide CMS with medical evidence of any adverse events related to these procedures, particularly in children who later sought to detransition; and complete financial data for all pediatric SRPs performed at the institution and paid, in whole or in part, by the Federal Government.[71]

In addition, on May 28, 2025, Secretary Kennedy wrote to hospitals, health care providers, health care risk managers, and State medical boards across the nation, asking them to read the HHS Review, and to make necessary updates to their ''treatment protocols and training for care for children and adolescents with gender dysphoria to protect them from these harmful interventions.'' [72]

These letters reaffirmed CMS' and HHS' commitment to following the highest standards of care and to adhering closely to the foundational principles of medicine, especially relating to doing no harm to America's children and in alignment with CMS's obligations to ensure baseline quality standards at institutions participating in the Medicare and Medicaid programs.

II. Provisions of the Proposed Regulations

We have undertaken a review of the current hospital health and safety standards (known as the CoPs) as well as the latest information regarding SRPs in children to ensure hospitals are best protecting the health and safety of children. The evidence as presented in the Review (see section I.B.2. of this proposed rule) indicates that SRPs lack the necessary outcomes data on safety and long-term effectiveness. CMS takes very seriously the absence of rigorous scientific data demonstrating the safety and effectiveness of SRPs and the considerable evidence regarding the risks. Based on this, we believe that certain SRPs (namely pharmaceutical and surgical interventions) are not consistent with the health and safety of children, given the risk of significant (long term) harms, known complications, and weak and uncertain evidence of benefits.

We therefore propose to add a new section to 42 CFR part 482, subpart C that would prohibit Medicare and Medicaid-participating hospitals from performing sex-rejecting procedures (SRPs) on any child (§ 482.46(a)). As set out in proposed § 482.46(a)(5), we propose to define SRPs as any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with a stated identity that differs from the individual's sex by either (1) intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits or (2) intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.

n.d., accessed 11 August 2025, *https://www.lgbtmap.org/equality-maps/healthcare/trans_shield_laws.*

[69] Arizona banned SRPs for transgender minors in 2022, but in 2023 the governor issued an executive order with ''shield'' style protections for SRPs that are still legal in the State.

[70] Department of Health & Human Servies, Centers for Medicaid & CHIP Services. ''Puberty blockers, cross-sex hormones, and surgery related to gender dysphoria.'' Received by State Medicaid Director, 7500 Security Blvd. Mail Stop S2–26–12, 11 Apr. 2025, Baltimore, Maryland, *https://www.cms.gov/files/document/letter-stm.pdf.*

[71] Department of Health & Human Services, Centers for Medicare and Medicaid Services. ''Urgent Review of Quality Standards and Gender Transition Procedures.'' 28 May 2025, Washington, DC, *www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.*

[72] U.S. Department of Health & Human Services [@HHSGov]. *X* (formerly Twitter), 28 May 2025, *https://x.com/HHSGov/status/1927791449476567043.*

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We propose at § 482.46(a)(1) through (4) to include several additional definitions critical to interpreting the proposal. We propose that the term ''child'' be defined as any individual younger than 18 years of age. We further propose that the term ''female'' be defined as an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We propose that the term ''male'' be defined as an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. Finally, we propose that the term ''sex'' is defined as an individual's immutable biological classification as either male or female.

At § 482.46(b), we are proposing exceptions to § 482.46(a) to protect the health and safety of children in certain rare and exceptional circumstances. Proposed exceptions include:

- *Procedures to treat an individual with a medically verifiable disorder of sexual development (§ 482.46(b)(1)).* This allows treatment for children who are born with certain medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other medical factors that can be medically verified and documented. Examples include a child with external biological sex characteristics that are irresolvably ambiguous, such as those born with 46 XX chromosomes with virilization, 46 XY chromosomes with under-virilization, or having both ovarian and testicular tissue.
- *Procedures for purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex (§ 482.46(b)(2)).* This permits procedures that are done for reasons entirely separate from changing a child's physical appearance to match a gender identity that differs from their biological sex, including procedures for children with a physical disorder, injury, or physical illness. In other words, the procedure must have a purpose separate from intending to change the body to not correspond to one's biological sex.
- *Treating Complications (§ 482.46(b)(3)).* This exception allows treatment for any infections, injuries, diseases, or other medical disorders that were caused by or made worse by previous SRPs. This exception allows physicians or other licensed practitioners to treat complications that arise from these procedures.

While we are proposing certain exceptions, any procedures or treatments under these exceptions must still be performed with the consent of the child's parent or legal guardian, as currently required under the patient rights CoP at § 482.13(b)(2), the medical records CoP at § 482.24 (c)(4)(v), the surgical services CoP at § 482.51(b)(2), and in compliance with applicable State law(s).

Practice of Medicine

Under Section 1801 of the Act, CMS may not ''exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, (42 U.S.C. 1395). However, we believe that providing the SRPs for children is not healthcare and hence are not subsumed under the term of ''the practice of medicine.'' Therefore, the proposed rule would not regulate the practice of medicine. As the Review notes regarding SRPs, when ''medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients.'' [73] As the Review states, ''in the domain of pediatrics, these norms limit the authority not only of patients (who in any case lack full decision-making capacity) but of parents as well.'' [74] The first obligation of the physician, under the Hippocratic Oath, originating in the fourth century BC, is to first do no harm, as the purpose of the practice of medicine is to heal. SRPs introduce a unique set of iatrogenic harms, especially, ''surgeries to remove healthy and functioning organs.'' [75] The Review states: ''to discharge their duties of nonmaleficence and beneficence, clinicians must ensure, insofar as reasonably possible, that any interventions they offer to patients have clinically favorable risk/benefit profiles relative to the set of available alternatives, which includes doing nothing.'' [76] As related previously in this proposed rule, the risk-benefit profile of these procedures for children is extremely poor. At the same time,'' the Review notes, ''there is increasing recognition of the risk and harms associated'' with pediatric sex-rejecting procedures, including ''possible outcomes, such as impaired cognitive function, greater susceptibility to hormone-sensitive cancers, cardiac disease, reduced bone density, sexual dysfunction, infection, and infertility [that] are objectively detrimental to health'' The Review concludes that''[s]uch medical harms, or plausible risks thereof, should not be imposed on children or adolescents in the absence of a reasonable expectation of proportionate medical benefit.'' [77]

There are other considerations for why the regulations proposed in this rule do not regulate the practice of medicine. A person's body (including its organs, organ systems, and processes natural to human development like puberty) are either healthy or unhealthy based on whether they are operating according to their biological functions. Organs or organ systems do not become unhealthy simply because the individual may experience psychological distress relating to his or her sexed body. For this reason, removing a patient's breasts as a treatment for breast cancer is fundamentally different from performing the same procedure solely to alleviate mental distress arising from gender dysphoria. The former procedure aims to restore bodily health and to remove cancerous tissue. In contrast, removing healthy breasts or interrupting normally occurring puberty to ''affirm'' one's ''gender identity'' involves the intentional destruction of healthy biological functions. This is not health care and hence imposing restrictions as this rule proposes does not limit the practice of medicine. The Review further notes there is lack of clarity about what SRPs' fundamental aims are, unlike the broad consensus about the purpose of medical treatments for conditions like appendicitis, diabetes, or severe depression.[78] Rather as discussed above, these procedures lack strong evidentiary foundations, and our

[73] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov, 2025. *https://opa.hhs.gov/gender-dysphoria-report* Pg. 15.

[74] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report* Pg. 225.

[75] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 128.

[76] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 226.

[77] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report* Pg. 227–228.

[78] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,*19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 24–26.

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understanding of long-term health impacts is limited and needs to be better understood. Nothing in this proposed rule prohibits or permits the basic legality of SRPs. Rather, this proposed rule would ensure patient safety and medical integrity. CMS would no longer directly or indirectly support harm to children by allowing facilities that engage in such harmful practices to receive Medicare and Medicaid funds.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements (ICRs).

A. Hospital Notifications to Patients

Proposed § 482.46 would require that hospitals not perform sex-rejecting procedures (SRPs) on children, barring certain exceptions. We expect that hospitals that are currently performing these procedures on children would need to inform the child and their parents or legal guardian who are seeking such procedures that they no longer perform such procedures. Based on our experience, we expect that the child's physician or the licensed practitioner providing this care would spend an average of 30 minutes writing each notification. In addition, they would spend 30 minutes answering any questions from the child and their parents or legal guardian. This leads to a total burden of 1 hour per patient.

To calculate the total provider burden across all patients, we first examined State laws and found that 25 States have active laws restricting SRPs.[79] Given these State laws that already prohibit these procedures, we do not expect that physicians or licensed practitioners in these States would be writing a significant number of notifications. While acknowledging that some children living in these States may be traveling to States that permit SRPs for children, we do not expect that this is a large number of children for two reasons. First, across States with these restrictions, nearly 45 percent of children were enrolled in Medicaid or CHIP as of March 2025 and these programs would not fund SRPs outside the State.[80] Second, a recent study showed that across States with restrictions on SRPs, the average driving time to the nearest clinic in a State without restrictions was 5.3 hours, with the average time in Florida reaching 9 hours.[81] As such, we base our estimate on the number of children affected for children in States that currently do not have restrictions but seek comments on this assumption.

The second step was to identify the number of individuals under the age of 18 who live in States that allow SRPs. We combined information on State restrictions with Census Bureau population estimates[82] and found that there are approximately 8,674,717 females and 9,165,563 males between the ages of 10 and 17 living in States that do not have active laws restricting SRPs. While acknowledging that children younger than 10 may be receiving SRPs, we believe this is a reasonable estimate of the population affected by the proposed requirement.

The third step was to identify the number of individuals under 18 years of age who may be receiving SRPs. A recent study[83] found that among children between the ages of 8 and 17 covered by private insurance, males received puberty blockers and hormones at a rate of 15.22 per 100,000 and 25.34 per 100,000, respectively. Meanwhile, females received puberty blockers and hormones at a rate of 20.81 per 100,000 and 49.9 per 100,000, respectively. Applying these rates to the number of males and females in States without active laws restricting SRPs,[84] we estimate that there are approximately 6,651 individuals receiving hormones and 3,200 individuals receiving puberty blockers for a total of 9,851 individuals. As the authors note, these rates are more likely to be generalizable to patients with private insurance in large care plans and they expect lower rates for those utilizing Medicaid and in less comprehensive care plans. Another study[85] used national data to estimate the rate of sex rejecting surgical procedures and found that in 2019, there were approximately 85 sex-rejecting surgical procedures for children with a gender dysphoria diagnosis. The same as our estimates for the number of children receiving puberty blockers and hormones, this estimate is for insured patients and there may be lower rates for those utilizing Medicaid and in less comprehensive care plans. Given the overlap in treatment for some patients who may receive both surgical procedures and hormones, we estimate that a maximum of 9,851 individuals under the age of 18 are receiving SRPs.

While hospitals often prescribed puberty blockers and hormone replacement therapy as part of sex-rejecting procedures, primary care providers and endocrinologists outside of hospitals, who would not be affected by these requirements, can also prescribe these treatments. A recent analysis found that approximately 52 percent of primary care physicians were not affiliated with a hospital.[86] We do not know the share of children receiving puberty blockers or hormone replacement therapy outside the hospital setting and, therefore, would not need to receive notification that

[79] Dawson, L., Kates, J. ''KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming Care.'' *KFF,* 24 Nov. 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/.*

[80] Centers for Medicare & Medicaid Servies. ''State Medicaid and CHIP Applications, Eligibility Determinations, and Enrollment Data.'' *Data.Medicaid.gov, https://data.medicaid.gov/dataset/6165f45b-ca93-5bb5-9d06-0db29c692a360/data.* Accessed 6 Aug.2025.

[81] Borah, Luca et. al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA,* vol. 330,4 (2023): 375–378. doi: 10.1001/jama.2023.11299.

[82] U.S. Census Bureau, U.S. Department of Commerce. ''Age and Sex.'' American Community Survey, ACS 1-Year Estimates Subject Tables, Table S0101, *https://data.census.gov/table/ACSST1Y2023.S0101?q=population+by+age+by+state.* (Accessed 26 Jul. 2025).

[83] Hughes Landon D. et al. ''Gender-Affirming Medications Among Transgender Adolescents in the US, 2018–2022.'' *JAMA Pediatrics,* vol. 179, 3, (2025): p.342–344. doi:10.1001/jamapediatrics.2024.6081.

[84] Dawson, L., Kates, J. ''KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming *Care.*'' *KFF,* 24 Nov. 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/.*

[85] Dai Dannie, et al. ''Prevalence of Gender-Affirming Surgical Procedures Among Minors and Adults in the US.'' *JAMA Network Open,* vol. 7, 6, 27 Jun. 2024, doi:10.1001/jamanetworkopen.2024.18814.

[86] Singh, Yashaswini et al. ''Growth of Private Equity and Hospital Consolidation in Primary Care and Price Implications.'' *JAMA Health Forum* vol. 6,1 e244935. 3 Jan. 2025, doi:10.1001/jamahealthforum.2024.4935.

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SRPs were no longer offered. Assuming that 25 percent of children are receiving care from primary care physicians or endocrinologists and that 52 percent of these providers are outside the hospital system, then 8,570 of the 9,851 children receiving treatment as identified above would need to receive notices and have discussions with their treating physician or licensed practitioner. We seek comments on data sources on the number of children receiving puberty blockers or hormone replacement therapy outside the hospital setting who would not be affected by the proposed requirement.

To estimate the total cost for this requirement, we assumed that a physician would write these notices. We calculated the physician's hourly rate by doubling the national mean salary for physicians (occupation code 29–1210) using the BLS' May 2024 National Occupational Employment and Wage Estimates for hospitals (NAICS code 622000),[87] leading to an hourly cost of $226.18 ($113.09 × 2). We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs. Utilizing these data, in Table 1, we estimate that this requirement would cost $1,938,363. We seek comments on the estimated time burden for physicians to provide written notices to their patients that the hospital is no longer providing SRPs.

TABLE 1—NOTIFICATION LETTERS TO PATIENTS

Employee type	Average hourly rate (a)	Hours per patient (b)	Number of patients (c)	Total cost (d = a × b × c)	Total hourly cost (e = b × c)
Physician	$226.18	1	8,570	$1,938,363	8,570

B. Updating Hospital Policies and Procedures

In addition to sending out notices to patients that they are no longer providing SRPs, hospitals will need to update their policies and procedures to ensure that they align with the proposed requirements.

To estimate the cost for hospitals to update their policies and procedures, we used data from the BLS' May 2024 National Occupational Employment and Wage Estimates for hospitals (NAICS code 622000),[88] and doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. Based on our experience, we estimate that updating the hospital's policies and procedures related to SRPs for children would take 3 hours of work from a physician (occupation code 29–1210) at $678.54 ($226.18 × 3 hours) and a member of the clerical staff (occupation code 43–6010) at $143.40 ($47.80 × 3 hours), and 3 hours of work from a lawyer (occupation code 23–1010) at $650.16 ($216.72 × 3 hours) to review the updated policies and procedures to ensure that they meet the legal guidelines. This leads to a total per facility cost of $1472.10.

To estimate the number of hospitals that would need to update their policies and procedures, we first used the CMS' Q2 2025 Provider of Services File—Hospitals & Non-Hospital Facilities dataset and identified a total of 4,832 Medicare/Medicaid certified hospitals.[89] We expect that even in States that have active bans on SRPs, some hospitals would still need to update their policies and procedures since many of these States have exceptions that conflict with the requirements in this proposed rule. We recognize, however, that not all hospitals offer SRPs for children, and increasingly more hospitals nationwide are ending these services.[90] Given these uncertainties, we assume that 75 percent, or 3,624 hospitals would need to update their policies and procedures. Using this estimate, we expect that hospitals would spend $5,334,890 updating their policies and procedures. We seek comments on this estimate, specifically whether there are data sources to more accurately estimate the number of hospitals nationwide that currently offer SRPs for children.

TABLE 2—COST FOR UPDATING FACILITY POLICIES AND PROCEDURES

Per hospital cost (a)	Hospitals (b)	Per hospital hourly cost (c)	Total cost (a × b)	Total hourly cost (b × c)
$1,472.10	3,624	9	$5,334,890	32,616

The information collections will be sent to OMB for approval under the OMB Control number: 0938–NEW.

If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this proposed rule.

[87] U.S. Bureau of Labor Statistics. ''Occupational Employment and Wage Statistics (OEWS) Tables.'' *Occupational Employment and Wage Statistics,* BLS.gov, May 2024, *https://www.bls.gov/oes/tables.htm.* Accessed 23 Jul. 2025.

[88] U.S. Bureau of Labor Statistics. ''Occupational Employment and Wage Statistics (OEWS) Tables.'' *Occupational Employment and Wage Statistics,* BLS.gov, May 2024, *https://www.bls.gov/oes/tables.htm.* Accessed 23 Jul. 2025.

[89] Centers for Medicare and Medicaid Services. ''Provider of Services File—Hospital & Non-Hospital Facilities, Q2 2025.'' *Data.CMS.gov, https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data.* Accessed 13 Aug. 2025.

[90] Cowan, Jill Cowan. ''Hospitals Are Limiting Gender Treatment for Trans Minors, Even in Blue States.'' *The New York Times,* 22 Jul. 2025, *https://www.nytimes.com/2025/07/22/us/trump-transgender-healthcare-california-hospitals.html.* Accessed 6 Aug. 2025.

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IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

Throughout the United States, thousands of children are receiving sex-rejecting procedures (SRPs), specifically pharmacological and surgical interventions, for gender dysphoria. As outlined in section I. and II. of this proposed rule, however, recent HHS and international analyses question the efficacy and safety of SRPs in children. To protect children's health and safety, we are proposing to prohibit hospitals subject to part 482 from performing SRPs on any child with certain exceptions to best protect children's health and safety.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96 354); section 1102(b) of the statute; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities. The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f) of Executive Order 12866.

As noted above in Table 1 and Table 2, estimated costs of approximately $7.3 million are due to the time that a physician or licensed practitioner would spend providing patients with notification that the hospital no longer provides these procedures and for hospitals to update their policies and procedures related to SRPs for children. Below, we estimate additional impacts from the proposed requirement.

1. Costs and Transfers

We estimated the value of treatments in hospitals that would change in response to the proposed requirements using data from a study analyzing the per person cost of these treatments based on commercial claims data from 1993 to 2019.[91] This study estimated that for SRPs that included testosterone, estrogens and anti-androgens, and GnRH, there was an average combined cost to payors of $755 per person in 2019 dollars. Adjusting for inflation,[92] this leads to an average cost of approximately $909 per patient in 2024 dollars. For surgical procedures, there was an average per procedure cost of $28,367 in 2019 dollars. Adjusting for inflation, this leads to an average cost of approximately $34,165 in 2024 dollars. Utilizing our estimate in the collection of information section that 8,570 children would be affected by our rule and that there are 85 surgical SRPs on children annually, we estimate an annual value of $7,790,130 (8,570 patients × $909) for non-surgical SRPs and $2,904,025 (85 patients × $34,165) for surgical SRPs, for a total annual value of $10,694,155.

For children who are currently receiving SRPs at hospitals, there is likely to be bifurcation in their response to the proposed requirement. Some of these children may no longer receive SRPs at non-hospital providers that are not covered by the proposed requirement due to factors, such as difficulty in identifying in-network providers that have available space and longer commute times to these providers.[93] [94] The end of SRPs for these children would result in a reduced payments from payors, including insurance companies and private persons, to hospitals. Other children, however, are likely to switch to other provider types that are not affected by this proposed requirement. For these children, the proposed requirement would result in a change in transfers from Medicare-certified hospitals to other providers.

In the absence of data showing the likely share of patients in each category, we assumed that 50 percent of affected children would fall into each of the categories described above. Using this percentage, we estimate that the proposed requirements would result in $5,347,077 in reduced costs for payors and a $5,347,077 change in transfers from hospitals to other provider types annually. We seek comments on our assumption regarding the share of patients in each group.

For children who continue receiving SRPs, there are the costs associated with switching providers. Dahl and Forbes (2023) estimate that 46-percent of individuals are willing to pay over $600 per person (in 2011 dollars, or approximately $821 when updated for inflation) to avoid switching medical providers.[95] [96] The full willingness-to-pay (WTP) distribution is not reported, but for purposes of this regulatory

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[91] Baker, Kellan, and Arjee Restar. ''Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population.'' *The Journal of Law, Medicine & Ethics,* vol. 50,3 (2022): 456–470. doi:10.1017/jme.2022.87

[92] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBIl1dfQ==*. Accessed 3 Dec. 2025.

[93] Borah, Luca et al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA* vol. 330,4 (2023): 375–378. doi:10.1001/jama.2023.11299.

[94] Gridley, Samantha J et al. ''Youth and Caregiver Perspectives on Barriers to Gender-Affirming Health Care for Transgender Youth.'' *The Journal of Adolescent Health,* vol. 59,3 (2016): 254–261. doi:10.1016/j.jadohealth.2016.03.017.

[95] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBIl1dfQ==*. Accessed 18 Aug. 2025.

[96] Dahl, Gordon B., and Forbes, Silke J. ''Doctor switching costs.'' *Journal of Public Economics* vol. 221, May (2023): pp. 104858.

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impact analysis, it is assumed that $821 is a reasonable estimate of an average that includes the 46-percent of WTP amounts above it and the 54-percent below. Applying this $821 amount to the above-estimated 8,570 affected patients (including 4,285 patients who would switch providers and 4,285 patients for whom the switching-cost estimate is a lower bound on the WTP to avoid the experience of being unable to switch [97] yields a cost estimate of $7,035,970 that declines over several years to an annual $3,517,985. Because the Dahl and Forbes estimate is derived from a choice between retaining or switching primary-care physicians—where finding substitute providers may be relatively easy as compared with finding, and maintaining patient-provider relationship with facilities offering the specialized treatment associated with adolescent gender dysphoria—this estimate may have a tendency toward understatement of the proposed rule's cost to patients for switching providers.

In Table 3, we estimate the costs and transfers associated with the proposed requirement over 10 years. Overall, we expect that this proposed rule would result in approximately $53.5 million in savings for payors due to some patients ending SRPs, with a cost of $44 million to patients who continue treatment at new providers for finding a new provider and for patients who would have paid to avoid the experience of being unable to switch providers. We also expect a change in transfers of $53.5 million from hospitals to other provider types as patients seek alternative sources of care. The effect attributable to this proposed rule might be lower in magnitude than the aggregate presented here if other actions, such as the HHS/CMS proposal titled ''Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children'' are finalized before finalization of *this* proposal.

TABLE 3—COSTS AND TRANSFERS FOR CHANGING PATIENT BEHAVIOR RELATED TO SEX-REJECTING PROCEDURES

Year	Costs		Transfers ($)
	Ending sex-rejection procedures ($)	Switching providers (probably tending toward cost under-estimation) ($)	
1	−5,347,077	7,035,970	5,347,077
2	−5,347,077	6,156,474	5,347,077
3	−5,347,077	5,276,978	5,347,077
4	−5,347,077	4,397,481	5,347,077
5	−5,347,077	3,517,985	5,347,077
6	−5,347,077	3,517,985	5,347,077
7	−5,347,077	3,517,985	5,347,077
8	−5,347,077	3,517,985	5,347,077
9	−5,347,077	3,517,985	5,347,077
10	−5,347,077	3,517,985	5,347,077
10 Year Total	−53,470,770	43,974,813	53,470,770

In developing our estimate, we acknowledge that this quantitative approach may fail to capture a societal cost pattern that may be somewhat concentrated in *upfront* transition activity—for example, the potential establishment of free-standing clinics to provide SRPs that would newly be prohibited at hospitals participating in Medicare.[98] There may also be costs for clinicians who provide SRPs for children at hospitals who would incur costs to move to other provider types where these procedures are allowed. We also acknowledge that some patients may choose new forms of treatment such as psychotherapy. Given these various uncertainties, we request comment on how to refine the estimation of regulatory costs.

2. Benefits

As we have noted throughout the proposed rule in Sections I and II, the proposed requirement is designed to ensure the health and safety of children by limiting SRPs given recent research that questions its efficacy and safety. Although we do not have quantitative financial data on the impact of the proposed rule's provision, we estimate the number of children who this proposed rule would positively affect using the same strategy used when estimating the rule's collection of information costs. Specifically, we expect that due to factors such as difficulty in identifying in-network providers that have available space and longer commute times to these providers [99] [100], half of the 8,570 (or 4,285) children who are receiving SRPs in hospitals would stop receiving these procedures leading to the avoidance of unnecessary health complications. As noted in the collection of information section, we assumed this percentage in the absence of quantitative data showing the number of children who will no longer seek SRPs. We seek comments on additional benefits that could emerge from these proposed requirements and sources of data to provide a quantitative estimate of the proposed rule's benefits. We also seek comments on sources of data to more accurately estimate the

[97] The latter portion of the estimate persists in any year when SRPs are estimated to occur at a reduced level due to the proposed rule. By contrast, the former effect is assumed to decline over the first several years of the analytic time horizon, as provider-switching patients age out of childhood.

[98] The cost of setting up separate specialty facilities (a process encompassing managerial, legal, and physical tasks) would exceed the cost of achieving only physical separation—estimated previously by the Department to be at least $20,000 to $40,000 per entity undertaking such actions. Please see *Compliance With Statutory Program Integrity Requirements,* 84 FR 7714, *https://www.federalregister.gov/d/2019-03461/* page-7782.

[99] Borah, Luca et al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA* vol. 330,4 (2023): 375–378. doi:10.1001/jama.2023.11299.

[100] Gridley, Samantha J et al. ''Youth and Caregiver Perspectives on Barriers to Gender-Affirming Health Care for Transgender Youth.'' *The Journal of Adolescent Health,* vol. 59,3 (2016): 254–261. doi: 10.1016/j.jadohealth.2016.03.017.

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number of children who will stop receiving SRPs.

C. Alternatives Considered

As we detailed earlier in this proposed rule, the growth in SRPs in children is a growing concern given recent research that questions its efficacy and safety. We believe that the changes we are proposing are necessary to ensure the health and safety of children throughout the United States and align with the best available scientific evidence. We acknowledge, however, that there are different standards that we could have used in developing these proposed requirements.

In developing this proposed rule, we considered aligning our requirements with those States that already have restrictions on SRPs but with a variety of exceptions they provide as outlined in Section 1.B of this proposed rule. For example, we could have allowed those currently receiving these procedures to continue receiving them. Ultimately, however, we have decided to adopt the proposed provisions with fewer exceptions than are allowed in these States to maximize health and safety for all children. We seek comments, however, on whether we should adopt one or more of the additional State exceptions related to SRPs.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the proposed rule when finalized, we assume that all hospitals will review this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is also possible that other individuals and providers will review this proposed rule. For these reasons we thought that doubling the number of Medicare or Medicaid certified hospitals (n = 4,832) would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 75 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this proposed rule is $132.44 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately ([9,500 words/250 words per minute] × 75 percent) 28.5 minutes for the staff to review 75 percent of this proposed rule. For each entity that reviews the rule, the estimated cost is $62.91 (0.475 hours × $132.44). Therefore, we estimate that the total cost of reviewing this regulation is $607,962 ($[62.91] × [9,664]).

E. Accounting Statement

As required by OMB Circular A–4 (available online at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 4 showing classification of the costs and benefits associated with the provisions of this proposed rule. This includes the total costs for hospitals providing notices to children and their parents that they are no longer providing SRPs as identified in Table 1, the cost for hospitals to update their policies and procedures in Table 2, the reduction in costs due to the ending of SRPs for some patients as well as an increase in cost for patients who seek new providers in Table 3, as well as the regulatory review costs. There are also transfer costs for patients seeking care at other providers as outlined in Table 3. There are $0 benefit estimates in the statement. This statement provides our best estimate for the Medicare and Medicaid provisions of this proposed rule.

TABLE 4—ACCOUNTING STATEMENT

Category	Estimate	Units		
		Year dollar	Discount rate (%)	Period covered
Annualized Monetized Costs ($million/year)	0.32–0.04	2024	7 or 3	2026–2035
Annualized Monetized Transfers ($million/year)	5.3	2024	7 or 3	2026–2035

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals (NAICS 6221) are considered small businesses either by the Small Business Administration's size standards with total revenues of $47.0 million or less in any single year or by the hospital's not for profit status. According to the 2022 Economic Census,[101] general medical and surgical hospitals (NAICS 6221) have revenues of $1.27 trillion.

Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. With estimated annual costs and reduction in transfers resulting in the loss of approximately $11.4 million in annual revenues for hospitals, which is approximately 0.0008 percent of revenues, this proposed rule would not have a significant economic impact as measured on a substantial number of small businesses or other small entities as measured by a change in revenue of 3 to 5 percent. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the statute requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the statute, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. With total requirement costs and the loss of transfers reducing hospital revenues by approximately $11.4 million annually for all 4,832 hospitals, or $2,194 per hospital, we expect that

[101] U.S. Census Bureau. ''All Sectors: Summary Statistics for the U.S., States, and Selected Geographies: 2022.'' *Economic Census, United States Census Bureau,* 2022, *data.census.gov/table/EC2200BASIC?q=EC2200BASIC.* Accessed 15 Dec. 2025.

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this proposed rule would have a negligible impact on small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This proposed rule does not mandate any spending requirements for State, local, or tribal governments, or for the private sector.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, pre-empts State law, or otherwise has federalism implications. This proposed rule would pre-empt State laws that prohibit SRPs for children that include exceptions for reasons beyond those exceptions provided in this proposed rule, including for children who are already undergoing these procedures. It would also pre-empt State laws requiring hospitals to provide SRPs.

Consistent with the Executive Order, we find that State and local laws that provide exceptions from the prohibition beyond those listed in this proposed rule, as well as State and local laws that require hospitals to provide SRPs for children, directly conflict with this exercise of CMS' statutory health and safety authority to prohibit providers subject to this proposed rule from providing these procedures.

Similarly, to the extent that State-run hospitals that receive Medicare and Medicaid funding are required by State or local law to provide SRPs for children except in those cases covered by our exceptions, there is direct conflict between the provisions of this proposed rule (prohibiting such procedures) and the State or local law (allowing them).

As is relevant here, this proposed rule preempts the applicability of any State or local law providing for SRPs to the extent such law provides broader grounds for these procedures than provided for by Federal law and are inconsistent with this proposed rule. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this proposed rule preempts State and local laws to the extent the State and local laws conflict with this proposed rule. The agency has considered other alternatives (for example, relying entirely on State laws prohibiting SRPs) and has concluded that the requirements established by this proposed rule are the minimum regulatory action necessary to achieve the objectives of the statute.

Given the growth in SRPs among children in recent years, we believe that the prohibition of these procedures for children is necessary to promote and protect patient health and safety. The agency has examined research on SRPs for children and concludes that it can cause permanent harm with uncertain benefits. We are inviting State and local comments on the substance as well as legal issues presented by this proposed rule, and its impact on them.

I. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' We followed the implementation guidance from OMB–M–25–20 (*https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf*) when estimating the proposed rule's impact related to the executive order. Specifically, we used a 7 percent discount rate when estimating the cost for the purposes of Executive Order 14192. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 17, 2025.

List of Subjects in 42 CFR Part 482

Grant programs health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 2. Section 482.46 is added to subpart C to read as follows:

§ 482.46 Condition of participation: Sex-rejecting procedures.

The hospital must not perform sex-rejecting procedures on any child.

(a) *Definitions.* As used in this section:

(1) ''Child'' means any individual younger than 18 years of age.

(2) ''Female'' means an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

(3) ''Male'' means an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

(4) ''Sex'' means an individual's immutable biological classification as either male or female.

(5) ''Sex-rejecting procedure'' means any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex either by:

(i) Intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits; or

(ii) Intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.

(b) Exceptions. The definition at paragraph (a)(5) of this section does not include procedures:

(1) To treat an individual with a medically verifiable disorder of sexual development;

(2) For purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex; or

(3) To treat complications, including any infection, injury, disease, or disorder that has been caused by or

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exacerbated by the performance of a sex-rejecting procedure.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23465 Filed 12–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 84

RIN 0945–AA27

Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department) issues this Notice of Proposed Rulemaking (NPRM) to revise 45 CFR 84.4(g) in the regulation implementing section 504 of the Rehabilitation Act of 1973 (section 504) as it applies to recipients of HHS funding (entitled ''Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance,'' 89 FR 40066 (''2024 Final Rule'')), published on May 9, 2024. This rule clarifies that the Department interprets the statutory exclusion of ''gender identity disorders not resulting from physical impairments'' from the definitions of ''individual with a disability'' and ''disability'' set forth at 29 U.S.C. 705(9) & (20)(F)(i), 42 U.S.C. 12211(b), to encompass ''gender dysphoria not resulting from a physical impairment'' for purposes of part 84. This clarification is necessary to resolve ambiguity introduced in the preamble to the 2024 Final Rule and to ensure compliance with the best reading of the plain language of the governing statute.

DATES: *Comments:* Submit comments on or before January 20, 2026.

ADDRESSES: You may submit comments to this proposed rule, identified by RIN Number 0945–AA27, by any of the following methods. Please do not submit duplicate comments.

Federal eRulemaking Portal: You may submit electronic comments at *https://regulations.gov* by searching for the Docket ID number XXXXX. Follow the instructions for submitting electronic comments. If you are submitting comments electronically, the department strongly encourages you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), the Department strongly encourages you to convert the PDF to ''print-to-PDF'' format, or to use some other commonly used searchable text format. Please do not submit the PDF in scanned format. Using a print-to-PDF allows the Department to electronically search and copy certain portions of your submissions to assist in the rulemaking process.

Regular, Express, or Overnight Mail: You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Disability NPRM, RIN 0945–AA27, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

All comments received by the methods and due date specified above, or officially post marked by the due date above, will be posted without change to content to *https://www.regulations.gov,* including any personal information provided, and such posting may occur after the closing of the comment period.

However, the Department may redact certain non-substantive content from comments before posting, including threats, hate speech, profanity, graphic images, or individually identifiable information about an individual third-party other than the commenter. In addition, comments or material designated as confidential or not to be disclosed to the public will not be accepted. Comments may be redacted or rejected as described above without notice to the commenter, and the Department will not consider in rulemaking any redacted or rejected content that would not be made available to the public as part of the administrative record. Because of the large number of public comments normally received on **Federal Register** documents, the Office for Civil Rights is not able to provide individual acknowledgements of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays.

Please note that comments submitted by fax or email and those submitted or postmarked after the comment period will not be accepted.

Docket: For a plain language summary of the proposed rule and complete access to background documents or posted comments, go to *https://www.regulations.gov* and search for Docket ID number XXXXX.

FOR FURTHER INFORMATION CONTACT: John Thompson, Office for Civil Rights, Department of Health and Human Services at (202) 545–4884 or (800) 537–7697 (TDD), or via email at *504@hhs.gov.*

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Background

Statutory Framework

Section 504 of the Rehabilitation Act of 1973, codified at 29 U.S.C. 794, prohibits discrimination on the basis of disability in federally assisted and federally conducted programs and activities. Specifically, 29 U.S.C. 794(a) provides: ''No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency[.]'' The HHS Office for Civil Rights (OCR) enforces section 504 as well as other statutes that prohibit discrimination on the basis of disability. Although the Rehabilitation Act predates the Americans with Disabilities Act of 1990 (ADA), Congress subsequently amended the Rehabilitation Act, through the Rehabilitation Act Amendments of 1992 (Pub. L. 102–569, sec. 102, 106 Stat 4344), to align key definitions in the Rehabilitation Act with key definitions in the ADA. Under these amendments, the term ''individual with a disability'' ''does not include an individual on the basis of . . . transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender

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STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL

STEVE MARSHALL
ATTORNEY GENERAL

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February 17, 2026

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

Submitted electronically via http://www.regulations.gov

Re: Comments on proposed rulemakings: (1) "Medicare and Medicaid Programs: Hospital Condition of Participation: Prohibiting Sex Rejecting Procedures for Children" (Docket No. CMS-2025-1822-0001), and (2)"Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children" (Docket No. CMS-2025-1823-0001).

Dear Secretary Kennedy:

On behalf of the States of Alabama, XX, and XX, we write to comment on two proposed rules to restrict federal funding from subsidizing sex-change procedures for minors. Because those procedures have not been shown to be safe or effective for treating gender dysphoria in minors—and, in fact, have been shown to carry a great risk of harm—we agree that the federal government should stop paying for them. It should also stop subsidizing hospitals that provide the treatments. We support the proposed rules.

We write to provide additional information regarding the purported "standards of care" used by some providers to justify providing sex-change procedures to minors. As the proposed rules note, the organization that authors the primary treatment guideline is the World Professional Association for Transgender Health (WPATH). *See* 90 Fed. Reg. 59441, 59444-45. And as the proposed rules also note, those guidelines "are not trustworthy according to accepted standards for evaluating guideline quality," *id.* at 59445—or, frankly, any other standard.

Many of our States have learned this firsthand through litigating to defend our laws prohibiting the provision of sex-change procedures to minors. For instance, in 2022, shortly after the Alabama legislature passed a law prohibiting

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pediatric sex-change procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[1] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[2] Its evidence-review team "found little to no evidence about children and adolescents."[3] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[4] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged. This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[6]

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[1] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[2] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10. Throughout this letter, the undersigned will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

[3] Ex.173(Doc.560-23):22.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186 (Doc.700-15):32.

[6] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; Leor Sapir, *"We're All Just Winging It": What The Gender*

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The Services should have this additional information as it considers finalizing the proposed rules.

* * *

WPATH published Standards of Care 8 (SOC-8) in September 2022.[7] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[8] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[9] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[10] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[11] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[12] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[13]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[14]—WPATH commissioned a legal review of SOC-8 and

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Doctors Say in Private, THE FREE PRESS (Dec. 3, 2025), https://www.thefp.com/p/were-all-just-winging-it-what-the; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

[7] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.

[8] *Id.* at S248-49.

[9] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[10] Ex.18(Doc.564-8):121:7-11.

[11] Ex.21(Doc.700-3):158:17-25.

[12] Ex.184(Doc.700-13):24.

[13] Ex.184(Doc.700-13):15.

[14] Ex.182(Doc.700-11):152.

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was in regular contact with movement attorneys.[15] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[16] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[17]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[18]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[19] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens of lawsuits in the US right now";[20] "I cannot overstate the importance of SOC 8 getting this right at this important time."[21] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[22]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[23] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[24]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[25]

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[15] Ex.4(Doc.557-4):vi.
[16] Ex.182(Doc.700-11):151.
[17] Ex.184(Doc.700-13):14.
[18] SOC-8, *supra* note 12, at S177.
[19] Ex.180(Doc.700-9):11.
[20] *Id.* at 64.
[21] Ex.181(Doc.700-10):43.
[22] *Id.* at 75.
[23] SOC-8, *supra* note 12, at S18.
[24] *Id.*
[25] Ex.181(Doc.700-10):36 (second closed parenthesis added).

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WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[26] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[27] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[28] all while authors and WPATH leaders raised such concerns internally.[29]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[30] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[31]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[32] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[33] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[34]

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[26] SOC-8, *supra* note 12, at S45-46.

[27] Ex.174(Doc.560-24):1-2.

[28] Ex.184(Doc.700-13):55.

[29] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[30] Ex.184(Doc.700-13):54.

[31] *See* Ex.187(Doc.700-16):4-5.

[32] Ex.170(Doc.700-4):61-64.

[33] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[34] Ex.170(Doc.700-4):143.

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After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[35] WPATH leaders met with Levine to discuss the age recommendations.[36] Levine's solution was simple: "She asked us to remove them."[37]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[38]

- "I'm also curious how the group feels about us making changes based on current US politics.... I agree about listening to Levine."[39]

- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[40]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[41] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[42]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[43] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[44]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[45] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines ... have a very weak methodology, written

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[35] Ex.186 (Doc.700-15):28.
[36] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[37] Ex.186 (Doc.700-15):11.
[38] *Id.* at 32.
[39] *Id.*
[40] *Id.* at 33.
[41] *Id.* at 17.
[42] *Id.* at 57.
[43] *Id.* at 17.
[44] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.
[45] Ex.187(Doc.700-16):13-14, 109.

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by few friends who think the same."[46] But the political reality soon set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[47] WPATH thus "remove[d] the ages."[48]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[49]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[50] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[51] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[52]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[53] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[54] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[55]

C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[56] Among other things, it boasts that WPATH managed conflicts of

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[46] *Id.* at 100.
[47] *Id.* at 191.
[48] *Id.* at 338.
[49] Ex.21(Doc.700-3):293:25–295:16.
[50] Ex.188(Doc.700-17):152.
[51] Ex.177(Doc.700-6):124.
[52] *Id.* at 119.
[53] Ex.188(Doc.700-17):113.
[54] *Id.*
[55] Ex.177(Doc.700-6):102.
[56] *See* SOC-8, *supra* note 12, at S247-51.

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interest and engaged an evidence-review team to conduct systematic literature reviews.[57] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[58] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[59]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[60] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[61]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[62] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[63]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[64] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider

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[57] *Id.*

[58] *Id.* at S247.

[59] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[60] Institute of Medicine, *supra* note 64, at 83.

[61] *Id.* (emphasis added).

[62] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[63] Ex.18(Doc.564-8):121:7-11.

[64] Institute of Medicine, *supra* note 64, at 78.

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that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[65] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[66]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[67] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[68] Dr. Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[69] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[70] "Unfortunately," she lamented, "this was not done here."[71] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[72]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[73]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[74] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[75]

Chapter authors were then to grade the recommendation statements based on the evidence.[76] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[77] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a

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[65] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[66] SOC-8, *supra* note 12, at S177.
[67] Ex.21(Doc.700-3):230:17-23.
[68] Ex.174(Doc.560-24):7.
[69] Ex.166(Doc.560-16):1.
[70] *Id.* (emphasis added).
[71] *Id.*
[72] SOC-8, *supra* note 12, at S177.
[73] Ex.21(Doc.700-3):232:13-15.
[74] SOC-8, *supra* note 12, at S250.
[75] *Id.* at S249-50.
[76] *Id.* at S250.
[77] *Id.*

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degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[78] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[79]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[80] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[81]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[82] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[83]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[84]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[85] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[86]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or

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[78] *Id.*

[79] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.

[80] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

[81] Ex.39(Doc.592-39):66:2–67:5.

[82] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[83] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[84] SOC-8, *supra* note 12, at S48.

[85] *Id.* at S46-47.

[86] *Id.* at S111.

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"very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[87] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[88] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[89] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[90] She reported: "[W]e found little to no evidence about children and adolescents."[91]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[92] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[93] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[94] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[95] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[96]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and

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[87] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.

[88] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[89] Ex.173 (Doc.560-23):22-25.

[90] *Id.* at 24.

[91] *Id.* at 22.

[92] *Id.*

[93] Ex.167(Doc.560-17):86-88.

[94] *Id.* at 37-38, 75-81.

[95] *Id.* at 37 (emphasis added).

[96] *Id.* at 38.

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neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[97] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[98]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[99]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[100]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[101] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[102] That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[103]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[104] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[105] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[106] No matter: The guideline that Plaintiffs rely on to ask this Court to reverse the trial court's factual findings recommends castration for men and boys who identify as "eunuch."

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[97] *Id.* at 91.

[98] *Id.* at 38.

[99] *Cf.* Ex.167(Doc.560-17):91.

[100] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).

[101] SOC-8, *supra* note 12, at S88.

[102] *Id.* at S88-89.

[103] Ex.21(Doc.700-3):172:19–173:25.

[104] *Id.*

[105] Ex.182(Doc.700-11):96.

[106] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

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And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[107] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[108] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[109] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[110] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[111]

Despite all this, advocates regularly promise that the WPATH Standards were developed using well-accepted processes and similar to other treatment guidelines. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[112]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[113] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[114]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[115] Problem was, Dr. Coleman "ha[d] no idea how

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[107] SOC-8, *supra* note 12, at S88.

[108] *Id.*

[109] *Id.*

[110] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[111] *Id.*

[112] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

[113] Ex.190(Doc.700-18):5 (capitalization altered).

[114] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[115] Ex.190(Doc.700-18):5-6.

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it was ever said that so many medical organizations ha[d] endorsed" the standards.[116] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[117]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[118] The AAP, Dr. Coleman said, rejected WPATH's request.[119] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[120] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[121]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[122] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[123] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[124] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing

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[116] *Id.*

[117] *Id.* at 6 (spelling corrected).

[118] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[119] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.

[120] Ex.189(Doc.560-39):15.

[121] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[122] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

[123] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[124] And online: https://adc.bmj.com/pages/gender-identity-service-series.

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viewpoints to the public.[125] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[126] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[127] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[128] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[129]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[130]

* * *

Much more could be said about how untrustworthy WPATH is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.... My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.... It occurred to me that how could anyone truly know how

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[125] *See generally* Ex.16(Doc.557-16).

[126] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[127] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[128] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[129] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[130] Ex.176(Doc.700-5):152.

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> important sexual function was to a relationship, to happiness? It isn't an easy question to answer....[131]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[132]

We thus commend the Services work in this area and support the proposed rules that would stop subsidizing sex-change procedures for minors.

Respectfully submitted,



Steve Marshall
Attorney General of Alabama

[131] Ex.176(Doc.700-5):68.
[132] Ex.180(Doc.700-9):59.

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From: Bowdre, Barrett

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Cc: Robertson, Katherine

Subject: Join 2/17 3pm CT - HHS letter re: sex-change procedures

Date: Friday, February 13, 2026 9:55:20 AM

Attachments: 2026.02.13 - Alabama et al Comment Letter DRAFT.docx
2025-23464.pdf
2025-23465.pdf
2025.10.20 - Alabama et al. Amicus Br. iso Ohio FILED.pdf

CAUTION: This email originated from outside of the Office of The Attorney General of Kansas organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi friends,

Alabama invites you to join a comment letter supporting two proposed regulations by the Centers for Medicare & Medicaid Services at HHS. The first would require States to ensure that their Medicaid and State CHIP plans do not fund sex-change procedures for minors. The second would prohibit hospitals from performing sex-change procedures on minors in order to be participate in Medicare and Medicaid programs.

The bad news is that **joins are due by Tuesday, February 17, at 3pm CT**. The good news is that you have seen 95% of the letter before. Because both proposed rules explain why they are departing from the purported "standards of care" recommended by American medical interest groups, we thought it could be helpful to shore up the administrative record with a bit more evidence about why the WPATH Standards cannot be trusted. So, our letter is basically a version of our well-worn WPATH brief. We filed a version of this brief in support of Ohio in October and were joined there by Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota,

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Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming.

I have attached our draft comment letter, the two regulations, and the Ohio brief. Please let me know if you have any questions or would like to join (and send along your AG's signature).

Again, **we can take joins until 3pm CT on Tuesday, February 17.**

Thanks,
Barrett

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From: Bowdre, Barrett

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Cc: Robertson, Katherine

Subject: Join 2/17 3pm CT - HHS letter re: sex-change procedures

Date: Friday, February 13, 2026 9:55:20 AM

Attachments: 2026.02.13 - Ala[redacted]ter DRAFT.docx
2025.[redacted].pdf
2025.[redacted].pdf
2025.10.20 - Ala[redacted]Ohio FILED.pdf

CAUTION: This email originated from outside of the Office of The Attorney General of Kansas organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi friends,

Alabama invites you to join a comment letter supporting two proposed regulations by the Centers for Medicare & Medicaid Services at HHS. The first would require States to ensure that their Medicaid and State CHIP plans do not fund sex-change procedures for minors. The second would prohibit hospitals from performing sex-change procedures on minors in order to be participate in Medicare and Medicaid programs.

The bad news is that **joins are due by Tuesday, February 17, at 3pm CT**. The good news is that you have seen 95% of the letter before. Because both proposed rules explain why they are departing from the purported "standards of care" recommended by American medical interest groups, we thought it could be helpful to shore up the administrative record with a bit more evidence about why the WPATH Standards cannot be trusted. So, our letter is basically a version of our well-worn WPATH brief. We filed a version of this brief in support of Ohio in October and were joined there by Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota,

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Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming.

I have attached our draft comment letter, the two regulations, and the Ohio brief. Please let me know if you have any questions or would like to join (and send along your AG's signature).

Again, **we can take joins until 3pm CT on Tuesday, February 17.**

Thanks,
Barrett

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In the
Supreme Court of Ohio

MADELINE MOE, *et al.*,	)	Case No. 2025-0472
	)	
Plaintiffs-Appellees,	)	On Appeal from the Franklin County Court of Appeals,
	)	
v.	)	Tenth Appellate District
	)	
DAVE YOST, *et al.*,	)	Court of Appeals
	)	Case No. 24AO-483
Defendants-Appellants.	)	

BRIEF OF *AMICI CURIAE* STATE OF ALABAMA AND 24 OTHER STATES IN SUPPORT OF APPELLANTS AND REVERSAL

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INTRODUCTION

By its own account, the Tenth District's reasoning rises or falls with WPATH—the World Professional Association for Transgender Health. Based on its cherrypicked reading of amicus briefs since rejected by the U.S. Supreme Court in *United States v. Skrmetti*, 145 S. Ct. 1815 (2025), the Tenth District concluded that, along with the Endocrine Society, WPATH is one of the "standard-bearers in gender-affirming care" and that its guidelines "are the current prevailing standards of care for the treatment of individuals with gender dysphoria." *See Moe v. Yost*, 2025-Ohio-941 (10th Dist. Mar. 18, 2025) ("Op."), ¶¶14, 19; *see also* ¶¶13 & n.8, 70 & n.32 (discussing *Skrmetti* amicus briefs supporting WPATH). The court's legal analysis was based on this factual finding. As it wrote, the court "consider[ed] the constitutional issues in this case by accepting the Guidelines as the prevailing standards of care." Op. ¶20.

For all the reasons the Ohio Attorney General explains in his brief, it is doubtful that the Ohio Constitution outsources the State's regulation of medicine to the very interest groups whose members are being regulated. So the Tenth District's starting premise is almost certainly wrong. If the General Assembly wished to regulate the prescription of opioids, for instance, it could do so in the face of conflicting "guidelines" by the American Pain Society. So, too, could it restrict children's access to opioids—again, even if the American Pain Society, and even if the child's parents, thought differently. So it is here.

Yet even if the Tenth District's reasoning were sound, reversal would still be warranted because the WPATH guidelines are simply not trustworthy. Even Plaintiffs now tacitly acknowledge that fact. Though they built their case on the promise that "[t]he medical profession's generally accepted guidelines for treating gender dysphoria are issued by the Endocrine Society

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and the World Professional Association for Transgender Health (WPATH),"[1] Plaintiffs now say that only "[t]he Endocrine Society Guideline is the standard of care widely accepted by the medical community across our country." *See* Appellees' Mem. in Response to Jurisdiction at 2. What happened?

What happened is court-ordered discovery. In 2022, shortly after the Alabama legislature passed a law prohibiting pediatric sex-change procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[2] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[3] Its evidence-review team "found little to no evidence

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[1] Br. of Appellants, No. 24AP-483 (10th Dist.), at 11 (emphasis added).

[2] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[3] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10.

Throughout this brief, *amici* will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

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about children and adolescents."[4] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[5] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[6] WPATH obliged.

This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[7] And Plaintiffs' counsel are well aware of this evidence, having been involved in other cases where it has been discussed. *See, e.g.*, *Skrmetti*, 145 S. Ct. at 1847-49 (Thomas, J., concurring) (noting "[r]ecent revelations [that] suggest that WPATH, long considered a standard bearer in treating pediatric gender dysphoria, bases its guidance on insufficient evidence and allows politics to influence its medical conclusions" (citation omitted)). One of their expert witnesses—Dr. Antommaria—even served as an expert witness in Alabama's case and thus had direct access to the discovery there.

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[4] Ex.173(Doc.560-23):22.

[5] Ex.174(Doc.560-24):1-2.

[6] Ex.186 (Doc.700-15):32.

[7] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

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No wonder Plaintiffs are running away from WPATH. But running to the Endocrine Society guideline is no answer because WPATH helped write it, too. As the Cass Review for England's National Health Service explained, the "two guidelines" are "closely interlinked, with WPATH adopting Endocrine Society recommendations, and acting as a co-sponsor and providing input to drafts of the Endocrine Society guideline."[8] Indeed, not only did WPATH sponsor both the 2009 and 2017 Endocrine Society guidelines, but the 2017 Endocrine Society guideline and WPATH's SOC-8 were also "closely linked through overlapping authors."[9] And the groups' guidelines "influenced nearly all the other guidelines" by other organizations, so there is simply no escaping WPATH's fingerprints in any of the pro-affirming guidelines.[10] As the Cass Review concluded, "[t]he circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."[11]

Plaintiffs thus cannot outrun WPATH. And they cannot escape the fact that they built their case on a faulty cornerstone. This Court should reverse.

INTEREST OF *AMICI CURIAE*

Like Ohio, *amici* States determined that sex-change procedures should not be made available to kids. That determination should not be controversial. *Amici* have always regulated healthcare. *See Dent v. West Virginia*, 129 U.S. 114, 121-24 (1889). And until a few years ago, the

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[8] *The Cass Review: Independent Review of Gender Identity Services for Children and Young People* 130 (Apr. 2024), https://perma.cc/3QVZ-9Y52; *see also* Jo Taylor et al., *Clinical Guidelines for Children and Adolescents Experiencing Gender Dysphoria or Incongruence: A Systematic Review of Guideline Quality (Part 1)*, ARCH. DIS. CHILD. S71 (2024), https://perma.cc/F3HW-FJAS ("These two guidelines are themselves linked through cosponsorship and like other guidelines lack a robust and transparent approach to their development.").

[9] Dep't of Health and Human Servs., *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* 133 (May 1, 2025), https://perma.cc/F236-84DW.

[10] *Cass Review*, *supra* note 8, at 130.

[11] *Id.*

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notion of providing sex-change procedures to children was practically unthinkable. So was the idea that the judiciary is the best branch to sort through the evidence and decide that kids suffering from gender dysphoria must be allowed to take powerful hormones that risk permanently changing their bodies and leaving them sterilized. *Amici* write to share a little about how we got here.

STATEMENT

I. The WPATH Guidelines Are Not Reliable.

WPATH published Standards of Care 8 (SOC-8) in September 2022.[12] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[13] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[14] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[15] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen

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[12] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.
[13] *Id.* at S248-49.
[14] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.
[15] Ex.18(Doc.564-8):121:7-11.

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[their] position in court."[16] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[17] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[18]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[19]—WPATH commissioned a legal review of SOC-8 and was in regular contact with movement attorneys.[20] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[21] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[22]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[23]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[24] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens

[16] Ex.21(Doc.700-3):158:17-25.
[17] Ex.184(Doc.700-13):24.
[18] Ex.184(Doc.700-13):15.
[19] Ex.182(Doc.700-11):152.
[20] Ex.4(Doc.557-4):vi.
[21] Ex.182(Doc.700-11):151.
[22] Ex.184(Doc.700-13):14.
[23] SOC-8, *supra* note 12, at S177.
[24] Ex.180(Doc.700-9):11.

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of lawsuits in the US right now";[25] "I cannot overstate the importance of SOC 8 getting this right at this important time."[26] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[27]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[28] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[29]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[30]

WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter,

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[25] *Id.* at 64.
[26] Ex.181(Doc.700-10):43.
[27] *Id.* at 75.
[28] SOC-8, *supra* note 12, at S18.
[29] *Id.*
[30] Ex.181(Doc.700-10):36 (second closed parenthesis added).

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for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[31] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[32] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[33] all while authors and WPATH leaders raised such concerns internally.[34]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[35] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[36]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the

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[31] SOC-8, *supra* note 12, at S45-46.

[32] Ex.174(Doc.560-24):1-2.

[33] Ex.184(Doc.700-13):55.

[34] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[35] Ex.184(Doc.700-13):54.

[36] *See* Ex.187(Doc.700-16):4-5.

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publisher for proofreading and typesetting.[37] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[38] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[39]

After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[40] WPATH leaders met with Levine to discuss the age recommendations.[41] Levine's solution was simple: "She asked us to remove them."[42]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[43]

- "I'm also curious how the group feels about us making changes based on current US politics.… I agree about listening to Levine."[44]

[37] Ex.170(Doc.700-4):61-64.
[38] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.
[39] Ex.170(Doc.700-4):143.
[40] Ex.186 (Doc.700-15):28.
[41] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[42] Ex.186 (Doc.700-15):11.
[43] *Id.* at 32.
[44] *Id.*

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- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[45]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[46] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[47]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[48] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[49]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[50] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines … have a very weak methodology, written by few friends who think the same."[51] But the political reality soon set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[52] WPATH thus "remove[d] the ages."[53]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical

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[45] *Id.* at 33.
[46] *Id.* at 17.
[47] *Id.* at 57.
[48] *Id.* at 17.
[49] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.
[50] Ex.187(Doc.700-16):13-14, 109.
[51] *Id.* at 100.
[52] *Id.* at 191.
[53] *Id.* at 338.

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guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[54]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[55] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[56] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[57]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[58] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[59] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[60]

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[54] Ex.21(Doc.700-3):293:25–295:16.
[55] Ex.188(Doc.700-17):152.
[56] Ex.177(Doc.700-6):124.
[57] *Id.* at 119.
[58] Ex.188(Doc.700-17):113.
[59] *Id.*
[60] Ex.177(Doc.700-6):102.

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C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[61] Among other things, it boasts that WPATH managed conflicts of interest and engaged an evidence-review team to conduct systematic literature reviews.[62] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[63] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[64]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[65] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[66]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were

[61] *See* SOC-8, *supra* note 12, at S247-51.
[62] *Id.*
[63] *Id.* at S247.
[64] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).
[65] Institute of Medicine, *supra* note 64, at 83.
[66] *Id.* (emphasis added).

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already enthusiastic about transitioning treatments.[67] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[68]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[69] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[70] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[71]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[72] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[73] Dr.

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[67] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.
[68] Ex.18(Doc.564-8):121:7-11.
[69] Institute of Medicine, *supra* note 64, at 78.
[70] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[71] SOC-8, *supra* note 12, at S177.
[72] Ex.21(Doc.700-3):230:17-23.
[73] Ex.174(Doc.560-24):7.

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Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[74] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[75] "Unfortunately," she lamented, "this was not done here."[76] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[77]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[78]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[79] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[80]

Chapter authors were then to grade the recommendation statements based on the evidence.[81] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved,"

[74] Ex.166(Doc.560-16):1.
[75] *Id.* (emphasis added).
[76] *Id.*
[77] SOC-8, *supra* note 12, at S177.
[78] Ex.21(Doc.700-3):232:13-15.
[79] SOC-8, *supra* note 12, at S250.
[80] *Id.* at S249-50.
[81] *Id.* at S250.

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"few downsides," and "a high degree of acceptance among providers."[82] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[83] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[84]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[85] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[86]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[87] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[88]

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[82] *Id.*
[83] *Id.*
[84] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.
[85] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.
[86] Ex.39(Doc.592-39):66:2–67:5.
[87] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.
[88] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

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At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[89]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[90] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[91]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or "very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[92] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[93] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

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[89] SOC-8, *supra* note 12, at S48.
[90] *Id.* at S46-47.
[91] *Id.* at S111.
[92] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.
[93] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

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E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[94] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[95] She reported: "[W]e found little to no evidence about children and adolescents."[96]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[97] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[98] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[99] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[100] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[101]

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[94] Ex.173 (Doc.560-23):22-25.
[95] *Id.* at 24.
[96] *Id.* at 22.
[97] *Id.*
[98] Ex.167(Doc.560-17):86-88.
[99] *Id.* at 37-38, 75-81.
[100] *Id.* at 37 (emphasis added).
[101] *Id.* at 38.

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This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[102] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[103]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[104]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[105]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[106] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[107] That's not an exaggeration. When asked at his

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[102] *Id.* at 91.
[103] *Id.* at 38.
[104] *Cf.* Ex.167(Doc.560-17):91.
[105] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).
[106] SOC-8, *supra* note 12, at S88.
[107] *Id.* at S88-89.

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deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[108]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[109] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[110] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[111] No matter: The guideline that Plaintiffs rely on to ask this Court to reverse the trial court's factual findings recommends castration for men and boys who identify as "eunuch."

And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[112] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[113] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[114] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[115] "The fictional pornography" "includes themes such as Nazi doctors

[108] Ex.21(Doc.700-3):172:19–173:25.
[109] *Id.*
[110] Ex.182(Doc.700-11):96.
[111] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.
[112] SOC-8, *supra* note 12, at S88.
[113] *Id.*
[114] *Id.*
[115] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

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castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[116]

Despite all this, Plaintiffs told the court below that the WPATH guideline was developed "using well-accepted processes" and is "comparable to treatment guidelines used in many other areas of medicine." Br. of Appellants, No. 24AP-483 (Tenth Appellate District), at 11-12. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[117]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[118] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[119]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He

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[116] *Id.*
[117] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.
[118] Ex.190(Doc.700-18):5 (capitalization altered).
[119] *Id.*; *see* Ex.16(Doc.557-16):¶103.

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noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[120] Problem was, Dr. Coleman "ha[d] no idea how it was ever said that so many medical organizations ha[d] endorsed" the standards.[121] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[122]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[123] The AAP, Dr. Coleman said, rejected WPATH's request.[124] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[125] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[126]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[127] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the

[120] Ex.190(Doc.700-18):5-6.
[121] *Id.*
[122] *Id.* at 6 (spelling corrected).
[123] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.
[124] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.
[125] Ex.189(Doc.560-39):15.
[126] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.
[127] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

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Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[128] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[129] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing viewpoints to the public.[130] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[131] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from

[128] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.
[129] And online: https://adc.bmj.com/pages/gender-identity-service-series.
[130] *See generally* Ex.16(Doc.557-16).
[131] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

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gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[132] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[133] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[134]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[135]

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Much more could be said about how untrustworthy Plaintiffs' once-favorite medical organization is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.… My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough…. It occurred to me that how could anyone truly know

[132] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[133] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[134] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[135] Ex.176(Doc.700-5):152.

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> how important sexual function was to a relationship, to happiness? It isn't an easy question to answer….[136]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[137]

II. The General Assembly Rejects The WPATH Model Of "Care," Which The Tenth District Rules It Cannot Do.

In January 2024, the Ohio General Assembly enacted the "Saving Ohio Adolescents from Experimentation" Act to prohibit doctors from administering puberty blockers, cross-sex hormones, and sex-change surgeries to minors for the purpose of gender transition. *See* R.C. 3129.02(A)(1), (2). In doing so, the State definitively rejected the WPATH model of "care."

Following a five-day trial, the trial court upheld the State's law against challenge. Com. Pl. Op. 12 (Aug. 6, 2024). The Tenth District reversed on two grounds, both premised on the reliability of the WPATH Standards of Care. *See* Op.¶20 ("[W]e find support for our decision to consider the constitutional issues presented in this case by accepting the Guidelines as the prevailing standards of care for gender dysphoria.").

First, the court held that the Healthcare Freedom Amendment restricted the General Assembly's authority to regulate medicine to instances where the regulation is "in accordance with the prevailing standards of care." Op.¶73. Because the Act's prohibitions on sex-change procedures for minors were *not* in accordance with the WPATH Standards, the court held, the Act violated the Healthcare Freedom Amendment.

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[136] Ex.176(Doc.700-5):68.
[137] Ex.180(Doc.700-9):59.

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Second, the Tenth District held that the Act violates the Due Course of Law Clause because it interferes with "a parent's fundamental right to direct the medical care of their child" in accordance with "medically accepted standards." Op.¶87. Here again, the court reasoned, because WPATH set the "standard," and Ohio departed from WPATH, the Act was unconstitutional.

This appeal followed. This Court stayed the Tenth District's order and accepted jurisdiction and agreed to review the judgment below. *See Moe v. Yost*, 2025-Ohio-1483; *Moe v. Yost*, 2025-Ohio-2537.

ARGUMENT

This case presents a question of fundamental importance to self-governance: whether the people's representatives in the Ohio General Assembly are bound by guidelines promulgated by interest groups like WPATH or, instead, interest groups like WPATH are bound by medical regulations enacted by the General Assembly. Who regulates whom?

The answer to that question matters in this case because children deserve so much better than the WPATH Standards. After spending years conducting a comprehensive review for the National Health Service in England, Dr. Hilary Cass summed up her findings: "I can't think of another area of paediatric care where we give young people a potentially irreversible treatment and have no idea what happens to them in adulthood."[138] No wonder countries in Europe are restricting minors' access to the "treatments." *See* Lavietes, *Britain Bans Puberty Blockers for Transgender Minors*, NBC NEWS (Dec. 11, 2024), https://perma.cc/3Q4SNV8E; Ghorayshi, *Scotland Pauses Gender Medications for Minors*, N.Y. TIMES (Apr. 18, 2024), https://perma.cc/4YV6- FCX5 (noting Scotland became "the sixth country in Europe to limit" access).

[138] Abbasi, *"Medication is Binary,"* BMJ (Apr. 2024), https://perma.cc/KUM3-XL2S.

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The co-chair of the adolescent chapter of WPATH's SOC-8, Annelou de Vries, does not even seem to disagree with Dr. Cass's assessment. Dr. de Vries is a seminal researcher in the field, having co-authored the original "Dutch studies" on which everything else has been built. In a recent essay, she tacitly admitted the truth of "the critique that there is insufficient evidence," and wrote to "question" the "normative assumption" that pediatric sex-change procedures "must necessarily result in 'effective' outcomes in order to be considered legitimate and essential care."[139] She suggested instead that sex-changes for kids be "provided and justified on the basis of personal desire and autonomy," that "effectiveness" be measured by how well the procedures "help individuals achieve their embodiment goals," and that any "experience of regret" be welcomed as "inherent to all lives."[140]

This case asks whether the Ohio General Assembly is powerless to disagree.

State Appellants' Proposition of Law No. 1:

> *The Due Course of Law Clause does not create a parental right to obtain drug-based "gender transitions" for a child.*

The Tenth District reasoned that Ohio's Due Course of Law Clause is coextensive with the Fourteenth Amendment's Due Process Clause, including its purported right to substantive due process. But there is no right for parents to obtain sex-change procedures for their children that is deeply rooted in our Nation's history and tradition, and the general recognition that parents can direct the medical care of their children does not afford them the ability to subject every restricted treatment to strict scrutiny (and make judges de facto medical regulators in the process). Were it

[139] Oosthoek, de Vries, et al., *Gender-affirming Medical Treatment for Adolescents*, 25 BMC MEDICAL ETHICS 154 (2024), https://perma.cc/8W4R-CEG7.
[140] *Id.*

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otherwise, parents could unlock access to vaccines before FDA approval and to euthanasia drugs that a State prohibits.

Nor does the Tenth District's restriction to "accepted standards" help matters. Op.¶103. It simply raises another problem: accepted by whom? Not the General Assembly or other government regulators, the Tenth District says, but WPATH. But our nation's "history and tradition" is that governments regulate medical providers, not the other way around. *E.g.*, *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 302 (2022) ("The Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion."). "This country does not have a custom of permitting parents to obtain banned medical treatments for their children and to override contrary legislative policy judgments in the process." *L.W. v. Skrmetti*, 83 F.4th 460, 475 (6th Cir. 2023). Indeed, "[i]f parents could veto legislative and regulatory policies about drugs and surgeries permitted for children, every such regulation—there must be thousands—would come with a springing easement: It would be good law until one parent in the country opposed it," at which point "either the parent would take charge of the regulation or the courts would." *Id.*

State Appellants' Proposition of Law No. 2:

> *The Health Care Freedom Amendment does not create a parental right to obtain drug-based "gender transitions" for a child.*

The Tenth District also wrongly deferred to WPATH when interpreting the Health Care Freedom Amendment. By its express terms, the Amendment "does not … affect any laws calculated to deter fraud or punish wrongdoing in the health care industry." Ohio Const. art. I, §21(d). The Act here does both by rejecting the fraudulent WPATH model of care and protecting minors from unproven, high-risk procedures that are justified by their primary proponents on grounds that

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children have the right to experience "regret."[141] The Health Care Freedom Amendment, enacted to prevent an individual mandate to compel insurance coverage, does nothing to the General Assembly's traditional power to regulate medicine—even when doing so departs from the wishes of the interest groups whose members are being regulated.

CONCLUSION

The Court should reverse the Tenth District's judgment.

Dated: October 20, 2025

Respectfully submitted,

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[141] Oosthoek, *supra* note 139.

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through the Local Notice to Mariners, Broadcast Notice to Mariners, Marine Safety Information Bulletins, or Coast Guard Advisory Notices.

(b) *Definitions.* As used in this section, *Designated Representative* means a Coast Guard coxswain, petty officer, or other officer or a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the security zone.

Foreign Naval Vessel means any naval vessel of a foreign state, which is not required to be licensed for entry into the U.S. for visit purposes under 22 CFR 126.6, provided it is not undergoing repair or overhaul.

U.S. Naval Vessel means any vessel owned, operated, chartered, or leased by the U.S. Navy; any pre-commissioned vessel under construction for the U.S. Navy, once launched into the water; and any vessel under the operational control of the U.S. Navy or a Combatant Command.

(c) *Regulations.* (1) Under the general security zone regulations in subpart C of this part, you may not enter the security zones described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's Representative on VHF–FM channel 16 or by telephone at (844) NYC–USCG. Those in a security zone must comply with all lawful orders or directions given to them by the COTP or the COTP representative.

(3) The Coast Guard Northeast District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov.*

Dated: December 16, 2025.

M.E. Platt,

Rear Admiral, U.S. Coast Guard, Commander, Coast Guard Northeast District.

[FR Doc. 2025–23435 Filed 12–18–25; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 441 and 457

[CMS–2451–P]

RIN 0938–AV73

Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would require that a State Medicaid plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under 18 and prohibit the use of Federal Medicaid dollars to fund sex-rejecting procedures for individuals under the age of 18. In addition, it would require that a separate State Children's Health Insurance Program (CHIP) plan must provide that the CHIP agency will not make payment under the plan for sex-rejecting procedures for children under 19 and prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures for individuals under the age of 19.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–2451–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2451–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2451–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *MedicaidSRPInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background [1]

Title XIX of the Social Security Act (the Act) authorizes Federal grants to the States for Medicaid programs to

[1] This document contains links to non-U.S. Government websites. We are providing these links because they contain additional information relevant to the topics discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are providing these links for reference only; linking to a non-U.S. Government website does not constitute an endorsement by CMS, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by U.S. Government websites do not apply to third-party sites.

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provide medical assistance to persons with limited income and resources and title XXI of the Act authorizes Federal grants to States to provide child health assistance to targeted low-income children under age 19 through a separate CHIP, a Medicaid-expansion program, or a combination of the two. Separate CHIPs are programs under which a State receives Federal funding from its title XXI allotment to provide child health assistance through coverage that meets the requirements of section 2103 of the Act and 42 CFR 457.402. For the purposes of this proposed rule, the term CHIP is used to refer to separate CHIPs. Medicaid and CHIP programs are administered primarily by the States, subject to Federal oversight and approval. Each State establishes its own Medicaid and CHIP eligibility standards, benefits packages, and payment rates in accordance with (and subject to) Federal statutory and regulatory requirements. If States comply with requirements in the Federal Medicaid and CHIP statutes and regulations (such as reflected in the provisions of their Federally-approved State plans), the Federal Government will match their expenditures with Federal funds. Each State Medicaid program and CHIP must be described and administered in accordance with a Federally approved State plan. This comprehensive document describes the nature and scope of the States' Medicaid program and CHIP and provides assurances that they will be administered in conformity with applicable Federal requirements.

Under title XIX, the Federal Government makes matching payments to States for medical assistance expenditures according to the formula described in sections 1903 and 1905(b) of the Act. Under title XXI, the Federal Government makes matching payments to States for child health assistance at the enhanced Federal medical assistance percentage (FMAP) established under section 2105 of the Act. Section 1903 of the Act requires that the Secretary of Health and Human Services (the Secretary) (except as otherwise provided) pay to each State which has a plan approved under title XIX of the Act, for each quarter, an amount equal to the FMAP of the total amount expended by the State during such quarter as medical assistance under the State plan. Section 1905(b) of the Act defines the FMAP. For CHIP, section 2105 requires the Secretary to pay each State with an approved plan under title XXI of the Act, for each quarter, an amount equal to the enhanced FMAP of expenditures in the quarter, paid from the State allotment. The enhanced FMAP, as defined at section 2105(b), for a State for a fiscal year, is equal to the FMAP (as defined in the first sentence of section 1905(b)) for the State increased by a number of percentage points equal to 30 percent of the number of percentage points by which (1) such FMAP for the State is less than (2) 100 percent; but in no case shall the enhanced FMAP for a State exceed 85 percent.

As relevant to this proposed rule, among the statutory requirements for Medicaid State plans, section 1902(a)(19) of the Act [2] requires that a State plan for medical assistance provide such safeguards as may be necessary to assure that care and services under the plan will be provided in a manner consistent with the best interests of the recipients. Furthermore, under section 1902(a)(30)(A) of the Act,[3] the State plan must provide such methods and procedures relating to payment for care and services as may be necessary to assure that payments are consistent with quality of care. Among the statutory requirements for CHIP State plans, under section 2101(a) of the Act, funds are provided to States to provide health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

Section 1102 of the Act requires the Secretary to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is charged under the Act. In Medicaid, these Secretarial functions would include oversight of Medicaid State programs for consistency with the requirements of sections 1902(a)(19) and 1902(a)(30)(A) of the Act. In CHIP, these Secretarial functions would include oversight of CHIP under section 2101(a), which calls for effective and efficient administration of CHIP and coordination with other health care programs, including Medicaid, and under section 2107(e) of the Act, carrying out the functions required by the Medicaid provisions that apply to title XXI in the same manner as they apply under title XIX.

On January 28, 2025, President Trump issued Executive Order (E.O.) 14187, Protecting Children from Chemical and Surgical Mutilation (E.O. 14187). Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions for specific programs, including Medicaid. The Centers for Medicare & Medicaid Services (CMS) is aware that the U.S. District Court for the Western District of Washington has issued a preliminary injunction that enjoins defendant agencies from enforcing or implementing section 4 of E.O. 14187 within the plaintiff States, as well as sections 3(e) or 3(g) of E.O. 14168, Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (E.O. 14168), to condition or withhold Federal funding based on the fact that a health care entity or health professional provides ''gender-affirming care'' within the plaintiff States. *Washington* v. *Trump*, 768 F. Supp. 3d 1239, 1282 (W.D. Wash. 2025). In addition, the U.S. District Court for the District of Maryland has issued a preliminary injunction that enjoins the Federal defendants in that case from conditioning, withholding, or terminating Federal funding under section 3(g) of E.O. 14168 and section 4 of E.O. 14187, based on the fact that a healthcare entity or health professional provides ''gender-affirming care'' to a patient under the age of 19 and required that written notice of this order be given to the aforementioned groups that Defendants may not take any steps to implement, give effect to, or reinstate under a different name the directives in section 3(g) of E.O. 14168 or section 4 of E.O. 14187 that condition or withhold Federal funding based on the fact that a healthcare entity or health professional provides ''gender-affirming medical care'' to a patient under the age of 19. *PFLAG, Inc.* v. *Trump*, 769 F. Supp. 3d 405, 455 (D. Md. 2025). We note that if this proposed rule were to be finalized, it would not conflict with those preliminary injunctions because, among other things, it would be based

[2] Section 1902(a)(19) of the Act states that a State plan for medical assistance must ''provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients.''

[3] Section 1902(a)(30)(A) of the Act states that a State plan for medical assistance must ''provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) of the Act) 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.''

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on independent legal authority and section 5(a) of E.O. 14187 and not the enjoined sections of the executive orders. In any event, any regulatory provisions on this issue would not be effective until the specified effective date of any final rule, and would not be implemented, made effective, or enforced in contravention of any court orders.

As further discussed later in this proposed rule, we propose to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act by adding a new subpart N to 42 CFR part 441 to prohibit the use of Federal Medicaid dollars to fund sex-rejecting procedures, as defined in this proposed rule, for individuals under the age of 18. In addition, we propose to implement section 2103 of the Act by revising subpart D of part 457 of the Act to prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures, as defined in this proposed rule, for individuals under the age of 19. These proposed changes would not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

A. The Rise of Sex-Rejecting Procedures for Treatment of Gender Dysphoria in Minors

Over the past decade, increasing numbers of children and adolescents have been diagnosed with gender dysphoria. The recorded prevalence of gender dysphoria/incongruence increased substantially in children and young people between 2011 and 2021, particularly in recorded females. Levels of anxiety, depression and self-harm were high, indicating an urgent need for better prevention and treatment of mental health difficulties in these patients [with gender dysphoria].[4]

Similar research in Germany showed increasing rates in the diagnosis of gender incongruence.[5] Additionally, research in England explained that ''[r]ecent increases in incidence of gender dysphoria/incongruence have a range of potential explanations, including social factors (for example, . . . increasing use of social media and networking); increasing rates of emotional distress and poor mental health in this age group, particularly for females; and changes in supply and delivery of healthcare.'' [6] The number of children receiving medical interventions for gender dysphoria rose significantly following the publication of the ''Dutch Protocol'' in an article in the *European Journal of Endocrinology in* 2006.[7] Over the past decade, increasing numbers of children have received diagnoses of gender dysphoria and received sex-rejecting procedures as recommended by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (ES).[8] [9] The WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC–8) noted that the creation of a chapter on adolescents was due in part to the ''exponential growth in adolescent referral rates.'' [10] Surveys measuring ''transgender'' identity find prevalence of 1.2 percent among adolescents and ''gender diverse'' identities as high as 9 percent.[11] WPATH also noted that female adolescents were seeking such procedures at twice to seven times the rate of males.[12]

Included in SOC–8 is the recommendation that care providers ''undertake a comprehensive biopsychosocial assessment of adolescents'' who seek medical transition [13] and ''involve relevant disciplines, including mental health and medical professionals,'' as well as parents, ''unless their involvement is determined to be harmful.'' [14]

The number of pediatric patients seeking sex-rejecting procedures can only be roughly estimated. In recent years, ''the United States—characterized by its decentralized and privatized healthcare system—saw the emergence of many new specialty gender clinics, along with a proliferation of independently practicing clinicians. According to a recent conservative estimate, as of March 2023 there were 271 clinics offering [pediatric medical transition] in the U.S., though 70 were inactive due to legislative restrictions.'' [15]

An approach for gender dysphoria, referred to in this proposed rule as sex-rejecting procedures,[16] can involve the use of puberty suppressing drugs to prevent the onset of puberty; cross-sex hormones to spur the secondary sex characteristics of the opposite sex; and surgeries including mastectomy and (in rare cases) vaginoplasty. ''Thousands of American children and adolescents have received these interventions.'' [17]

A study published in 2023 estimated that between 2016 and 2020, nearly 3,700 children between the ages of 12 and 18 diagnosed with gender dysphoria underwent surgical procedures, including over 3,200 children who had breast or chest surgery, and over 400 children who had genital surgery.[18] Another analysis found that between 2017 and 2021, more than 120,000 children ages 6 to 17 were diagnosed with gender dysphoria and, of that group, more than 4,700 started taking puberty blockers and more than 14,000 started hormonal therapy.[19] However, as discussed later in this proposed rule, current medical evidence does not support a favorable

[4] Stuart William Jarviset al., ''Epidemiology of gender dysphoria and gender incongruence in children and young people attending primary care practices in England: retrospective cohort study,'' *Archives of Disease in Childhood* 110 (2025): 612, doi:10.1136/archdischild-2024–327992.

[5] Christian J. Bachmann et al., ''Gender identity disorders among young people in Germany: Prevalence and trends, 2013–2022. An analysis of nationwide routine insurance data,'' *Deutsches Ärzteblatt International* 121 (2024): 370–371, doi:10.3238/arztebl.m2024.0098. ''Gender incongruence'' as defined by ICD–11 is ''characterized by a marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' See ''International Classification of Diseases 11th Revision (ICD–11),'' World Health Organization, accessed September 9, 2025, *https://icd.who.int/en/*.

[6] Jarvis et al., ''Epidemiology of gender dysphoria,'' 619.

[7] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, ''Clinical management of gender identity disorder in adolescents: A protocol on psychological and pediatric endocrinology aspects,'' *European Journal of Endocrinology* 155, Supp 1 (2006): S131–S137, *https://doi.org/10.1530/eje.1.02231*.

[8] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,'' *International Journal of Transgender Health* 23, Supp 1 (2022): S1–S258, *https://doi.org/10.1080/26895269.2022.2100644*.

[9] Wylie C. Hembree et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658*.

[10] E. Coleman et al., ''Standards of Care,'' S43.

[11] E. Coleman et al., ''Standards of Care,'' S43.

[12] E. Coleman et al., ''Standards of Care,'' S43.

[13] Medical transition refers to the provision of hormonal or surgical interventions, as adapted from the Department of Health and Human Services, ''Treatment for Pediatric Gender Dysphoria Review of Evidence and Best Practices,'' (November 19, 2025): 29, *https://opa.hhs.gov/sites/default/files/2025-11/gender-dysphoria-report.pdf* [hereinafter ''HHS Review''].

[14] Jennifer Block, ''US transgender health guidelines leave age of treatment initiation open to clinical judgment,'' *BMJ* 378 (2022), *https://doi.org/10.1136/bmj.o2303*. See also E. Coleman et al., ''Standards of Care,'' S50, S56, S58.

[15] HHS Review, 57–58. See Luca Borah et al., ''State restrictions and geographic access to gender-affirming care for transgender youth,'' *JAMA* 330, no. 4 (2023): 375–378, doi:10.1001/jama.2023.11299.

[16] In this proposed rule, we have sought to use the term ''sex-rejecting procedures'' to refer to the set of procedures encompassed in the proposed definition.

[17] HHS Review, 9.

[18] Jason D. Wright et al., ''National Estimates of Gender-Affirming Surgery in the US,'' *Jama Network Open* 6, no. 8 (2023), doi:10.1001/jamanetworkopen.2023.30348.

[19] Robin Respaut and Chad Terhune, ''Putting numbers on the rise in children seeking gender care,'' *Reuters,* October 6, 2022, *https://www.reuters.com/investigates/special-report/usa-transyouth-data/*.

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risk/benefit profile for the use of chemical or surgical procedures in children to treat gender dysphoria.

B. Medical Evidence Regarding Sex-Rejecting Procedures for Minors

The existing guidelines to support the care of children and adolescents experiencing gender dysphoria around the world vary in their methodological rigor and quality.

On May 1, 2025, the United States Department of Health and Human Services (HHS) released a comprehensive review of the evidence and best practices for promoting the health of children and adolescents diagnosed with gender dysphoria.[20] On November 19, 2025, HHS published a final version of the review following conclusion of the peer review process (HHS Review).[21] The HHS Review, informed by an evidence-based medicine approach, indicated serious concerns about outcomes associated with certain medical interventions, such as puberty blockers, cross-sex hormones, and surgeries, that attempt to transition children and adolescents away from their sex.[22] The HHS Review highlights evidence pointing to significant risks associated with the use of these procedures, including irreversible harms such as infertility, and finds extremely weak evidence of benefit. Significantly, the HHS Review finds that the evidence base does not support conclusions about the effectiveness of medical and surgical interventions in improving mental health or reducing gender dysphoria symptoms, stating that ''[a]nalysis of the biological plausibility of harms is necessary, and suggests that some short- and long-term harms are likely (in some cases expected) sequalae of treatment.'' [23] Likewise, the data considered in the HHS Review indicate that the risk/benefit profile of medical and surgical interventions for children and adolescents diagnosed with gender dysphoria is unfavorable. While the HHS Review itself does not make clinical, policy, or legislative recommendations, it provides critical insights that should inform policymakers as they make decisions to promote health and safety, especially for vulnerable populations such as minors.

Specifically, the HHS Review conducted an overview of systematic reviews—also known as an ''umbrella review''—to evaluate the evidence regarding the benefits and harms of hormonal and surgical interventions for children and adolescents diagnosed with gender dysphoria. Existing systematic reviews of evidence, including several that have informed health authorities in Europe, were assessed for methodological quality. The umbrella review found that the overall quality of evidence concerning the effects of sex-rejecting procedures on psychological outcomes, quality of life, regret, or long-term health, is very low.

Although the HHS Review acknowledges that systematic reviews offer limited evidence regarding the harms of sex-rejecting procedures in minors, it also provides plausible explanations for why evidence of harms may not have been sought, detected or reported. This may be due to several factors: the relatively recent adoption of hormonal and surgical treatment approaches, shortcomings in existing studies in consistently monitoring and reporting adverse effects, and publication bias. Even in the absence of strong evidence from large-scale population studies, the HHS Review notes, based on what is known about human physiology and the effects and mechanisms of the pharmacological agents used, there are known and plausible risks of significant harms from puberty blockers, cross-sex hormones, and surgeries. These include ''infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, psychiatric disorders, surgical complications, and regret.'' [24]

The HHS Review documents the weak evidence and growing international retreat from the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors [25] and the ''risk of significant harms.'' [26] The HHS Review explains that ''many treatments (*e.g.* surgery, hormone therapy) can lead to relatively common and potentially serious long-term adverse effects.'' [27] The HHS Review includes a methodologically rigorous assessment of evidence underpinning the use of surgical or endocrine interventions, including puberty blockers and cross-sex hormones, while also drawing on international practice evaluations such as the United Kingdom's Cass Review, described in more detail below. The HHS Review documents serious concerns regarding the lack of reliable evidence of benefits, and risks of significant harms for this model of care that have mounted in recent years, and points to psychotherapy (talk therapy) as a noninvasive alternative. The HHS Review makes clear that ''the evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain.'' [28] The HHS Review cites widely accepted principles of medical ethics to conclude that when ''medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients.'' [29]

We are aware that approximately 17 State Medicaid programs cover sex-rejecting procedures for children, citing guidelines from several major U.S. medical professional associations (American Medical Association, the American Academy of Pediatrics, and the American Psychological Association) who have issued statements deeming sex-rejecting procedures, which they refer to as ''gender-affirming care,'' safe and effective.[30] [31] [32] [33] These medical society endorsements further supported adoption of sex-rejecting procedures by clinicians across the U.S. The HHS Review explains why such guidelines, including the WPATH Standards of Care for the Health of Transgender and

[20] HHS Review, 1. ''HHS Releases Comprehensive Review of Medical Interventions for Children and Adolescents with Gender Dysphoria,'' U.S. Department of Health and Human Services, released May 1, 2025, *https://www.hhs.gov/press-room/gender-dysphoria-report-release.html.*

[21] ''HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures,'' U.S. Department of Health and Human Services, released November 19, 2025, *https://www.hhs.gov/press-room/hhs-releases-peer-reviewed-report-discrediting-pediatric-sex-rejecting-procedures.html.*

[22] See ''Information Quality Guidelines,'' Office of the Assistant Secretary for Planning and Evaluation (ASPE), accessed August 11, 2025, *https://aspe.hhs.gov/topics/data/information-quality-guidelines;* ''HHS Information Quality Peer Review,'' ASPE, accessed August 11, 2025, *https://aspe.hhs.gov/hhs-information-quality-peer-review.*

[23] HHS Review, 134.

[24] HHS Review, 10.

[25] HHS Review, 63–65.

[26] HHS Review, 10.

[27] HHS Review, 230.

[28] HHS Review, 15.

[29] HHS Review, 15.

[30] Stacy Weiner, ''States are banning gender-affirming care for minors. What does that mean for patients and providers?,'' *AAMCNews,* February 20, 2024, *https://www.aamc.org/news/states-are-banning-gender-affirming-care-minors-what-does-mean-patients-and-providers.*

[31] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' American Psychological Association, released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[32] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* January 6, 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[33] ''Criminalizing Gender Affirmative Care with Minors,'' American Psychological Association, accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

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Gender Diverse People, Version 8 (SOC–8), are not trustworthy according to accepted standards for evaluating guideline quality. As the HHS Review documents in detail, the creation of SOC–8 marked a ''clear departure from the principles of unbiased, evidence-driven clinical guideline development.'' [34] In the context of developing its recommendations, WPATH suppressed systematic reviews of evidence, failed to manage conflicts of interest, and relied on legal and political considerations rather than clinical ones.[35] A recent systematic review of international guideline quality concluded that ''[h]ealthcare professionals should consider the lack of quality and independence of available guidance when utilizing this [WPATH and Endocrine Society international guidelines] for practice.'' [36]

1. European Approaches for the Treatment of Pediatric Gender Dysphoria

The HHS Review's current findings are aligned with conclusions reached by multiple European countries. Sweden, Finland, and the United Kingdom conducted independent systematic reviews of evidence commissioned by their public health authorities. ''All three concluded that the risks of medicalization [37] may outweigh the benefits for children and adolescents with gender dysphoria at the population level, and subsequently sharply restricted access to medical gender transition interventions for minors.'' [38] These three countries now recommend exploratory psychotherapy as the first line of treatment. Sweden and Finland reserve hormonal interventions only for exceptional cases, recognizing their experimental status.[39] [40] [41]

In particular, the most influential effort to date has been the United Kingdom's Cass Review—a 4-year independent evaluation of pediatric gender medicine that was published in April 2024.[42] The findings of the Cass Review led to the closure of the United Kingdom's Gender Identity Development Service (GIDS), which had been given a rating of ''inadequate'' by the Care Quality Commission in 2021. The Cass Review recommended a restructuring of the care delivery model—away from the centralized ''gender clinic'' model of care toward a more holistic framework centering on psychosocial support, to be delivered through regional hubs. The Cass Review's findings also led the United Kingdom to ban the use of puberty blockers outside of clinical trials, and to significantly restrict cross-sex hormones. While cross-sex hormones are still officially an available treatment, the National Health Service (NHS) recently revealed that since the Cass Review was published, no minor has been found eligible to receive cross-sex hormones according to the updated policy. In the United Kingdom, minors have never received gender dysphoria-related surgery through the NHS.

In 2022, Sweden's National Board of Health and Welfare (NBHW) reviewed and updated its guidelines for minors under the age of 18. Sweden's NBHW determined that the risks of puberty suppressing treatment with GnRH-analogues (injectable drugs that prevent the ovaries and testicles from producing sex hormones) and gender-affirming hormonal treatment likely outweigh the possible benefits.[43] Specifically, Sweden's NBHW outlined that the first line of treatment should be mental health support and exploratory psychological care. Hormonal interventions can be a last resort measure for some youth. Sweden has made the decision to no longer offer gender transition [sex-rejecting procedures] to minors outside of research settings, and restricted eligibility to the early childhood-onset of gender dysphoria.

In 2020, Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued guidelines that called for psychosocial support as the first line treatment, hormone therapy on a case-by-case basis after careful consideration, and no surgical treatment for minors. Finland has restricted eligibility for hormone therapy to minors with early childhood-onset of gender dysphoria and no mental health comorbidities.[44]

In Denmark, more than 1300 minors with gender incongruence were ''referred to the national service between 2016 and 2022 with increasing referral numbers over time,'' of which females constituted 70 percent.[45] The

[34] HHS Review, 181.

[35] HHS Review, 182.

[36] Jo Taylor et al., ''Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),'' *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65-s72, doi:10.1136/archdischild-2023–326499.

[37] ''Medicalization'' means ''the act of considering something to be a medical problem, or representing it as a medical problem.'' Cambridge Dictionary, accessed August 8, 2025, *https://dictionary.cambridge.org/us/dictionary/english/medicalization*. This definition is based on a plain meaning approach and note that the authors of the study did not otherwise supply a specific definition for the term.

[38] HHS Review, 255. See Jonas F. Ludvigsson et al., ''A systematic review of hormone treatment for children with gender dysphoria and recommendations for research,'' *Acta Paediatrica* 112, no. 11 (2023): 2279–2292, *https://doi.org/10.1111/apa.16791;* National Institute for Health and Care Excellence (NICE), ''Evidence Review: Gender Affirming Hormones for Children and Adolescents with Gender Dysphoria,'' (2020), *https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_Gender-affirming-hormones_For-upload_Final.pdf;* National Institute for Health and Care Excellence (NICE), ''Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria,'' (2020), *https://cass.independent-review.uk/wp-content/uploads/2022/09/20220726_Evidence-review_GnRH-analogues_For-upload_Final.pdf;* I. Pasternack et al., ''Lääketieteelliset menetelmät sukupuolivariaatioihin liittyvän dysforian hoidossa: Systemaattinen katsaus [Medical approaches to treating gender dysphoria: A systematic review],'' Summaryx Oy (2019); Jo Taylor et al., ''Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review,'' *Archives of Disease in Childhood* 109, Supp 2 (2024): s33–s47, doi:10.1136/archdischild-2023–326669; Jo Taylor et al., ''Masculinising and feminising hormone interventions for adolescents experiencing gender dysphoria or incongruence: A systematic review,'' *Archives of Disease in Childhood* 109, Supp 2 (2024): s48–s56, doi:10.1136/archdischild-2023–326670.

[39] ''Children and young people's gender services: implementing the Cass Review recommendations,'' NHS England, last updated August 29, 2024, *https://www.england.nhs.uk/long-read/children-and-young-peoples-gender-services-implementing-the-cass-review-recommendations/*.

[40] ''Care of children and adolescents with gender dysphoria-summary of national guidelines,'' The Swedish National Board of Health and Welfare (Socialstyrelsen), December 2022, *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf*.

[41] ''One Year Since Finland Broke with WPATH 'Standards of Care','' Society for Evidence Based Gender Medicine, July 2, 2021, *https://segm.org/Finland_deviates_from_WPATH_prioritizing_psychotherapy_no_surgery_for_minors*.

[42] Hilary Cass, ''Independent review of gender identity services for children and young people: Final report,'' (2024), *https://cass.independent-review.uk/home/publications/final-report/*.

[43] ''Care of children and adolescents with gender dysphoria-summary of national guidelines,'' The Swedish National Board of Health and Welfare (Socialstyrelsen), December 2022, *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf*. See also the Swedish National Board of Health and Welfare (Socialstyrelsen), ''Care of children and young people with gender Dysphoria—national knowledge support with recommendations for the profession and decision makers,'' (2022), *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf*.

[44] Council for Choices in Healthcare in Finland, ''Summary of a recommendation by COHERE Finland,'' June 16, 2020, *https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474*.

[45] Nanna Ravnborg et al., ''Gender Incongruence in Danish Youth (GenDa): A Protocol for a Retrospective Cohort Study of Danish Children and Adolescents Referred to a National Gender Identity Service,'' *Journal of Clinical Medicine* 13 (2024), *https://doi.org/10.3390/jcm13226658*.

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increase in the number of referrals for these procedures and reports of regret or reversal of hormone-induced changes to the body led Denmark to take an approach that focuses on assessment and psychosocial support for minors, and postpones decisions on hormone therapy, including puberty blockers and cross-sex hormones, in circumstances ''when gender incongruence has been brief,'' such as ''when there are concerns about the stability of the experienced gender identity.''[46]

In Norway, the Norwegian Commission for the Investigation of Health Care Services (UKOM), an independent State-owned agency, made recommendations in 2023 on the treatment offered to children and young people with gender incongruence.[47] The recommendations consisted of: defining puberty blockers and surgical treatment for children as experimental, revising national guidelines based on a systematic knowledge summary, and consideration for a national registry to improve quality and reduce variation in patient treatment. Norway's public health authority has signaled an intention to respond to UKOM's concerns by considering whether the current treatment guidelines need to be adjusted.[48]

Other countries which have restricted various approaches to treatment for minors (or have contemplated restrictions) include: New Zealand,[49] Italy,[50] Brazil,[51] and Australia.[52]

In sum, there is growing international concern about the use of hormonal and surgical interventions for pediatric gender dysphoria. We are aware that some medical associations have endorsed sex-rejecting procedures, but as the HHS Review makes clear, their endorsement is not based on sound principles of evidence-based medicine. In addition to other issues, we solicit comment of any published findings that measure the effects of similar restrictions as proposed on insurers, providers, and patients in these countries.

2. Medical Professional Societies Supporting Sex-Rejecting Procedures

We are aware that numerous organizations[53] (including the American Medical Association (AMA),[54] the American Academy of Pediatrics (AAP),[55] and the American Psychological Association[56][57]) have issued statements supporting access to sex-rejecting procedures, including for minors. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the U.S. are the WPATH and the ES clinical practice guidelines and the AAP guidance document. We reviewed each of these documents and agree with the conclusions of a recent systematic review of international guideline quality by researchers at the University of York (the York appraisal) that found all three documents as very low quality and should not be implemented.[58]

As the HHS Review notes regarding the role of medical organizations in the treatment of pediatric gender medicine:

U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition (PMT). This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.[59]

The Endocrine Society (ES) issued clinical practice guidelines in 2017 entitled ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.''[60] As the HHS Review notes:

In WPATH and ES guidelines, the principal goal of CSH administration [cross sex hormone] is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations. Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.[61]

The HHS Review states:

The ES 2017 guideline, which used the GRADE [Grading of Recommendations Assessment, Development and Evaluation] framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base. Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents. The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a ''satisfactory physical appearance'' while putting the lowest value on avoiding physical harms. The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower

[46] Ravnborg et al., ''Gender Incongruence in Danish Youth (GenDa).''

[47] Norwegian Healthcare Investigation Board (Ukom), ''Pasientsikkerhet for barn og unge med kjønnsinkongruens [Patient safety for children and adolescents with gender incongruence],'' March 2023, *https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag.*

[48] Jennifer Block, ''Norway's guidance on paediatric gender treatment is unsafe, says review,'' *BMJ* 380 (2023), doi:10.1136/bmj.p697.

[49] Eva Corlett, ''New Zealand bans puberty blockers for young transgender people,'' *The Guardian,* November 19, 2025, *https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.*

[50] Alvise Armellini, ''Italy moves to tighten controls on gender-affirming medical care for minors,'' *Reuters,* August 5, 2025, *https://www.reuters.com/business/healthcare-pharmaceuticals/italy-moves-tighten-controls-gender-affirming-medical-care-minors-2025-08-05/.*

[51] AFP, ''Brazil prohibits hormone therapy for transgender minors,'' *MSN News,* April 20, 2025, *https://www.msn.com/en-in/news/other/brazil-prohibits-hormone-therapyfor-transgender-minors/ar-AA1D66l7.*

[52] Australian Associated Press, ''Queensland halts prescription of puberty blockers and hormones for children with gender dysphoria,'' *The Guardian,* January 28, 2025, *https://www.theguardian.com/australia-news/2025/jan/28/queensland-halts-prescription-of-puberty-blockers-and-hormones-for-children-with-gender-dysphoria.*

[53] ''Medical Organization Statements,'' Advocates For Trans Equality's Trans Health Project, accessed November 20, 2025, *https://transhealthproject.org/resources/medical-organization-statements/.*

[54] ''Clarification of Evidence-Based Gender-Affirming Care H–185.927,'' American Medical Association, last modified 2024, *https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml.*

[55] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* January 6, 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[56] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' American Psychological Association, released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[57] ''Criminalizing Gender Affirmative Care with Minors,'' American Psychological Association, accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

[58] HHS Review, 141.

[59] HHS Review, 15.

[60] Wylie C. Hembree et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658.*

[61] HHS Review, 124.

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value on avoiding harm from potentially prolonged pubertal suppression.[62]

As explained in Chapter 9 of HHS Review, the guidelines issued by the World Professional Association for Transgender Health (WPATH) ''have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines.'' [63] As the HHS Review points out: ''Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH Standards of Care guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.'' [64] In 2022, WPATH issued guidelines entitled ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8'' (SOC–8).[65] These guidelines relaxed eligibility criteria for children to access sex-rejecting procedures, and ultimately recommend that adolescents wishing to undergo sex-rejecting procedures receive them. Besides the problems identified in systematic reviews of international guidelines, as the HHS Review states, ''in the process of developing SOC–8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC–8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.'' [66]

The HHS Review goes on to explain: ''The recommendations are couched in cautious-sounding language, stating that GD should be 'sustained over time,' particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase 'several years, leaving critical decisions open to broad and subjective interpretation.' '' [67]

Regarding the WPATH guidelines, the HHS review states:

On the surface, WPATH SOC–8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a ''comprehensive biopsychosocial assessment'' prior to initiating medical interventions in order ''to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care.'' At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases (ICD–11) diagnosis of ''Gender Incongruence of Adolescence and Adulthood,'' which, unlike the DSM–5 diagnosis of ''Gender Dysphoria,'' requires only ''marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' Because SOC–8 defines transgender in a similar way (''people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth'') and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC–8 effectively recognizes transgender identification as a medical condition justifying medical interventions.[68]

The HHS Review also argues: ''Although WPATH's guidelines do not necessarily discourage mental healthcare, they likewise do not require it as a precondition for PMT [pediatric medical transition]. Some guideline authors opposed even minimal requirements for mental health support, arguing that such provisions were analogous to ''conversion therapy.'' SOC–8's only formal recommendation is for a ''comprehensive biopsychosocial assessment,'' although WPATH emphasizes that its guideline is ''flexible,'' thereby leaving room for considerable variation in clinical practice.'' [69]

While AMA and the AAP have not issued their own treatment guidelines, they support the ES and WPATH guidelines, as discussed previously in this proposed rule. AAP issued a policy statement in 2018 supporting the use of puberty blockers, cross-sex hormones, and surgeries for minors.[70] In support of sex-rejecting surgeries, AAP stated that while ''current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.'' The AAP reaffirmed its policy statement in 2023, but also stated that it was conducting its own review of the evidence and guideline development—which still have not been released.[71] Regarding the AAP policy statement, the HHS Review states:

The AAP 2018 policy statement is not technically a CPG [clinical practice guideline] but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD. Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs [puberty blockers], CSH, and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7. As noted in Chapter 2, the AAP's policy statement's use of ''gender diverse'' casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.[72]

In addition to other issues, we solicit comment of any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients in international settings as well as the U.S.

C. United States' State Bans of and Coverage of Sex-Rejecting Procedures

State lawmakers have adopted policy positions reflecting the emerging evidence of sex-rejecting procedures administered to youth. There are 27 States and one Territory that have enacted laws restricting sex-rejecting procedures.[73] These include Alabama,

[62] HHS Review, 147.

[63] HHS Review, 157.

[64] HHS Review, 157.

[65] E. Coleman et al., ''Standards of Care.''

[66] HHS Review, 14.

[67] HHS Review, 165.

[68] HHS Review, 194–195.

[69] HHS Review, 196.

[70] Jason Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, ''Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents,'' *Pediatrics* 142, no. 4 (2018), *doi.org/10.1542/peds.2018-2162*.

[71] Alyson Sulaski Wyckoff, ''AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update,'' *AAP News,* August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy.*

[72] HHS Review, 148–149.

[73] See ''Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions,'' KFF,

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Arkansas, Arizona, Florida, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Carolina, New Hampshire,[74] North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. As of August 8, 2025, some of these States have ongoing litigation proceedings impacting whether the State laws are partially or fully enjoined by a court.

There are a mix of age ranges for these bans. Of the 28 States and Territories with enacted laws/policies (in effect or not), 25 States prohibit some sex-rejecting procedures to young people under the age of 18, two States prohibit them for those under the age of 19, and Puerto Rico prohibits them for those under the age of 21.

Of the 24 States and one Territory with restriction statutes in effect as of August 8, 2025, 21 States and one Territory prohibit *both* the prescribing of at least one type of sex-rejecting medication *and* surgeries.[75] No State bans only medications without also banning surgeries. However, all the States and the Territory with restrictions provide exceptions to the law/policies. The most common exceptions include procedures to treat:

- A medically verifiable disorder of sexual development. This allows treatment for children who are born with medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other medical factors that can be medically verified.
- Any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of gender transition procedures.
- A physical disorder, physical injury, or physical illness that would otherwise place the minor in danger of death or impairment of bodily function.

We note that 12 States provide tapering off periods for patients who started puberty blockers or hormones before enactment of the State restriction, with some specifying specific dates (for example, in South Carolina services cannot go beyond January 31, 2025) and others specifying a period of time from the time of enactment (ranging between 6 months and 1 year). Ten States have grandfather clauses primarily allowing minors who were already receiving treatment to continue receiving it indefinitely. However, we note that many of these States do not provide such exceptions or grandfather clauses for purposes of prohibitions on State funding, including for State funding under the Medicaid program and CHIP, for sex-rejecting procedures.

Conversely, 14 States and the District of Columbia have shield laws protecting some or all sex-rejecting procedures, and three States have executive orders (State EOs) protecting these procedures. These States are Arizona,[76] California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. Shield laws and State E.O.s often describe various types of sex-rejecting procedures broadly, including medications and surgeries, and include these under broader definitions of protected health care activities. These laws and State E.O.s generally attempt to shield providers and recipients (of all ages) against laws in other States that restrict these services. They also often protect providers from adverse action by medical malpractice insurers and licensure boards and allow for their address to remain confidential. One State, Maine, has a shield law specific to minors that allows minors 16 and over to receive hormone therapy when the guardian has refused sex-rejecting procedures. Four States explicitly provide child abuse and child custody protections for parents who supported their children in receiving sex-rejecting procedures. Four States have requirements for sex-rejecting procedures to be covered under health plans. Arizona requires coverage for State employee health plans. Illinois, Oregon, and Vermont require some level of coverage of sex-rejecting procedures by all health insurance providers. Vermont includes an exception for services that do not comply with Federal law.

Some States may experience negative financial impacts as a result of having built their Medicaid programs and CHIPs, including policies and operations, on the understanding that we would make Federal Medicaid and CHIP payments to States for services that this proposed rule would define as sex-rejecting procedures. We believe protecting children enrolled in Medicaid and CHIP from the harms of sex-rejecting procedures, including possible long-term and irreversible harms, outweighs the possible financial costs some States may experience if they begin to pay with State funds the full cost of sex-rejecting procedures for children enrolled in Medicaid and CHIP.

Providers in these States may be concerned that this proposed regulation would interfere with the physician-patient relationship. This proposed regulation would only prohibit Federal Medicaid and CHIP payment for certain services and does not require providers to communicate certain advice or information to patients. Federal Medicaid and CHIP payments will still be available for mental health counseling and psychotherapy for gender dysphoria. We believe a prohibition on Federal Medicaid and CHIP payments for sex-rejecting procedures is needed to avoid the possibility of minors receiving irreversible or risky pharmaceutical or surgical interventions, particularly in circumstances where the minor may be of an age to not have the capacity to understand the irreversible or long-term risks of these procedures or have the capacity to continue to communicate with providers their preferences regarding treatment after treatment has already begun.

Certain medical providers may also be relying on continued Federal funding for sex-rejecting procedures. These providers may face financial harm by the loss of the revenue from the proposed limitations on Federal payment for these procedures; however, these providers have other avenues to continue to receive compensation for providing medical care. Providers may continue to receive payment for pharmaceutical or surgical interventions for purposes of aligning a child's physical appearance or body with an asserted identity that differs from the child's sex from sources other than Medicaid or CHIP. Providers may also receive payment for these services when

last updated June 18, 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker;* ''Equality Maps: Bans on Best Practice Medical Care for Transgender Youth,'' Movement Advancement Project, accessed August 11, 2025, *https://www.lgbtmap.org/equality-maps/healthcare/youth_medical_care_bans.*

[74] New Hampshire's laws go into effect January 1, 2026 under NH HB712 and NH HB377.

[75] Arizona and New Hampshire currently do not prohibit sex-rejecting procedures using medications; however, New Hampshire has a new policy (NH HB377) taking effect January 1, 2026, that would restrict sex-rejecting procedures using medications for minors. Nebraska currently restricts, but does not fully ban, access to sex-rejecting procedures using medications, so it was not included in this count.

[76] Arizona banned pediatric sex-rejecting surgeries in 2022. However, in 2023 the governor issued an executive order which removes the exclusion of coverage for sex-rejecting surgery under the state's healthcare plan for state employees and prohibits investigative assistance to impose criminal or civil liability or professional sanctions on persons or entities for providing, assisting, seeking, or obtaining gender affirming care.

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providing these procedures for the exempted purposes as outlined in the proposed rule. Lastly, providers may be paid through Medicaid and CHIP for providing other types of care for individuals diagnosed with gender dysphoria, such as psychotherapy.

We also recognize that Medicaid and CHIP beneficiaries and their families would be impacted by this proposed rule. Families of these beneficiaries may look to obtain other health insurance or privately pay for these services. Medicaid and CHIP beneficiaries who are unable to find alternative means to pay for these services may either have to rely on other methods of intervention such as psychotherapy or mental health counseling, or never begin receiving these services because of this proposed rule, if finalized. We are concerned about the difficulties that these minors may experience and encourage other, less invasive, ways to support these individuals, such as encouraging psychotherapy as a first line of treatment.

This proposed rule would help to protect these children from the risks of adverse effects of sex-rejecting procedures. CMS carefully considered the scope of its limitation on Federal Medicaid and CHIP payments and permits coverage of other procedures, such as psychotherapy, which does not carry the same concerns of pharmaceutical or surgical interventions included in the definition of sex-rejecting procedures. Moreover, CMS does not believe Federal Medicaid and CHIP payment for these sex-rejecting procedures is consistent with quality of care given the state of the research into the effectiveness of these procedures for the purposes included in our proposed definition of this term, namely as treatments for gender dysphoria. In light of the HHS Review, CMS believes State reliance on certain medical organizations and the SOC–8 to justify covering sex-rejecting procedures is misplaced.

In addition to other issues, we solicit comment on any published studies or findings that measure the effects of similar restrictions as proposed (or laws protecting these procedures) on insurers, providers, and patients in these States.

Recently, the U.S. Supreme Court in United States v. Skrmetti, 605 U.S. 495 (2025), upheld Tennessee's law restricting certain surgical and chemical interventions for minors diagnosed with gender dysphoria (and similar conditions), referred to as Senate Bill 1 or ''SB1'' in litigation challenging that law under the Equal Protection Clause of the U.S. Constitution. SB1 prohibits a healthcare provider from performing medical procedures, including surgery, and prescribing puberty blockers, for a minor for the purpose of enabling the minor to identify with a purported identity inconsistent with the minor's sex. At the same time, SB1 allows healthcare providers to perform medical procedures for minors if the procedure is to treat a minor's congenital defect, precocious puberty, disease, or physical injury. On June 18, 2025, the Court found that SB1's prohibition of certain medical procedures for minors diagnosed with gender dysphoria incorporates classifications based on age and medical use—not the minor's sex. Because the classifications turned on age and medical use rather than sex, the Court held that SB1 was not subject to heightened scrutiny under the Equal Protection Clause of the Fourteenth Amendment and went on to find the law satisfied rational basis review. As discussed in more detail later in this proposed rule, like the law at issue in *Skrmetti,* this proposed rule would not discriminate on the basis of sex and it is not based on an invidious discriminatory purpose. The proposed rule is animated by significant child safety concerns when sex-rejecting procedures are used for certain medical uses–that is to align a child's physical appearance or body with an asserted identity that differs from the child's sex.

D. Psychotherapy as the First Line Treatment for Children Diagnosed With Gender Dysphoria

Since 2010, there has been a significant increase in mental health conditions among teens and young adults.[77] Current research has not revealed a simple explanation for this rise in the need for youth mental health services. The etiology of gender dysphoria remains understudied.[78] However, patients presenting to pediatric gender medicine clinics have a high rate of comorbid mental health conditions.[79]

We believe interested parties supporting the use of sex-rejecting procedures to treat gender dysphoria in children may state that limiting access to these treatments (which prohibiting Federal Medicaid and CHIP funding for them could do) will exacerbate these comorbidities and lead to adverse mental health outcomes and increase suicide risks. As noted previously, the Cass Review emphasized the lack of robust evidence regarding the effectiveness of interventions such as puberty blockers and cross-sex hormones to treat gender dysphoria and incongruence in children and adolescents.[80] Taylor et al. recently conducted a review of 23 international, national, and regional clinical guidelines that contained recommendations about the management of children/adolescents experiencing gender dysphoria. They found that the majority of these guidelines were developed without an independent or evidence-based approach and raised questions about the credibility of available guidance.[81] As Sweden's national health authority has recommended, ''[p]sychosocial support that helps adolescents deal with natal puberty without medication needs to be the first option when choosing care measures.'' [82]

While evidence on the benefits of medical and surgical interventions to improve mental health or reduce symptoms of gender dysphoria is lacking, psychotherapy has been proven to be an effective intervention for many of the neurodevelopmental disorders and mental health conditions that are highly prevalent in children and adolescents, including those frequently co-occurring in patients diagnosed with gender dysphoria.[83] Psychotherapy and mental health counseling are non-invasive interventions that would remain available to youth under Medicaid's mandatory Early and Periodic Screening, Diagnostic and Treatment (EPSDT) provisions in section 1905(r) of the Act. EPSDT requires the provision of screening, vision, dental, and hearing services, and such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) of the Act to correct or ameliorate defects and physical and mental illness and conditions discovered by the screening services, whether or not such services are covered under the State plan. Most children enrolled in Medicaid are entitled to coverage of robust and comprehensive psychotherapy services under EPSDT . We note that under a State's EPSDT program, States may only include tentative limits on services and must take into account the individual needs of the child. Thus, EPSDT is key

[77] Patrick McGorry et al., ''The Lancet Psychiatry Commission on youth mental health,'' Lancet Psychiatry 11, no. 9 (September 2024): 731–774, doi:10.1016/S2215–0366(24)00163–9.

[78] HHS Review, 257.

[79] HHS Review, 68.

[80] Cass, ''Cass Review.''

[81] Jo Taylor et al., ''Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1),'' *Archives of Disease in Childhood* 109, Supp. 2 (2024): s65-s72, doi:10.1136/archdischild–2023–326499.

[82] HHS Review, 256.

[83] HHS Review, 257–260.

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to ensuring that children receive appropriate mental health screenings and treatments. Furthermore, we have developed numerous resources to provide information regarding services and good practices for children and youth with mental health conditions.[84] While EPSDT is not a required CHIP benefit for States that have separate CHIPs, many States with such programs have opted to provide EPSDT services that mirror the Medicaid standards set out at section 1905(r) of the Act to children enrolled in CHIP. In addition, section 2103(c)(7) of the Act requires States to provide mental health services in CHIP that are applied in the same manner as required under section 2726(a) of the Public Health Service Act [([42 U.S.C. 300gg–26(a)])] for group health plans under such section.

E. States' Duty To Ensure Medicaid and CHIP Services for Children Are Consistent With Quality of Care and the Best Interests of Beneficiaries

Under section 1902(a)(19) of the Act, State Medicaid agencies are required to ensure that Medicaid-covered services are in the best interests of beneficiaries; as relevant to this proposed rule, children under age 18. Additionally, States are required, under section 1902(a)(30)(A) of the Act, to ensure that Medicaid payments for Medicaid covered services are consistent, in relevant part, with quality of care. Under section 2101(a) of the Act, CHIP programs are required to provide health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children, including State Medicaid programs. The research described previously in this proposed rule indicates that sex-rejecting procedures lack the necessary outcomes data to reasonably rely on for evidence of long-term effectiveness.

On April 11, 2025, we issued a letter to State Medicaid Directors to ensure Medicaid agencies were aware of growing utilization of certain interventions offered to children to treat gender dysphoria, and to remind States of their statutory responsibilities to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interests of recipients.[85] In the letter, we also stated that due to the underdeveloped body of evidence, the use of sex-rejecting procedures to treat gender dysphoria lacks reliable evidence of long-term benefits for minors and are now known to cause long-term and irreparable harm for some children.[86] A second letter, issued on May 28, 2025, was sent to a number of hospitals to address significant issues concerning quality standards and specific procedures affecting children diagnosed with gender dysphoria. The letter requested hospitals to provide information on their policies and procedures related to the adequacy of informed consent protocols for children diagnosed with gender dysphoria, including how children are deemed capable of making these potentially life changing decisions and when parental consent is required; changes to clinical practice guidelines and protocols that the institution plans to enact in light of the recent comprehensive review and guidance released by the Department; medical evidence and any adverse events related to these procedures, particularly children who later look to detransition; and complete financial data for all pediatric sex-rejecting procedures performed at the institution and paid, in whole or in part, by the Federal Government.[87]

As outlined previously in this proposed rule, we take very seriously the absence of rigorous scientific data demonstrating the effectiveness of sex-rejecting procedures and the considerable evidence regarding the risks. Given the potential risks and lack of clear benefits associated with sex-rejecting procedures, we believe that covering them with Federal Medicaid or CHIP funding would be, for Medicaid beneficiaries, inconsistent with their best interests and with quality of care; and, for CHIP beneficiaries, inconsistent with the provision of health care services to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. In this section, we describe how this proposed rule would intersect with existing statutory and regulatory provisions.

1. Intersection With Nondiscrimination (Section 1557 of the Patient Protection and Affordable Care Act)

This proposed rule is not a form of sex discrimination in violation of section 1557 of the Patient Protection and Affordable Care Act (Affordable Care Act).[88] Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities, any part of which is receiving Federal financial assistance.

A Federal court recently considered the question of whether the prohibition on sex discrimination found in section 1557 of the Affordable Care Act includes discrimination on the basis of gender identity. On October 22, 2025, in *State of Tennessee et al* v. *Kennedy et al,*[89] the district court declared that ''HHS exceeded its statutory authority when (1) it interpreted Title IX, as incorporated into Section 1557, to prohibit discrimination on the basis of gender identity, and (2) when it implemented Section 1557 regulations concerning gender identity and 'gender affirming care.' '' Accordingly, the Court vacated the following regulations to the extent that they expand Title IX's definition of sex discrimination to include gender-identity discrimination: 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(b)(3), and 460.112(a), and 45 CFR 92.101(a)(2)(iv), 92.206(b)(1)–(4), § 92.207(b)(3) through(5), 92.8(b)(1), 92.10(a)(1)(i), and 92.208.[90]

[84] ''Children and Youth,'' Medicaid, accessed June 12, 2025, *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/children-and-youth.*

[85] CMS, ''Puberty Blockers, Cross-sex Hormones, and Surgery Related to Gender Dysphoria,'' April 11, 2025, *https://www.cms.gov/files/document/letter-stm.pdf.*

[86] CMS, ''Puberty Blockers.''

[87] Department of Health & Human Services, Centers for Medicare and Medicaid Services, Urgent Review of Quality Standards and Gender Transition Procedures, May 28, 2025, *www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.*

[88] The Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1049), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA''.

[89] *Tennessee* v. *Kennedy*, ---F. Supp. 3d---,1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025).

[90] As part of a 2024 rulemaking implementing section 1557 of the Affordable Care Act, HHS amended 42 CFR 440.262, 438.3(d) and 438.206(c)(2) to specifically include discrimination based on ''gender identity'' as a form of ''sex discrimination,'' and amended 42 CFR 457.495 to cross-reference amended 440.262. The amendments to sections 438.3(d) and 438.206(c)(2) also apply to CHIP managed care through cross references in §§ 457.1201(d) and 457.1230(a) that predated the section 1557 rulemaking. These amendments to the Medicaid and CHIP rules were based on sections 1902(a)(4), 1902(a)(19), and 2101(a) of the Act. See Nondiscrimination in Health Programs and Activities, 89 FR 37522 (May 6, 2024). In *Tennessee* v. *Kennedy*, ---F. Supp. 3d---, 1:24CV161–LG–BWR, 2025 WL 2982069 (S.D. Miss. Oct. 22, 2025), the court vacated 42 CFR 440.262, 438.3(d)(4), and 438.206(c)(2) (among others) ''to the extent that they expand Title IX's definition of sex discrimination

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Notwithstanding the outcome of this litigation, the Court's holding in *Skrmetti,* as explained previously in this proposed rule and expounded upon below, supports our position that this proposed rule would not discriminate on the basis of sex. In 2023, Tennessee enacted a State law,[91] SB1, which, in relevant part, prohibits a healthcare provider from performing certain medical procedures, including surgery, and from prescribing puberty blockers, for a minor for the purpose of enabling the minor to identify with a purported identity inconsistent with the minor's sex.[92] SB1 does not prohibit healthcare providers from providing those procedures if done to treat a minor's congenital defect, precocious puberty, disease, or physical injury. The U.S. Supreme Court analyzed SB1 under the Equal Protection Clause of the Fourteenth Amendment and held that SB1 does not turn on sex-based classifications, noting ''the law does not prohibit conduct for one sex that it permits for the other.'' [93]

Like SB1, this proposed rule would apply uniformly to all children regardless of the child's sex. This proposed rule would treat all children the same when it would prohibit a State Medicaid or CHIP agency from covering, as part of its Federally funded Medicaid program and CHIP, the procedures that the proposed rule would define as sex-rejecting procedures. At the same time, this proposed rule would permit State Medicaid and CHIP agencies to continue to so cover procedures when the child has a medically verifiable disorder of sexual development, needs the procedure for a purpose other than attempting to align the child's physical appearance or body with an asserted identity that differs from the child's sex, or has complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Further, this proposed rule would be neither arbitrary nor based on an invidious discriminatory purpose. Rather, based on the review of current research and the reasoning for similar conclusions reached and actions taken by multiple European countries discussed previously in this proposed rule, we believe that Medicaid and CHIP coverage and payment of sex-rejecting procedures are not in the best interests of minors and not consistent with quality of care or the effective and efficient standard required under section 2101(a) of the Act. Therefore, we are proposing to prohibit Federal funding for these procedures in Medicaid and CHIP. This proposal is based on careful consideration of the facts as described in detail in section I.B. of this proposed rule and on our determination that the risks of sex-rejecting procedures for children outweigh the benefits. We continue to support Medicaid and CHIP coverage of services for children that research shows may be helpful for treating gender dysphoria in children without the risks of harm. Further, while State laws may differ, State Medicaid agencies are not currently specifically prohibited under Federal law from covering sex-rejecting procedures for Medicaid beneficiaries who are 18 years of age and older.

2. Intersection With Sufficiency of Amount, Duration, and Scope (§ 440.230(c))

This proposed rule would also be consistent with 42 CFR 440.230, which provides that a Medicaid State plan must specify the amount, duration, and scope of covered services. CMS has long afforded State Medicaid agencies considerable flexibility under § 440.230 to establish the amount, duration, and scope of covered Medicaid services, and to develop State-specific medical necessity criteria and utilization control procedures for covered services. State-specific limits on amount, duration, and scope are frequently applied based on an assessment of a beneficiary's specific circumstances, rather than being blanket limitations. In addition to specifying the amount, duration, and scope of covered services, historically, States have determined whether, and how, to cover services and we make Federal Medicaid payments to States if the services otherwise complied with Federal law and regulation. Within CHIP, under § 457.402(x), States have the ability to add coverage of additional services if recognized by State law.

Some States may be using the authorities under sections 1905 and 2110 of the Act, such as sections 1905(a)(6) and 2110(a)(24) of the Act,[94] to cover sex-rejecting procedures as services that are recognized under State law.

However, this flexibility under § 440.230 is not absolute. Section 440.230 requires State Medicaid agencies to comply with certain guidelines when determining the amount, duration, and scope of covered services. States must detail their proposed coverage of services in a State plan amendment and submit the State plan amendment to CMS for approval. We review the State plan amendment to ensure that States meet these guidelines. For example, under § 440.230(b), State Medicaid agencies must ensure that any covered service is sufficient in amount, duration, and scope to reasonably achieve its purpose. If a state limits the amount, duration or scope of a service without exception for medical necessity, the State must explain to us the reasoning and evidence to support the limitation prior to CMS approving the State's submission. Similarly in CHIP, the flexibility under § 457.402(x) is not absolute. Section 457.60 requires States to submit a State plan amendment when a State is making a change in policy or operation of the program that affects the benefits provided. Like in Medicaid, States must detail their proposed coverage of services in a State plan amendment and submit the State plan amendment to CMS for approval. We review the State plan amendment to ensure that States meet these guidelines.

For this proposed rule, we have considered the risk/benefit profile of sex-rejecting procedures for the purposes included in our proposed definition and the alternative treatments available, before determining that a national response prohibiting Federal Medicaid funding for sex-rejecting procedures for children under age 18 enrolled in Medicaid and under age 19 enrolled in CHIP is warranted. This prohibition includes circumstances in which a provider may determine that a sex-rejecting procedure is medically necessary for a child diagnosed with gender dysphoria.

to include gender identity discrimination'' and declared HHS had ''exceeded its statutory authority when (1) it interpreted Title IX, as incorporated into Section 1557, to prohibit discrimination on the basis of gender identity, and (2) when it implemented Section 1557 regulations concerning gender identity and 'gender affirming care.'" See also Texas v. Becerra, No. 6:24–CV–211–JDK (E.D. Tex. Aug. 30, 2024), in which the court entered a nationwide stay of certain regulations of the final rule, including 42 CFR 440.262, 438.3(d)(4), and 438.206(c)(2). Given *Skrmetti's* holding, we believe that the outcome of this litigation will not affect the proposed rule. As a result, CMS does not further discuss 42 CFR 440.262, 438.3, and 438.206 in this proposed rule.

[91] Tenn. Code Ann. § 68–33–101 *et seq.*

[92] As defined by SB1, ''minor'' means an individual under eighteen (18) years of age. Tenn. Code Ann. § 68–33–102.

[93] *United States* v. *Skrmetti,* 145 S. Ct. 1816 (2025).

[94] Section 1905(a)(6) of the Act states ''medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law'' and section 2110(a)(24) of the Act defines ''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 . . . (24) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services . . . if recognized by State law . . .''

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Lastly, this proposed rule is consistent with § 440.230(c), which prohibits State Medicaid agencies from arbitrarily denying or reducing the amount, duration, or scope of a covered service to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition. This proposed rule reflects the agency's efforts to address significant concerns about the risk/benefit profile of sex-rejecting procedures for the uses included in our proposed definition of that term, due to the safety concerns, risks of irreversible harm, long-term health outcomes, and unestablished effectiveness associated with those uses, as explained previously. This proposed rule takes into account the different risk/benefit profiles of different uses of these procedures, which is why it focuses on purposes that might be associated with a particular diagnosis, type of illness or condition. Our proposed definition of sex-rejecting procedures would exclude from the definition certain uses of these procedures for which the risk/benefit profile creates less significant concerns. Additionally, other treatments, such as mental health treatment, would remain Federally funded for children diagnosed with gender dysphoria.

As discussed previously in this proposed rule, we have considered the concerns of States, providers, and beneficiaries who have relied on CMS making Federal Medicaid and CHIP payment for these services. Notwithstanding the potential financial burden to States, providers, and individuals, and the psychological and physical impact on beneficiaries who wish to receive these services, a nationwide prohibition on Federal Medicaid and CHIP payments for these services is warranted. We believe that the concerns of States, providers and beneficiaries described previously in this proposed rule are outweighed by the potential harm of sex-rejecting procedures for minors, including potential long-term harm, especially when the possible benefits of these services are unproven and the procedures are irreversible. More data is needed on how the procedures that the proposed rule would define as sex-rejecting procedures in children under age 18 in Medicaid and under age 19 in CHIP affect the long-term health of such individuals, including any impact on fertility, and whether these procedures result in, or increase the risk of, sexual dysfunction, impaired boned density, adverse cognitive impacts and other health deviations, as mentioned previously.

3. Intersection With Early and Periodic Screening, Diagnostic and Treatment (EPSDT)

This proposed rule also would be consistent with States' obligations under the EPSDT requirement, even though it would limit States' longstanding flexibility to develop State-specific processes for determining when a service is medically necessary for an EPSDT-eligible beneficiary under section 1905(r)(5) of the Act. Under EPSDT, States must cover medically necessary services described in section 1905(a) of the Act for most Medicaid eligible children under the age of 21. Children eligible for EPSDT generally include beneficiaries under the age of 21 enrolled: in Medicaid through a categorically needy group; in Medicaid through a medically needy group in a State that has elected to include EPSDT in the medically needy benefit package; in a Medicaid-expansion CHIP program; or in a separate CHIP program that has elected to cover EPSDT. This includes beneficiaries with an institutional level of care who are eligible for Medicaid by virtue of their enrollment in a home and community-based services (HCBS) waiver under section 1915(c) of the Act. EPSDT is not available to beneficiaries without satisfactory immigration status who are eligible only for treatment of an emergency medical condition and other groups of individuals under age 21 who are eligible only for limited services as part of their Medicaid eligibility, such as, for example, family planning services.

Under this proposed rule, sex-rejecting procedures for the uses included in our proposed definition would no longer be Federally funded as Medicaid-covered services for individuals under the age of 18 or as CHIP-covered services for individuals under the age of 19, because such services may pose a risk of harm to children, including long-term irreversible harm, and result in adverse outcomes on their health including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, and psychiatric disorders. We are not endorsing or requiring any particular treatment modality for gender dysphoria.

In our prior EPSDT coverage guidance,[95] [96]we discuss how States should approach their determination of whether a service is medically necessary. In this prior guidance, we emphasize that States (or their delegated entity) must take into account the particular needs of the child. We explain that States should consider the child's long-term needs, not just what is required to address the immediate situation. The State should consider all aspects of a child's needs, including nutrition, social development, and mental health and substance use disorders. Accordingly, while sex-rejecting procedures have been covered by some State Medicaid programs to address gender dysphoria to alleviate its symptoms, these procedures can involve use of puberty suppressing drugs to prevent the onset of puberty and cross-sex hormones to spur the secondary sex characteristics of the opposite sex. For children under 18 (or under 19 in CHIP) who have undergone the suppression of puberty, these procedures may pose a significant risk of harm, including possible long-term harm to a child's health, including the risk of infertility and bone density loss, as discussed previously.

As discussed previously in this proposed rule, some State Medicaid programs and CHIPs have relied upon clinical guidelines that have failed to meet the principles of unbiased, evidence-driven clinical guideline development. As a result of this reliance, State Medicaid programs and CHIPs have developed coverage criteria which may not have considered the full effects of all aspects of a child's needs (including long-term needs) as required under EPSDT.

F. Prohibition on Federal Funding and Coverage in a Separate CHIP

Title XXI of the Act allows States to implement CHIP as a separate CHIP, a Medicaid-expansion program, or a combination of the two. Title XXI-funded Medicaid expansion programs generally follow Medicaid rules. This section relates to separate CHIPs.

States with separate CHIPs receive Federal funding from the title XXI allotment to provide child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act and regulations at § 457.402. Section 2101(a) of the Act calls for the provision of CHIP in a manner that is effective and efficient and coordinated with other sources of

[95] CMS, ''EPSDT–A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,'' June 2014, *https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-coverage-guide.pdf.*

[96] CMS, State Health Official Letter #24–005, ''Best Practices for Adhering to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Requirements,'' September 26, 2024, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho24005.pdf.*

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health benefits coverage for children, notwithstanding section 2110(a)(24) of the Act that allows States to cover additional services that are recognized by State law. While CMS recognizes the considerable State flexibility provided to States under section 2110(a)(24) of the Act, CMS has concluded that it is in the best interest of children under age 19 enrolled in CHIP to no longer permit Federal funding for coverage of procedures when utilized for purposes of sex-rejecting procedures because such services may result in adverse outcomes on their health including infertility/sterility, sexual dysfunction, impaired bone density accrual, diverse cognitive, cardiovascular disease and metabolic disorders, and psychiatric disorders. Therefore, CMS has concluded it is most efficient and effective, and in the best interests of children, for CHIP to align and coordinate with the Medicaid program.

Section 2103 of the Act and § 457.410 allow States to choose any of the following four types of health benefits coverage for separate CHIPs: (1) Benchmark coverage in accordance with § 457.420; (2) Benchmark-equivalent coverage in accordance with § 457.430; (3) Existing comprehensive State-based coverage in accordance with § 457.440; and (4) Secretary-approved coverage in accordance with § 457.450. Regardless of the type of health coverage selected by a State, States are required to provide all services identified at § 457.410(b) to children enrolled in CHIP. In addition to these services, States have the flexibility to cover additional services at § 457.402, which lists the services included in ''child health assistance.'' In addition to the specified services, § 457.402(x) permits states to select additional services and treatments that it will cover. The majority of separate CHIP States have elected Secretary-approved coverage. Under Secretary-approved coverage at § 457.450, the Secretary currently has the discretion to determine whether the coverage provided by a State is appropriate coverage for the population of targeted low-income children covered under the program. Recently, there have also been changes to allowable procedures under the benchmark coverage options for CHIP under § 457.420 as described later in this proposed rule.

On June 20, 2025, we issued the ''Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability,'' final rule (90 FR 27074) (referred to hereafter as the ''2025 Marketplace final rule''), which prohibits issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to the essential health benefit (EHB) requirements—from providing coverage for ''specified sex-trait modification procedures'' as an EHB beginning with Plan Year 2026. This prohibition was proposed and finalized because section 1302(b)(2)(A) of the ACA requires that the scope of the EHB be equal to the scope of benefits provided under a typical employer plan, and coverage of such procedures is not typically included in employer-sponsored plans.[97] In addition, on January 31, 2025, the U.S. Office of Personnel Management issued letter 2025–01A, which prohibited coverage of certain surgeries and hormone treatments for covered individuals in Federal Employees Health Benefits (FEHB) and Postal Service Health Benefits (PSHB) Programs under age 19. That letter was amended by letter 2015–01B, issued on August 15, 2025, which eliminated the age limit and advised that for Plan Year 2026, chemical and surgical modification of an individual's sex traits through medical interventions (to include ''gender transition'' services) will no longer be covered under the FEHB or PSHB Programs. Specifically, it excludes hormone treatments that pertain to chemical and surgical modification of an individual's sex traits (including as part of ''gender transition'' services) and clarifies that carriers should not exclude coverage for entire classes of pharmaceuticals. For example, GnRH agonists may be prescribed during in vitro fertilization (IVF), for reduction of endometriosis or fibroids, and for cancer treatment or prostate cancer/tumor growth prevention.[98]

As previously noted, section 2101(a) of the Act provides 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. As outlined previously in this proposed rule, while the prohibitions on coverage are not identical, they will effectively result in prohibition of coverage of sex-rejecting procedures in both the FEHB Program and as an EHB beginning with Plan Year 2026. Therefore, we are proposing to add a new section § 457.476 to prohibit Federal financial participation for sex-rejecting procedures under CHIP, to align CHIP with Medicaid, the FEHB Program, and EHBs. Although title XXI of the Act does not apply EHB rules under a separate CHIP, the services which must be covered under title XXI also are EHBs. We note that similar to Medicaid, this proposed change in CHIP would not prohibit Federal payment for procedures undertaken to treat a child with a medically verifiable disorder of sexual development; for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

We also note that section 2107(e) of the Act applies numerous provisions in Medicaid in the same manner to title XXI as would be the case under this proposed rule.

We take very seriously the weak evidence base supporting the safety or effectiveness of sex-rejecting procedures in minors, and the plausible evidence of harm, for the purposes included in our proposed definition. Based on these factors, we propose to prohibit Federal CHIP funds for sex-rejecting procedures for the purposes included in our proposed definition. It is also important to reiterate that these regulatory changes would not prohibit the use of Federal CHIP dollars for mental health treatments for conditions such as gender dysphoria.

II. Provisions of the Proposed Regulations

A. General Discussion

We propose to exercise our separate authorities under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to add a new subpart N to part 441 to prohibit Federal Financial Participation (FFP) in Medicaid for sex-rejecting procedures for the purposes included in our proposed definition for individuals under the age of 18, as this is the age of majority in most States. For CHIP, we

[97] Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability, 90 FR 27152 (June 25, 2025). While portions of the ''Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability,'' final rule (90 FR 27074), have been challenged, the requirement that issuers of non-grandfathered individual and small group market health insurance coverage—that is, issuers of coverage subject to the essential health benefit (EHB) requirements—cannot provide coverage for ''specified sex-trait modifications'' as an EHB will begin with Plan Year 2026.

[98] U.S. Office of Personnel Management (OPM) FEHB Program Carrier Letter, Letter Number 2025–01A, ''Addendum to Call Letter for Plan Year 2026,'' January 31, 2025, *https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-1a.pdf.* Amended by OPM FEHB Programs Carrier Letter, Letter Number 2025–01B, ''Subject: Chemical and Surgical Sex-Trait Modification Services for Plan Year 2026 Proposals,'' August 15, 2025, *https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-01b.pdf.*

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propose to exercise our authority under section 2103(c) of the Act to revise subpart D of 42 CFR part 457 to prohibit the use of Federal CHIP dollars to fund sex-rejecting procedures for the purposes included in our proposed definition for individuals under the age of 19, as this age aligns with the statutory definition of ''child'' at 2110(c)(1) of the Act. While this proposal aligns with section 5(a) of E.O. 14187, we are also proposing this change based on current evidence, which does not conclusively support the use of sex-rejecting procedures to treat gender dysphoria in children. It is important to emphasize that these proposed regulatory changes would not prohibit the use of Federal Medicaid or CHIP dollars for mental health treatments for conditions such as gender dysphoria. Nor would these proposed changes prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP. We note that this proposed rule also does not prohibit Federal reimbursement of procedures undertaken (i) to treat a child with a medically verifiable disorder of sexual development; (ii) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (iii) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

B. Prohibition on Medicaid Payment for Sex-Rejecting Procedures (§ 441.800)

We propose to add a new subpart N to 42 CFR part 441 to protect Medicaid beneficiaries and ensure Medicaid payments are consistent with quality of care by prohibiting Federal Medicaid payments to States for sex-rejecting procedures provided to children under the age of 18. The basis and purpose of proposed subpart N (as described previously in this proposed rule) is reflected in proposed § 441.800.

Within new subpart N, we propose at § 441.802(a) that State Medicaid plans must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18. Per 42 CFR 430.10, the State plan is the vehicle through which States assure that their Medicaid programs will be administered in conformity with title XIX of the Act (including sections 1902(a)(19) and 1902(a)(30)(A) of the Act) and CMS' implementing regulations, and the State plan must also contain all information necessary for CMS to determine whether the plan can serve as a basis for FFP. Proposed § 441.802(a) would not preclude States from covering sex-rejecting procedures with State-only funding outside of their Federally-matched Medicaid programs. We propose at § 441.802(b) that FFP would not be available in State expenditures for sex-rejecting procedures for children under the age of 18.

Proposed § 441.801 would define sex-rejecting procedures as any pharmaceutical or surgical intervention that attempts to align a child's physical appearance or body with an asserted identity that differs from the child's sex either by: (1) intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or (2) intentionally altering a child's physical appearance or body, including amputating, minimizing, or destroying primary or secondary sex-based traits such as the sexual and reproductive organs. However, our proposed definition also provides that the term sex-rejecting procedures would not include procedures undertaken: (i) to treat a child with a medically verifiable disorder of sexual development; (ii) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (iii) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

Given States' obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to assure care and services are provided consistent with the best interests of Medicaid recipients and that payments are consistent with quality of care, respectively, we believe that our proposed prohibition of FFP in State expenditures for sex-rejecting procedures for children under age 18 is necessary given the lack of an adequate evidence base for the effectiveness of these treatments for the purposes that would be included in our proposed definition and the significant potential for negative and irreversible side effects.

We note that CMS has imposed age limitations on the availability of Federal funding for certain procedures in the Medicaid program before. CMS has long prohibited, at § 441.253, Federal funding for permanent sterilizations furnished to individuals under age 21, motivated by concerns about potential coercion, informed consent, and patient regret that were based on data specifically related to permanent sterilizations (see preamble discussion at 43 FR 52146, 52151 through 52153). In this context, our concerns about the effectiveness of sex-rejecting procedures and the plausible evidence of harm motivate our proposal to prohibit Federal funding for sex-rejecting procedures for children under the age of 18. Specifically, this proposed rule recognizes that the more cautious approach of psychosocial support to treat individuals diagnosed with gender dysphoria prior to age 18—the legal age of majority in nearly all U.S. States and Territories [99] [100]—better protects children and youth from adverse effects of any such procedures.

Three states have a different, higher age of majority. Alabama and Nebraska's age of majority is 19 and Mississippi has the highest age of majority at 21.[101] This rule would not conflict with the age of majority in Alabama, Nebraska and Mississippi because these States recognize higher ages of majority than this proposed rule. Under this proposed rule, sex-rejecting procedures would be available for Medicaid coverage at age 18, which is a lower age than the age of majority in these States. Additionally, nothing in this proposed rule preempts State authority to regulate the age of majority in their State, nor does it interfere with a State's ability to fund these services with State-only funds. Further, it is clear that in making policy choices for the administration of a Federal program, State law is not controlling. This proposed rule would make age 18 the floor of Federal coverage for sex-rejecting procedures under the Medicaid program, should a State include such procedures in their program.

We originally considered establishing the prohibition on Federal reimbursement of sex-rejecting procedures to individuals under age 19 as we are now proposing for CHIP.

[99] CMS is aware that 3 States—Alabama, Nebraska, and Mississippi—recognize higher ages as the age of majority. See ''Age of Majority by State 2025,'' World Population Review, accessed August 11, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.* CMS is proposing to prohibit FFP in State expenditures within the Medicaid program for sex-rejecting procedures for children under the age of 18 to correspond to the legal age of majority used by the overwhelming majority of States and Territories. Because section 2110(c)(1) of the Act defines ''child'' for purposes of CHIP as an individual under age 19, CMS is proposing to prohibit FFP in State expenditures within CHIP for sex-rejecting procedures for children under age 19.

[100] ''Age of Majority by State 2025,'' World Population Review, accessed September 9, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.*

[101] ''Age of Majority by State 2025,'' World Population Review, accessed September 9, 2025, *https://worldpopulationreview.com/state-rankings/age-of-majority-by-state.*

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However, age 19 has no specific meaning for the Medicaid program and, as stated, is a year older than the legal age of majority in nearly all U.S. States and Territories. By comparison, this is not true under CHIP, as the statutory definition of a child in CHIP under section 2110(c)(1) of the Act is an individual under 19 years of age. In addition to other issues, we solicit comment on the operational feasibility of States in implementing the under age 18 prohibition in Medicaid and the under age 19 prohibition in CHIP.

As discussed previously, States have obligations under sections 1902(a)(19) and 1902(a)(30)(A) of the Act to ensure that Medicaid-covered care and services are provided in a manner consistent with the best interests of beneficiaries and to assure that payments for Medicaid-covered care and services are consistent with quality of care. For the reasons discussed in this proposed rule, CMS believes prohibiting Federal Medicaid funding for sex-rejecting procedures for children under the age of 18 is warranted to help ensure that States meet these statutory obligations.

We believe that the proposed definition of sex-rejecting procedures provides an appropriate degree of clarity and certainty regarding which sex-rejecting procedures would and would not be subject to the prohibitions at proposed § 441.802. We believe the proposed definition is narrowly tailored and appropriate to exclude only treatments CMS has determined to lack sufficient evidence of safety for their intended purposes. Examples such as procedures to treat precocious puberty, therapy subsequent to a traumatic injury, or the use of hormone replacement therapy to treat a growth hormone deficiency would not fall under the proposed definition of sex-rejecting procedures, and Federal Medicaid payment for such procedures would therefore not be prohibited for individuals under the age of 18, when medically necessary. As the HHS Review explains, central precocious puberty and gender dysphoria are distinct clinical entities. In addition, because the proposed definition is narrowly tailored in this way, we believe that States will be able to administer Medicaid coverage for drugs in a manner that is consistent with both the proposed rule and the requirements in section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, if manufacturers enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act, payment is available for the CODs covered under that NDRA for medically accepted indications.[102] As defined in section 1927(k)(6) of the Act, ''medically accepted indications'' mean use for a COD approved under the Federal Food, Drug, and Cosmetic Act or approved for inclusion in any of the compendia described in subsection 1927(g)(1)(B)(i) of the Act. 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. In addition, we note that this proposed rule only applies to pharmaceuticals that are used in the proposed definition and would not apply to other pharmaceuticals that are prescribed to a child.

As noted previously, the proposed definition of sex-rejecting procedures categorically would exclude procedures undertaken (1) to treat a child with a medically verifiable disorder of sexual development; (2) for purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or (3) to treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s). We reiterate that these proposed regulatory changes would not prohibit the use of Federal Medicaid dollars for mental health treatments for conditions such as gender dysphoria.

In addition, to further explain the meaning of terms used in the proposed sex-rejecting procedures definition, we also propose definitions at new § 441.801 that would apply to subpart N of part 441. We propose to define FFP for purposes of subpart N of part 441 as Federal financial participation, recognizing the longstanding term used in the Medicaid program to describe the Federal Government's matching arrangement with States and Territories. We also propose to define ''female'' as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We propose to define ''male'' as a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. We propose to define ''sex'' as a person's immutable biological classification as either male or female.

A landmark study of and model for anisogamy established that differences in gamete size, and the associated differences in gamete production time, lead to stable sexual dimorphism and the establishment of two biological sexes: ovum producers (females) and sperm producers (males).[103] Additionally, more recent literature acknowledges differences in sex roles but maintains that such differences can still be traced to the concept of anisogamy and the resultant sexual dimorphism that remain the root cause of sex specific selection, the sex roles, and the determination of biological sex.[104] We believe our proposed definitions of female, male, and sex are appropriately rooted in this concept and biological reality. In addition to other issues, we solicit comments on whether these proposed definitions of ''sex'', ''male'', and ''female'' could pose challenges to States in operationalizing this proposed prohibition on Federal reimbursement of sex-rejecting procedures or other aspects of the Medicaid program or CHIP.

Given the weak evidence base underlying sex-rejecting procedures for children and the potential risk of harm, including long-term harm, we believe this proposed rule appropriately implements the directives to States under sections 1902(a)(19) and 1902(a)(30)(A) of the Act that care and treatment provided under Medicaid must be in the best interests of recipients, and that payment for services must be consistent with quality of care.

C. Prohibition on CHIP Payment for Sex-Rejecting Procedures

We propose to revise subpart D in 42 CFR part 457 to prohibit Federal CHIP payments to States for sex-rejecting procedures provided to children. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with section 2101(a) of the Act by prohibiting Federal financial participation in payments by

[102] The NDRA does not have a specific OMB number, however the OMB package that contains all of the information a manufacturer has to report once entering into an NDRA is included in CMS 367a–367e.

[103] G.A. Parker et al., ''The origin and evolution of gamete dimorphism and the male-female phenomenon,'' *Journal of Theoretical Biology* 36, no. 3 (1972): 529–553, *https://doi.org/10.1016/0022-5193(72)90007-0.*

[104] Lukas Schärer et al., ''Anisogamy, chance and the evolution of sex roles,'' *Trends in Ecology & Evolution* 27, no. 5 (2012): 260–264, *https://doi.org/10.1016/j.tree.2011.12.006.*

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States for sex-rejecting procedures for a child under the age of 19. This would create consistency between CHIP coverage and Medicaid.

The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. The definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

We believe that our proposed prohibition of Federal CHIP payment for sex-rejecting procedures is necessary given the need to align CHIP coverage with coverage of these services in Medicaid, the lack of scientific evidence regarding the effectiveness of these treatments, and the significant potential for negative and often irreversible side effects when used for the purposes included in our proposed definition in children.

For each of these provisions outlined previously in this proposed rule, we anticipate stopping the Federal reimbursement of sex-rejecting procedures immediately upon the effective date of the rule finalizing these provisions, for both Medicaid and CHIP.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule (CMS–2451–F, RIN 0938–AV73), if this proposed rule is finalized.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Statistics for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialist	13–1000	43.76	43.76	87.52
General and Operations Manager	11–1021	64.00	64.00	128.00

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Definitions (§ 441.801)

We anticipate that the proposed definitions (adding and defining ''female'', ''male'', ''sex'', and ''sex-rejecting procedure'') may result in the need for some States to amend existing policy/manual documents where those items are inconsistent with the parameters of this proposed rule. However, we do not anticipate that this would impact any active claims/billing forms or their instructions.

We estimate a potential of 56 Medicaid respondents and 56 CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. Based on research discussed in section I.1.C. (United States' State Bans of and Coverage of Sex-Rejecting Procedures) of this proposed rule, approximately 27 States and one Territory have laws enacted restricting some or all of the *sex*-rejecting *procedures* that would be covered by this proposed rule. For these States and Territories, we do not anticipate State staff will need to conduct a review of policy documents for Medicaid or CHIP as these procedures are currently banned (or will be banned).

For the remainder of States and Territories, we assume that State staff will conduct a review for both Medicaid policy documents and CHIP policy documents. As a result, we estimate 28 States and Territories that would need to amend their existing policy documents consistent with these definitions. We estimate it will take 3 hours at $87.52/hr for a Business Operations Specialist to review existing State policy documents to ensure consistency with the proposed definitions and 1 hour at $128.00/hr for a General and Operations Manager to review and approve the necessary State policy document changes.

In aggregate we estimate a one-time State burden of 112 hours (28 States × 4 hr/response) at a cost of $10,936 [(3 hr × $87.52/hr × 28 States) + (1 hr × $128.00/hr × 28 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of $5,468 ($10,936 * 0.5). We assumed all services meeting the proposed definition would no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

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2. ICRs Regarding the Prohibition on Payment for Sex-Rejecting Procedures (§ 441.802)

If this proposed rule is finalized, the following changes and associated SPA template will be made available for public review/comment under control number CMS–10398 #97, OMB 0938–1148) via the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, the following scores the potential impact for preparing and submitting the SPA. We will revisit these preliminary estimates during the standard PRA process and revise if needed.

Under the proposed provision, States and Territories would be required to submit SPAs specifically indicating adherence to the prohibition on claiming Federal funding of sex-rejecting procedures for individuals under the age of 18 for Medicaid and for individuals under the age of 19 for CHIP. The content of the SPA would be a simple recitation of the prohibition. As indicated above, the template will be made available for public review and comment if this proposed rule is finalized. We intend to require all States and Territories to submit this template for approval as part of their State plan.

We estimate a potential of 56 Medicaid and CHIP respondents consisting of 50 States, the District of Colombia, American Samoa, Commonwealth of the Mariana Islands, Guam, Puerto Rico, and the US Virgin Islands. We estimate it will take 2 hours at $87.52/hr for a Business Operations Specialist to prepare an initial SPA and 1 hour at $128.00/hr for a General and Operations Manager to review and approve the SPA for submission to CMS.

In aggregate, we estimate a one-time State burden of 168 hours (56 States × 3 hr/response) at a cost of $16,970 [(2 hr × $87.52/hr × 56 States) + (1 hr × $128.00/hr × 56 States)]. When taking into account the Federal administrative match of 50 percent, we estimate a one-time State cost of $8,485 ($16,970 * 0.5). We assumed all services meeting the proposed definition would no longer be covered by Medicaid nor CHIP, and thus not eligible for Federal matching funds.

C. Summary of Proposed Requirements and Burden Estimates

TABLE 2—PROPOSED REQUIREMENTS/BURDEN ESTIMATES

Regulation section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Respondents	Responses (per State)	Total responses	Time per response (hr)	Total time (hr)	Labor costs ($/hr)	Total cost ($)	State cost ($)
§ 441.801	N/A	28 States and Territories	1	28	4	112	Varies	10,936	5,468
§ 441.802	CMS–10398 #97, OMB 0938–1148.	56 States and Territories	1	56	3	168	Varies	16,970	8,485
Total		56	2	84	Varies	280	Varies	27,906	13,953

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the proposed rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the proposed rule (CMS–2451–P, RIN 0938–AV73), the ICR's CFR citation, and the OMB control number.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Statement of Need

Throughout the U.S., thousands of children are receiving sex-rejecting procedures for the purpose of attempting to align their bodies with an asserted identity that differs from their sex. As outlined in this proposed rule, however, the current medical evidence does not support conclusively these interventions and indicates that they might lack clear benefits while posing a health and safety risk to children. To help ensure that Medicaid services are provided in a manner consistent with the best interests of the recipients and that Medicaid payments are consistent with quality of care, we are proposing a prohibition on State Medicaid Agencies from providing payment under the plan for sex-rejecting procedures for children under the age of 18 and proposing a prohibition on State CHIPs from providing payment under the plan for sex-rejecting procedures for children under the age of 19.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan

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programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Impacts on Federal Expenditures and Other Transfers

We estimate that this proposal would reduce Federal Medicaid spending by about $188 million from fiscal year 2027 through fiscal year 2036 (in real 2027 dollars). To estimate the impact of this proposal, we analyzed data from T–MSIS TAF v8.0 for 2023. We selected all claims with a gender dysphoria diagnosis and in the following claims categories: inpatient hospital with surgical procedure; outpatient hospital with surgical procedure; and professional services and prescription drugs with hormone therapy. We included fee-for-service and managed care encounter data. We also analyzed this data by beneficiary age group and counted only spending for individuals ages 17 and younger. We note that the proposed policy would not prohibit payment by a State Medicaid agency for these services for those age 18, and those individuals and costs are not included as part of the estimates. This data also includes CHIP expenditures for these services.

For 2023, we identified about $31 million in total computable Medicaid and CHIP spending for these services and individuals. States that had not banned gender dysphoria treatments for children as of 2023 accounted for 76 percent of spending, including 92 percent of inpatient treatment with surgery and 87 percent of outpatient treatment with surgery.

TABLE 3—MEDICAID EXPENDITURES ON GENDER DYSPHORIA TREATMENT BY CATEGORY OF SERVICE AND AGE GROUP, 2023

	Age 6–12	Age 13–14	Age 15–18	Total
Inpatient hospital with surgery	$0	$0	$180,553	$180,553
Outpatient hospital with surgery	15,526	23,534	2,145,082	2,184,142
Professional services hormone therapy	482,924	1,180,610	3,089,948	4,753,482
Prescription drug hormone therapy	2,566,749	6,130,955	14,779,884	23,477,588
Total	3,065,198	7,335,099	20,195,468	30,595,765

Source: Analysis of T–MSIS TAF v8.0.
Note: The T–MSIS data includes enrollment and spending by age groups, which includes ages 15–18 as one group. The policy in this proposed rule would only affect Medicaid enrollees under age 18 (ages 15–17), but the table above includes spending for individuals age 18. We note that we have adjusted for this when developing the estimates in the RIA.

We projected this spending forward from 2023 through 2035 using projected growth in Medicaid and CHIP spending on children from the Mid-Session Review of the President's fiscal year 2026 Budget. We assumed all services would no longer be covered by Medicaid or CHIP, and thus not eligible for Federal matching funds. We solicit comment on whether states that currently cover services would continue to cover these services absent FFP as described in this proposed rulemaking.

States that currently cover these services under Medicaid would see the largest reductions in Medicaid spending. We also assumed about 3 percent of spending would be delayed until individuals reach age 18, reflecting 50 percent of the surgical procedures being paid by Medicaid and CHIP in the future. Absent data or analysis on the impact of prohibitions on these procedures, we assumed some individuals would ultimately receive these services once eligible and believe 50 percent is reasonable (considering that some individuals would no longer be eligible for Medicaid in the future and some individuals may find other sources of coverage).

Table 4 shows the annual impact of the proposal on total and Federal Medicaid and CHIP spending in millions of dollars. These estimates assume the policies in the proposed rule would be effective as of October 1, 2026. Total Medicaid and CHIP spending would be reduced by $318 million over 10 years, Federal spending would be reduced by $188 million, and State spending would be reduced by $130 million (in real 2027 dollars). Actual impacts may vary from these estimates. We have relied on the most recently available program data for this analysis and projections of future enrollment and spending. Actual future costs may vary if enrollment and spending are higher or lower than projected.

TABLE 4—PROJECTED IMPACTS OF PROHIBITING COVERAGE OF SEX-REJECTING PROCEDURES FOR INDIVIDUALS UNDER 18 ON MEDICAID SPENDING

[In millions of real 2027 dollars]

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027–2036
Total	−30	−30	−30	−31	−32	−32	−32	−33	−34	−34	−318
Federal	−18	−18	−18	−18	−19	−19	−19	−19	−20	−20	−188
State	−12	−12	−12	−13	−13	−13	−13	−14	−14	−14	−130

We have made reasonable assumptions about how individuals may use these services in the future. A greater or lesser number of individuals may still receive coverage for these services upon reaching age 18 than we have assumed. In addition, it is possible some individuals may find alternative coverage for these services (for example,

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States covering services without Federal funding, or private insurance). We have also not estimated if there would be any other impacts on Federal expenditures (for example, increases in other healthcare services related to gender dysphoria).

2. Costs

In addition, the proposed rule may result in several costs. States would need to update State plans or waivers to comply with the proposed changes to covered benefits. Those impacts are described in section III. of this proposed rule. In addition, the changes in this proposed rule may prevent or delay individuals from receiving these healthcare services.

3. Alternatives

As an alternative to this proposed rule, we considered taking no action to require that a State Medicaid or CHIP plan must provide that the Medicaid or CHIP agency will not make payment under the plan for sex-rejecting procedures for children in Medicaid under the age of 18 and children in CHIP under the age of 19 and to prohibit the use of Federal Medicaid or CHIP dollars to fund sex-rejecting procedures for these individuals. On January 28, 2025, President Trump issued E.O. 14187, Protecting Children from Chemical and Surgical Mutilation. Section 5(a) of that order directs the Secretary to take all appropriate actions consistent with applicable law to end what the order refers to as the chemical and surgical mutilation of children including regulatory and sub-regulatory actions for specific programs, including Medicaid. In alignment with the Executive Order and the evidence outlined in section I.B. of this proposed rule, CMS decided to pursue this proposed policy. These proposed changes would not prevent States from providing coverage for sex-rejecting procedures with State-only funds outside of the Federally-matched Medicaid program or CHIP.

D. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant economic impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all hospitals and other healthcare providers are small entities as that term is used in the RFA (including small businesses, small nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other healthcare providers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, approximately 96 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards. According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards,* the health care industries impacted fall in the North American Industrial Classification System (NAICS) 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; and 622110 General Medical and Surgical Hospitals. Table 5 shows the industry size standards for each of these health care industries.

TABLE 5—HEALTH CARE INDUSTRY SIZE STANDARDS

NAICS (6-digit)	Industry subsector description	SBA size standard/ small entity threshold (million)	Total small businesses
446110	Pharmacies and Drug Stores	$37.5	18,461
621111	Offices of Physicians (except Mental Health Specialists)	16.0	129,117
621112	Offices of Physicians, Mental Health Specialists	13.5	12,325
621493	Freestanding Ambulatory Surgical and Emergency Centers	19.0	5,569
621498	All Other Outpatient Care Centers	25.5	9,801
622110	General Medical and Surgical Hospitals	47.0	1,169

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html*.

Tables 6 through 11 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These tables aim to provide an understanding of the disproportionate impacts among firms, between small and large firms.

TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES

[$37.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	18,461	100	$3,930,615.08
<$100K	560	3	50,953.57
$100K–$499K	1,733	9	292,525.68
$500–$999K	1,764	10	753,448.41
$1M–$2.499M	4,810	26	1,760,637.01
$2.5M–$4.999M	5,159	28	3,606,681.53
$5M–$7.499M	2,137	12	6,079,067.38
$7.5M–$9.999M	869	5	8,624,350.98
$10M–$14.999M	762	4	11,934,971.13
$15M–$19.999M	318	2	16,805,396.23
$20M–$24.999M	146	1	21,375,342.47
$25M–$29.999M	98	1	26,077,561.22
$30M–$34.999M	64	0	27,529,546.88
$35M–$39.999M	41	0	30,746,414.63

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TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES—Continued

[$37.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
LARGE FIRMS			
Receipts>$40M	396	N/A	672,827,431.82

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 7—NAICS 621111 OFFICES OF PHYSICIANS (EXCEPT MENTAL HEALTH SPECIALISTS)

[$16.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	129,117	100	$1,463,302.41
<$100K	11,119	9	51,195.79
$100K–$499K	44,138	34	296,376.77
$500–$999K	30,224	23	712,231.21
$1M–$2.499M	24,522	19	1,559,970.11
$2.5M–$4.999M	10,388	8	3,475,423.18
$5M–$7.499M	3,799	3	6,048,868.65
$7.5M–$9.999M	1,945	2	8,498,150.64
$10M–$14.999M	2,003	2	11,844,361.46
$15M–19.999M	979	1	16,517,796.73
LARGE FIRMS			
Receipts >$20M	3,782	N/A	116,848,659.18

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 8—NAICS 621112 OFFICES OF PHYSICIANS, MENTAL HEALTH SPECIALISTS

[$13.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	12,325	100	$634,311.40
<$100K	2,125	17	52,448.00
$100K–$499K	6,341	51	261,018.29
$500–$999K	2,092	17	686,686.90
$1M–$2.499M	1,206	10	1,496,716.42
$2.5M–$4.999M	338	3	3,331,017.75
$5M–$7.499M	111	1	5,735,522.52
$7.5M–$9.999M	52	0	8,039,461.54
$10M–$14.999M	60	0	10,485,850.00
LARGE FIRMS			
Receipts >$15M	212	N/A	14,421,103.77

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 9—NAICS 621493 FREESTANDING AMBULATORY SURGICAL AND EMERGENCY CENTERS

[$19.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	5,569	100	$2,713,466.15
<$100K	353	6	48,246.46
$100K–$499K	1,249	22	287,140.11
$500–$999K	867	16	724,727.80
$1M–$2.499M	1,265	23	1,648,132.81
$2.5M–$4.999M	845	15	3,602,647.34
$5M–$7.499M	413	7	5,999,140.44
$7.5M–$9.999M	223	4	8,392,170.40
$10M–$14.999M	241	4	11,472,634.85
$15M–19.999M	113	2	16,496,955.75
LARGE FIRMS			
Receipts >$20M	610	N/A	46,366,978.69

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

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TABLE 10—NAICS 621498 ALL OTHER OUTPATIENT CARE CENTERS

[$25.5 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	9,801	100	$2,124,005.00
<$100K	1,079	11	48,916.59
$100K–$499K	2,925	30	283,037.26
$500–$999K	1,832	19	719,524.02
$1M–$2.499M	1,990	20	1,545,938.69
$2.5M–$4.999M	790	8	3,409,083.54
$5M–$7.499M	289	3	5,739,238.75
$7.5M–$9.999M	193	2	7,644,943.01
$10M–$14.999M	292	3	10,567,616.44
$15M–$19.999M	184	2	13,609,652.17
$20M–$24.999M	137	1	16,169,890.51
$25M–$29.999M	90	1	21,218,188.89
LARGE FIRMS	.....	.....	.....
Receipts >$30M	1,008	N/A	55,938,203.37

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

TABLE 11—NAICS 622110 GENERAL MEDICAL AND SURGICAL HOSPITALS

[$47.0 Million size standard]

Firm size (by receipts)	Firm count	% of small firms	Avg. revenue
SMALL FIRMS	1,169	100	$17,598,603.93
<$100K	59	5	49,491.53
$100K–$499K	150	13	270,466.67
$500–$999K	54	5	696,814.81
$1M–$2.499M	28	2	1,522,000.00
$2.5M–$4.999M	28	2	3,739,428.57
$5M–$7.499M	35	3	6,512,657.14
$7.5M–$9.999M	51	4	8,550,588.24
$10M–$14.999M	124	11	11,777,798.39
$15M–$19.999M	132	11	16,993,166.67
$20M–$24.999M	121	10	22,389,727.27
$25M–$29.999M	100	9	26,686,900.00
$30M–$34.999M	99	8	31,329,858.59
$35M–$39.999M	66	6	35,617,636.36
$40M–44.999M	122	10	42,184,385.25
$45M–$49.999M	1,169	5	17,598,603.93
LARGE FIRMS	.....	.....	.....
Receipts >$50M	1,404	N/A	884,790,689.46

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html.*

Individuals and States are not included in the definition of a small entity.

As shown in Table 12, all the industries combined, according to the 2022 Economic Census, earned approximately $2,364,153,884,000, while the small firms for all the industries combined earned approximately $325,819,624,000. Table 13 in section V.E. estimates a $31.6 million reduction in total annualized monetized transfers from the Federal Government and States to health care providers. This total estimated reduction represents less than 1 percent of the total revenues of the health care industries impacted and the total revenues of the small firms in the health care industries impacted. It also represents less than 1 percent of the total revenues of each health care industry impacted and the total revenues of the small firms in each health care industry impacted. As a result, this proposed rule if finalized would result in a change in revenue of less than 1 percent for the impacted health care industries.

TABLE 12—TOTAL REVENUES, ALL FIRMS AND SMALL FIRMS, BY NAICS CLASSIFICATION

NAICS	Total revenues (all firms)	Revenue test* (%)	Total revenues (small firms)	Revenue test* (%)
446110 Pharmacies and Drug Stores	$339,002,748,000.00	0.01	$72,563,085,000.00	0.04
621111 Offices of Physicians (except Mental Health Specialists)	630,858,846,000.00	0.00	188,937,217,000.00	0.02
621112 Offices of Physicians, Mental Health Specialists	10,875,162,000.00	0.29	7,817,888,000.00	0.40
621493 Freestanding Ambulatory Surgical and Emergency Centers	43,395,150,000.00	0.07	15,111,293,000.00	0.21
621498 All Other Outpatient Care Centers	77,203,082,000.00	0.04	20,817,373,000.00	0.15

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TABLE 12—TOTAL REVENUES, ALL FIRMS AND SMALL FIRMS, BY NAICS CLASSIFICATION—Continued

NAICS	Total revenues (all firms)	Revenue test* (%)	Total revenues (small firms)	Revenue test* (%)
622110 General Medical and Surgical Hospitals	1,262,818,896,000.00	0.00	20,572,768,000.00	0.15
Total	2,364,153,884,000.00	0.00	325,819,624,000.00	0.01

Source: 2022 Statistics of U.S. Businesses, available at *https://www.census.gov/programs-surveys/susb.html*.
*Calculated using an estimated reduction in total annualized monetized transfers of $31.6 million (as shown in Table 13) as a percentage of total revenues.

As its measure of significant economic impact on a substantial number of small entities,

HHS uses a change in revenue of more than 3 to 5 percent. According to Table 12, we do not believe that the 3 to 5 percent threshold will be reached by the proposed requirements in this rule for NAICS 446110 Pharmacies and Drug Stores; 622111 Offices of Physicians (except Mental Health Specialists); 621112 Offices of Physicians, Mental Health Specialists; 621493 Freestanding Ambulatory Surgical and Emergency Centers; 621498 All Other Outpatient Care Centers; or 622110 General Medical and Surgical Hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities in these industries.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. The proposed rule would not mandate significant spending costs on State, local, or Tribal governments in the aggregate, or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. This proposed rule will have a substantial direct effect on the ability of States to receive Federal Medicaid funds for sex-rejecting procedures furnished to children under age 18 and on the ability of States to receive Federal CHIP funds for sex-rejecting procedures furnished to children under age 19.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 13 showing the classification of the impact associated with the provisions of this proposed rule.[105]

TABLE 13—ACCOUNTING STATEMENT

Transfers	Estimate (million)	Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($/year)	$18.7	2027	7	2027–2036
	18.7	2027	3	2027–2036
Quantitative: • Estimated reduction in transfers from Federal Government to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				
Annualized Monetized ($/year)	12.9	2026	7	2027–2036
	12.9	2026	3	2027–2036
Quantitative: • Estimated reduction in transfers from States to healthcare providers (including hospitals, physicians, and pharmacies) and to beneficiaries due to no longer covering sex-rejecting procedures for individuals under 18.				

Table 13 shows the annualized monetized transfer values required under OMB Circular A–4. At a discount rate of 7 percent, the annualized monetized transfers are $18.7 million to the Federal government and $12.9 million to the States, reflecting a reduction in payment for these services to healthcare providers. At a discount rate of 3 percent, the annualized monetized transfers are also $18.7 million to the Federal government and $12.9 million to the States.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid

[105] The effects attributable to this proposed rule might be lower in magnitude than the aggregates presented here if other actions, such as the HHS/CMS proposal titled ''Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures on Children,'' are finalized before finalization of this proposal.

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Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

Grant programs—health, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 1. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Part 441 is amended by adding subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.
441.800 Basis and purpose.
441.801 Definitions.
441.802 General rules.

§ 441.800 Basis and purpose.

Basis and purpose. The purpose of this section is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

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

(1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat a child with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or.

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) A State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 457.476 is added to subpart D to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) Basis and purpose. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23464 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Medicare and Medicaid certified hospitals must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of children and reflect HHS' review of recent information on the safety and efficacy of sex-rejecting procedures (SRPs) on children. The revisions to the requirements would prohibit hospitals from performing sex-rejecting procedures on children.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3481–P.

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Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

Grant programs—health, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

CHIP, Grant programs—health, Health professions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 1. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Part 441 is amended by adding subpart N to read as follows:

Subpart N—Prohibition on Federal Medicaid Funding for Sex-Rejecting Procedures Furnished to Children

Sec.
441.800 Basis and purpose.
441.801 Definitions.
441.802 General rules.

§ 441.800 Basis and purpose.

Basis and purpose. The purpose of this section is to implement sections 1902(a)(19) and 1902(a)(30)(A) of the Act to protect Medicaid beneficiaries and ensure Medicaid payment is consistent with quality of care by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 18.

(a) As relevant to this subpart, section 1902(a)(19) of the Act requires that States ensure that care and services will be provided in a manner consistent with the best interests of the recipients.

(b) As relevant to this subpart, section 1902(a)(30)(A) of the Act requires that States' payment methods be consistent with quality of care.

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

Female means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

Male means a person of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

Sex means a person's immutable biological classification as either male or female.

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

(1) Intentionally disrupting or suppressing the normal development of natural biological functions, including primary or secondary sex-based traits; or

(2) Intentionally altering a child's physical appearance or body, including amputating, minimizing or destroying primary or secondary sex-based traits such as the sexual and reproductive organs.

(3) For purposes of this definition, the term *sex-rejecting procedure* does not include procedures undertaken—

(i) To treat a child with a medically verifiable disorder of sexual development; or

(ii) For purposes other than attempting to align a child's physical appearance or body with an asserted identity that differs from the child's sex; or.

(iii) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of sex-rejecting procedure(s).

§ 441.802 General rules.

(a) A State plan must provide that the Medicaid agency will not make payment under the plan for sex-rejecting procedures for children under the age of 18.

(b) FFP is not available in State expenditures for sex-rejecting procedures for children under the age of 18.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 3. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 457.476 is added to subpart D to read as follows:

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

(a) Basis and purpose. The purpose of this section is to ensure that CHIP is operated in an effective and efficient manner that is coordinated with other sources of health benefits coverage, including Medicaid, for children consistent with 2101(a) by prohibiting Federal financial participation in payments by States for sex-rejecting procedures for a child under the age of 19.

(b) The prohibition on Federal financial participation for payments by States for sex-rejecting procedures for children applies in the same manner described in Medicaid at § 441.802 to a State administering a separate CHIP except that it applies to children under the age of 19 in accordance with the definition of a targeted low-income child at § 457.310. This prohibition applies to CHIP regardless of the type of health benefit coverage option described at § 457.410. For purposes of this section, the definitions applied under Medicaid at § 441.801 apply equally to a separate CHIP.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23464 Filed 12–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Medicare and Medicaid certified hospitals must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of children and reflect HHS' review of recent information on the safety and efficacy of sex-rejecting procedures (SRPs) on children. The revisions to the requirements would prohibit hospitals from performing sex-rejecting procedures on children.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2026.

ADDRESSES: In commenting, please refer to file code CMS–3481–P.

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Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3481–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3481–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: CMS Office of Communications, Department of Health and Human Services; email *press@cms.hhs.gov.*

For technical inquiries: CMS Center for Clinical Standards and Quality. Department of Health and Human Services. *HospitalSRPInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Background

On January 28, 2025, President Trump signed Executive Order (E.O.) 14187 ''Protecting Children from Chemical and Surgical Mutilation.'' [1] In particular, Section 5(a) of the order directs the Secretary of HHS consistent with applicable law to ''take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and subregulatory actions, which may involve [. . .]: Medicare or Medicaid conditions of participation or conditions for coverage.'' CMS has developed this proposed rule in compliance with this E.O. As further discussed in this proposed rule, we describe CMS' statutory authority related to patient health and safety standards (known as Medicare ''Conditions of Participation'' (CoPs), ''Conditions for Coverage'' (CfCs), or simply ''Requirements''), summarize data on the rise of sex-rejecting procedures (SRPs) on children, review the latest information on SRPs in children as described in the HHS Review (the Review), provide an overview of State laws, as well as prior CMS actions on this topic. We propose to add a new section to 42 CFR part 482, subpart C that would prohibit Medicare-participating hospitals from performing sex-rejecting procedures (SRPs) on any child (§ 482.46(a)).

A. Statutory Authority

CMS has broad statutory authority under the Social Security Act (the Act) to establish health and safety regulations, which includes the authority to establish requirements that protect the health and safety of children. Section 1861(e)(9) of the Act, applicable to hospitals that participate in the Medicare program, explicitly gives CMS the authority to enact regulations that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in a hospital, while section 1871 of the Act gives CMS the authority to prescribe regulations as necessary to carry out the administration of the program. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, entitled ''Conditions of Participation'' for Hospitals. Section 1905(a) of the statute provides that Medicaid payments from States may be applied to hospital services. Under regulations at §§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii), hospitals that provide inpatient and outpatient services, respectively, to Medicaid enrollees are required to meet the Medicare CoPs to also participate in Medicaid. In this way, the CoPs regulate the safety of all patients in a facility that is subject to 42 CFR part 482, regardless of payor (for example, Medicare, Medicaid, private insurance, and self-pay).

The CoPs for hospitals include specific, process-oriented requirements for certain hospital services or departments. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals.

B. Sex-Rejecting Procedures for Children With Gender Dysphoria

1. The Rise of Chemical and Surgical Interventions for Children as Part of Sex-Rejecting Procedures for Gender Dysphoria

Gender dysphoria is a condition defined by the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM–5–TR) as a ''marked incongruence between one's experienced/expressed gender and assigned gender'' that ''must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.'' [2] [3] Over the past decade, increasing numbers of children have been diagnosed with gender dysphoria and been treated with SRPs.[4] [5] SRPs can encompass a range of hormonal and surgical interventions: pharmacological interventions including puberty blocking medications to delay the onset of puberty, cross-sex hormone therapy to promote secondary sexual

[1] ''Protecting Children from Chemical and Surgical Mutilation.'' *The White House,* 28 Jan. 2025, *https://www.whitehouse.gov/presidential-actions/2025/01/protecting-children-from-chemical-and-surgical-mutilation/.*

[2] Coleman, E., et al. ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online,* doi:10.1080/26895269.2022.2100644.

[3] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders.* 5th ed. Edition, Text Revision, American Psychiatric Publishing,2022, *https://doi.org/10.1176/appi.books.9780890425787.*

[4] Coleman Eli, et. al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022 pp. S1–S259. *Taylor & Francis Online, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.*

[5] Hembree, Wylie C., et al., ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.'' *The Journal of Clinical Endocrinology & Metabolism,* vol. 102, no. 11 (13 September 2017, pp. 3869–3903, *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

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characteristics associated with the opposite biological sex, and surgical procedures (such as chest/breast and genital surgery).[6] [7]

The recorded prevalence of SRPs for children with gender dysphoria varies across sources. A study published in 2023 estimated that between 2016 and 2020, nearly 3,700 children aged 12 to 18 years old diagnosed with gender dysphoria underwent SRPs (2.50 per 100,000),[8] including an estimated 3,200 chest/breast procedures (2.17 per 100,000) [9] and 400 genital surgeries (0.27 per 100,000).[10] [11] Another study documented that almost 0.2 percent (or almost 2 in every 1,000) of 17-year-olds [12] with private insurance received SRP hormone treatment between 2018 through 2022.[13] [14]

While Medicare does not pay for a significant number of SRP procedures for children, we conclude that, based on the previously cited data, hospitals that participate in Medicare perform a considerable number of these procedures every year. We further note that the Medicare hospital CoPs apply to hospitals providing services to patients receiving Medicaid covered services ((§§ 440.10(a)(3)(iii) and 440.20(a)(3)(ii)). Approximately half of U.S. children receive health care through Medicaid.

2. Medical Evidence Regarding Sex-Rejecting Procedures in Children

The rising numbers of children seeking and receiving SRPs in recent years [15] has spurred ongoing debates regarding the safety and efficacy of these interventions.

a. The HHS Review

In compliance with Executive Order (E.O.) 14187, ''Protecting Children from Chemical and Surgical Mutilation'' [16] signed on January 28, 2025 (as discussed previously in this proposed rule), HHS released a preliminary comprehensive review of the evidence and best practices for treating pediatric gender dysphoria on May 1, 2025.[17] On November 19, 2025, HHS published a final version following the conclusion of a peer review process.[18] the Review provides an overview of systematic reviews—also known as an ''umbrella review''—to evaluate the evidence of the benefits and harms of SRPs in children. Several existing systematic reviews of evidence that have informed health authorities in Europe were assessed for methodological quality.

The Review itself does not provide clinical or policy recommendations. Instead, it analyzes evidence and best practices for children experiencing gender dysphoria. The Review also contains an ethics review that applies widely accepted principles of medical ethics to the practice of SRPs in children.[19] Accordingly, the Review states:

''As demonstrated throughout this Review, the presuppositions that guide [pediatric medical transition (PMT)] have not been shown to be valid; the nature, probability and magnitude of risks associated with PMT have not been distinguished with sufficient clarity; PMT proponents' estimates of the probability of harm and benefit have not been shown to be reasonable, as judged by known facts and available studies; and the risks of serious impairment that PMT involves have not been shown to be justified. For these reasons, administering PMT to adolescents, even in a research context, is in tension with well-established ethical norms for human subjects research.'' [20]

The Review (as further discussed in Section I.B.c. of this proposed rule) provides evidence of the clinical realities of SRPs in the United States, documenting the abandonment of medical guardrails. For example, the Review highlights how a protocol establishing SRPs in minors originated in the Netherlands and quickly spread to other Western countries without rigorous testing, and was codified in medical guidelines, which later did away with some of their already contested safeguards.[21] The Endocrine Society (ES) incorporated puberty blockers and hormones into their 2009 and 2017 clinical practice guidelines, recommending hormonal interventions for certain pediatric patients with gender dysphoria while also acknowledging the lack of reliable evidence for these treatments.[22] ES justified this recommendation in a ''values and preferences'' statement that places a higher priority on ''avoiding a[n] unsatisfactory physical outcome when secondary sex characteristics have

[6] Coleman, Eli, et al. ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[7] Hembree, Wylie C., et. al. ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline.'' *The Journal of Clinical Endocrinology & Metabolism.* vol. 102, no. 11, 1 November 2017, *https://academic.oup.com/jcem/article/102/11/3869/4157558.*

[8] CMS calculation: The annual number of overall SRPs (Breast/chest surgery, genital surgery, and other cosmetic procedures) on children aged 12 to 18 years is 740. The annual estimated number of children aged 12 to 18 according to U.S, Census Bureau data is 29,600,770. This results in annual estimate of 2.17 chest/breast procedures per 100,000 children aged 12 to 18 ((643/29,600,770) × 100,000 =2.50)). This calculation assumes 1 SRP per person.

[9] CMS calculation: The annual number of breast/chest surgeries on children aged 12 to 18 years is 643. The annual estimated number of children aged 12 to 18 according to U.S, Census Bureau data is 29,600,770. This results in annual estimate of 2.17 breast/chest surgeries per 100,000 children aged 12 to 18 ((643/29,600,770) × 100,000 =2.17)). This calculation assumes 1 breast/chest surgery per person.

[10] CMS calculation: The annual number of genital surgeries on children aged 12 to 18 years is 81. The annual estimated number of children aged 12 to 18 according to U.S. Census Bureau data is 29,600,770. This results in annual estimate of 0.27 genital procedures per 100,000 children aged 12 to 18 ((81/29,600,770) × 100,000 =0.27)). This calculation assumes 1 genital surgery is done per person.

[11] Wright J. D., et al. ''National estimates of gender-affirming surgery in the US.'' *JAMA Network Open,* vol. 6, no. 8, e2330348, 23 Aug. 2023, *http://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707.*

[12] CMS calculation: Per the article, the highest rate of hormone treatment occurs at age 17 with 140 AFAB adolescents (assigned female at birth) receiving testosterone (per 100,000 is 0.14% (140/100,000) ×100=0.14%)) and 82 AMAB adolescents (assigned male at birth) receiving estrogen (per 100,000 is 0.082% (82/100,000) ×100 =0.082%). This results in 222 (82+140= 222) per 100,000 or 0.222 (0.14% + 0.082% = 0.222). This calculation assumes 1 sex rejecting hormone treatment is done per person.

[13] Hughes Landon D., et al., ''Gender-affirming medications among transgender adolescents in the US.'' *JAMA Pediatrics,* 179,3 (2025): 342–344. doi:10.1001/jamapediatrics.2024.6081, *https://pubmed.ncbi.nlm.nih.gov/39761053.*

[14] CMS calculation: 140 + 82 = 222. This results in an estimate of 222 SRP hormone treatment per 100,000 children aged 17, between 2018 through 2022. This calculation assumes 1 SRP hormone treatment is done per person.

[15] Wright, Jason D., et al.. ''National Estimates of Gender-Affirming Surgery in the US.'' *JAMA Network Open,* vol. 6, no. 8, 23 Aug. 2023, doi:10.1001/jamanetworkopen.2023.30348, *http://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808707.*

[16] 90 FR 8771 (February 3, 2025).

[17] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office Of Population Affairs,* 1 May 2025. *https://opa.hhs.gov/gender-dysphoria-report.*

[18] U.S. Department of Health and Human Services (HHS), ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,*19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report.*

[19] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 218–246.

[20] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg., 246.

[21] Biggs, M. (2023b). The Dutch Protocol for juvenile transsexuals: Origins and evidence. *Journal of Sex & Marital Therapy, 49*(4), 348–368.

[22] Hembree, Wylie C., et al. ''Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline.'' *Journal of Clinical Endocrinology & Metabolism,* vol. 94, 9, 2009: 3132–52/doi:10.1210/jc.2009–0354.

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become manifest and irreversible'' than on ''avoiding potential harm from early pubertal suppression.'' [23]

The World Professional Association for Transgender Health (WPATH) endorsed a similar approach and most recently recommend these in their Standards of Care, Version 8 (SOC–8).[24] However, as carefully documented in the Review, the creation of SOC–8 marked ''a clear departure from the principles of unbiased, evidence-driven clinical guideline development.'' [25] The HHS Review cites court documents containing internal WPATH communications used when developing SOC–8 that show WPATH suppressed systematic reviews of evidence after learning that these reviews would not support its preferred medical approach. WPATH also failed to manage conflicts of interest and eliminated age minimums for hormones and most surgeries due to political pressures.[26] A recent systematic review of international guidelines did not recommend either the WPATH or ES guidelines for clinical use after determining they ''lack developmental rigour and transparency.'' [27]

b. International Reviews of SRPs in Children

The Review also describes practice reversals in several European countries (Norway, Finland, Sweden, Denmark, United Kingdom) following systematic reviews of evidence.

In 2020, Finland's Council for Choices in Health Care, a monitoring agency for the country's public health services, issued guidelines stating that ''gender reassignment of minors is an experimental practice.'' While not banning SRPs outright, the guidelines state ''based on studies examining gender identity in minors, hormonal interventions [puberty blockers, hormone therapy] may be considered before reaching adulthood in those with firmly established transgender identities, but it must be done with a great deal of caution, and no irreversible treatment should be initiated.'' [28] For children with gender dysphoria prior to and worsening at the onset of puberty, the report recommends that ''puberty suppression treatment [that is, puberty blockers] may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications.'' This is similar to past recommendations, and as before, these treatments would be limited to research settings for payment by the nation's health service. For children with gender dysphoria that have undergone puberty, the guidelines recommend that decisions regarding initiation of hormone treatment that alter sex characteristics be ''based on thorough, case-by-case consideration, [. . .] [and] only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria [. . .] and that no contraindications [that is, mental health conditions] are present.'' Previously, recommendations noted that hormone therapy should not begin before age 16 in this group and that patients under 18 may receive 3 to 6 months of puberty blockers prior to beginning hormone therapy. The current report mentions no age or month specific treatment guidelines. The report continues to recommend that all such interventions be done in a research setting. The report adds that ''[i]nformation about the potential harms of hormone therapies is accumulating slowly and is not systematically reported'' and calls for further rigorous research of the benefits and risks of these treatments. Consistent with past recommendations, the report adds that ''surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors.'' [29]

In 2022, Sweden's National Board of Health and Welfare (NBHW) reviewed and updated its guidelines for treatment of children with gender dysphoria.[30] [31] At the population level, NBHW issued ''weak, negative recommendation as guidance to the healthcare system'' that the risks of hormone treatment (which included gonadotropin releasing hormones (GnRH) also known as puberty blockers) and mastectomy likely outweigh the expected benefits for most adolescents. NBHW concludes that ''existing scientific evidence is insufficient for assessing the effects of puberty suppressing and gender-affirming hormone therapy on gender dysphoria, psychosocial health and quality of life of adolescents with gender dysphoria.'' While not banning access to SRPs, NBHW suggests restricting such treatments to exceptional circumstances or research settings, and adhering to the original ''Dutch protocol'' criteria including ''existence of the incongruence since childhood, the stability of gender identity over time, clear distress caused by the onset of puberty, and the absence of factors that complicate the diagnostic assessment.'' [32] The report did not discuss SRP surgeries aside from mastectomy.

In the United Kingdom, the National Health Service (NHS) commissioned a comprehensive review of the existing literature on SRPs and the prevailing service model. The 4-year independent evaluation of pediatric gender medicine (PGM), known as the ''Cass Review,'' was published by Dr. Hilary Cass in April 2024. The Cass review concluded that the evidence base for SRPs in children is ''remarkably weak'' and recommended restructuring of the service model towards prioritization of psychotherapy.[33]

In terms of research quality, the Cass Review notes that the number of studies on gender dysphoria treatment in children is very low, with small study sizes that have inconsistent metrics, low

[23] Hembree, Wylie C., et al. ''Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. Endocrine Practice,'' 23(12), 2017: 1437–1437.

[24] Coleman, Eli, et al. ''Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7.'' *International Journal of Transgenderism,* 13(4), 165–232.

[25] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,,* p. 181.

[26] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* p. 157–186.

[27] Taylor, Jo, et al. ''Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review.'' *Archives of Disease in Childhood,* vol. 109, Suppl. 2, s33-s47, 30 Oct. 2024, doi:10.1136/archdischild–2023–326669.

[28] Council for Choices in Health Care Finland. ''Finnish 2020 COHERE Guidelines for Minors Finland)'' certified translation. IFTCC Archives, 2020, *https://archive.iftcc.org/finnish-2020-cohere-guidelines-minors-finland-certified-translation.*

[29] Council for Choices in Health Care Finland. ''Finnish 2020 COHERE Guidelines for Minors Finland)'' certified translation. IFTCC Archives, 2020, *https://archive.iftcc.org/finnish-2020-cohere-guidelines-minors-finland-certified-translation.*

[30] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and adolescents with gender dysphoria: Summary of National Guidelines.'' Dec. 2022. *https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330.*

[31] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and young people with gender Dysphoria—National knowledge support with recommendations for the profession and decision makers.'' 16 Dec. 2022. *https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf.*

[32] The National Board of Health and Welfare (Socialstyrelsen). ''Care of children and adolescents with gender dysphoria-summary of national guidelines.'' Dec 2022, *https://www.socialstyrelsen.se/publikationer/care-of-children-and-adolescents-with-gender-dysphoria--summary-of-national-guidelines--december-2022-2023-1-8330/.*

[33] Cass, Hilary ''Cass Review Final Report.'' *The National Archives,* Apr. 2024, *https://cass.independent-review.uk/home/publications/final-report.*

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quality methods (uncontrolled observational studies), results of low certainty, and lack of longitudinal data (that is, do not follow youth into adulthood; average duration of hormone treatment is between 1 year and 5.8 years). The Cass Review notes that this weak evidence base makes conclusions regarding the benefits versus risk of gender dysphoria treatment in children extremely difficult to assess. The Cass Review also critiques WPATH guidelines, noting that WPATH's own systemic review acknowledges a high risk of bias in study designs, small sample sizes, and confounding variables.

Regarding guideline development, the Cass Review notes that most current guidelines have not followed the international standards for guideline development, including the WPATH guidelines. As such, the Cass Review only recommends two guidelines: the Finnish guideline (2020) and the Swedish guideline (2022) as discussed above. However, the Cass Review notes that even these guidelines lack clear recommendations regarding certain aspects of practice and ''would be of benefit if they provided more detailed guidance on how to implement recommendations.''

While not banning access to puberty blockers, Dr. Cass concluded in a July 2023 letter that ''because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, [puberty blockers] should only be offered under a research protocol [for treatment of pediatric gender dysphoria].'' NHS England and National Institute for Health and Care Research (NIHR) have enacted this recommendation as of December 2024. Exceptions are permitted for non-gender dysphoria-related medical conditions (*i.e.* precocious puberty) and for those patients already on treatment.[34] For hormone interventions, the Cass Review highlights a lack of high-quality research assessing the (long-term) outcomes of hormone interventions in children with gender dysphoria. Given this weak evidence base, Dr. Cass notes that ''no conclusions can be drawn about the effect [of hormone interventions] on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health.'' the Cass Review ultimately calls for caution, better research (prospective studies with long-term outcome data), honest communication with patients about the limitations of current knowledge, and development of evidence-based guidelines that acknowledge the limitations of current evidence. Of note, in the United Kingdom, children have never received gender dysphoria related surgery as paid by the NHS; Cass therefore did not systemically review evidence for gender dysphoria related surgeries in children.

Norway and Denmark are exploring or have enacted similar restrictions, though neither have issued direct bans of SRPs. In 2023, the Norwegian Commission for the Investigation of Health Care Services (Ukom), an independent State-owned agency, made recommendations on the treatment for youth with gender dysphoria.[35] The recommendations consisted of: defining SRPs (that is, puberty blockers, hormonal therapies, and surgical treatment) as ''experimental treatment,'' revising national guidelines based on a systematic knowledge summary, and consideration for a national registry to improve quality and reduce variation in patient treatment.While not banning access to SRPs, Norway's public health authorityhas signaled an intention torespond to UKOM's concerns with an adjustment to the current treatment guidelines.[36] While also not banning access to SRPs, Denmark has also taken a cautious approach to hormone interventions (that is, puberty blockers and cross-sex hormones) pending more evidence of its beneficial effects becoming available.[37] Notably, Denmark does not offer surgical treatment to children with gender dysphoria before age 18 as paid for by its national health service.[38] Other countries that have considered or restricted various gender dysphoria treatments for children include Italy,[39] Brazil,[40] New Zealand,[41] and Australia.[42]

c. Medical Professional Societies Supporting SRPs

We are aware that major medical organizations [43] (including the American Medical Association (AMA),[44] the American Academy of Pediatrics (AAP),[45] and the American Psychological Association [46] [47]) have issued statements supporting access to SRPs, including for children. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the U.S. are the WPATH and the ES clinical practice guidelines and the AAP guidance document.[48] We reviewed

[34] Department of Health and Social Care. ''Ban on puberty blockers to be made indefinite on experts' advice.''*GOV.UK,* 11 Dec. 2024. *https://www.gov.uk/government/news/ban-on-puberty-blockers-to-be-made-indefinite-on-experts-advice.*

[35] Norwegian Healthcare Investigation Board (Ukom). ''Pasientsikkerhet for barn og unge med kjønnsinkongruens [Patient safety for children and adolescents with gender incongruence].'' March 2023, *https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag.*

[36] Block, Jennifer. ''Norway's guidance on paediatric gender treatment is unsafe, says review,'' *BMJ (Clinical research ed.)* vol. 380 697, 23 Mar. 2023, doi:10.1136/bmj. p697.

[37] Hansen, Mette Vinther et al., ''Sundhedsfaglige tilbud til børn og unge med kønsubehag [Healthcare services for children and adolescents with gender dysphoria],'' *Ugeskrift for Laeger [The Journal of the Danish Medical Association]* 3 July 2023, *https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag.*

[38] Hansen, Mette Vinther et al., ''Sundhedsfaglige tilbud til børn og unge med kønsubehag [Healthcare services for children and adolescents with gender dysphoria],'' *Ugeskrift for Laeger [The Journal of the Danish Medical Association]* 3 July 2023, *https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag.*

[39] Armellini, Alvise. ''Italy moves to tighten controls on gender-affirming medical care for minors.'' *Reuters.* 5 Aug. 2025. *https://www.reuters.com/business/healthcare-pharmaceuticals/italy-moves-tighten-controls-gender-affirming-medical-care-minors-2025-08-05.*

[40] AFP. ''Brazil prohibits hormone therapy for transgender minors.'' *MSN News.* 17 Apr. 2025. *https://www.msn.com/en-in/news/other/brazil-prohibits-hormone-therapyfor-transgender-minors/ar-AA1D66l7.*

[41] Corlett, Eva. ''New Zealand Bans Puberty Blockers for Young Transgender People.'' *The Guardian,* Guardian News and Media, 19 Nov. 2025, *https://www.theguardian.com/world/2025/nov/19/new-zealand-bans-new-prescriptions-of-puberty-blockers-for-young-transgender-people.*

[42] Australian Associated Press. ''Queensland halts prescription of puberty blockers and hormones for children with gender dysphoria.'' *The Guardian,* 28 Jan. 2025. *https://www.theguardian.com/australia-news/2025/jan/28/queensland-halts-prescription-of-puberty-blockers-and-hormones-for-children-with-gender-dysphoria.*

[43] Advocates For Trans Equality. ''Medical Organization Statements.'' *A4TE's Trans Health Project, https://transhealthproject.org/resources/medical-organization-statements/.*

[44] ''Clarification of Evidence-Based Gender-Affirming Care H–185.927,'' *American Medical Association Policy Finder,* American Medical Association, 2024, *https://policysearch.ama-assn.org/policyfinder/detail/%22Clarification%20of%20Evidence-Based%20Gender-Affirming%20Care%22?uri=%2FAMADoc%2FHOD-185.927.xml.*

[45] Alyson Sulaski Wyckoff, ''AAP continues to support care of transgender youths as more states push restrictions,'' *AAP News,* 6 Jan. 2022, *https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender.*

[46] ''APA adopts groundbreaking policy supporting transgender, gender diverse, nonbinary individuals,'' *American Psychological Association,* released February 28, 2024, *https://www.apa.org/news/press/releases/2024/02/policy-supporting-transgender-nonbinary.*

[47] ''Criminalizing Gender Affirmative Care with Minors,'' *American Psychological Association,* accessed September 2, 2025, *https://www.apa.org/topics/lgbtq/gender-affirmative-care.*

[48] The American Academy of Pediatrics' (AAP) 2018 Policy Statement was reaffirmed in 2023 (Rafferty et al., 2018); the Endocrine Society's (ES) published in 2017 represents the most recent published version (Hembree et al., 2017); the World Professional Association for Transgender Health's (WPATH) most recent clinical practice guideline is

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each of these documents and agree with the HHS Review that discusses the conclusions of a recent systematic review of international guideline quality by researchers at the University of York (the York Appraisal) that found all three documents are very low quality and should not be implemented.[49]

As the HHS Review notes regarding the role of medical organizations in the treatment of pediatric gender medicine:

''U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition. This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.'' [50]

The Endocrine Society (ES) issued clinical practice guidelines in 2017 entitled ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.'' [51] As the HHS Review notes:

''In WPATH and ES guidelines, the principal goal of CSH administration is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations. Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.'' [52]

The HHS Review states:

''The ES 2017 guideline, which used the GRADE [Grading of Recommendations Assessment, Development and Evaluation] framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base. Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents. The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a ''satisfactory physical appearance'' while putting the lowest value on avoiding physical harms. The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower value on avoiding harm from potentially prolonged pubertal suppression.'' [53]

As explained in Chapter 9 of HHS Review, the guidelines issued by the World Professional Association for Transgender Health (WPATH) ''have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines.'' [54] As the HHS Review points out: ''Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH Standards of Care guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.'' [55] In 2022, WPATH issued guidelines entitled ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8'' (SOC–8).[56] These guidelines relaxed eligibility criteria for children to access sex-rejecting procedures and ultimately recommends that adolescents wishing to undergo sex-rejecting procedures receive them. Besides the problems identified in systematic reviews of international guidelines, as the HHS Review states, ''in the process of developing SOC–8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC–8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.'' [57] The HHS Review goes on to explain: ''The recommendations are couched in cautious-sounding language, stating that GD should be ''sustained over time,'' particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase ''several years'', leaving critical decisions open to broad and subjective interpretation.[58]

Regarding the WPATH guidelines, the HHS review states:

''On the surface, WPATH SOC–8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a ''comprehensive biopsychosocial assessment'' prior to initiating medical interventions in order ''to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care.'' [59]At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases (ICD–11) diagnosis of ''Gender Incongruence of Adolescence and Adulthood,'' which, unlike the DSM–5 diagnosis of ''Gender Dysphoria,'' requires only ''marked and persistent incongruence between an individual's experienced gender and the assigned sex.'' [60] Because SOC–8 defines transgender in a similar way (''people whose gender identities and/or gender expressions are not what is typically

Standards of Care, Version 8 (SOC–8) (Coleman et al., 2022).

[49] HHS Review pg. 141.

[50] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 15.

[51] Wylie C. Hembree et al. ''Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,'' *The Journal of Clinical Endocrinology & Metabolism* 102, no. 11 (2017): 3869–3903, *https://doi.org/10.1210/jc.2017-01658.*

[52] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 124.

[53] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 147.

[54] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 157.

[55] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* pg. 157.

[56] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[57] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 14.

[58] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 165.

[59] E. Coleman et al., ''Standards of Care for the Health of Transgender and Gender Diverse People, Version 8.'' *International Journal of Transgender Health,* vol. 23, suppl. 1, 2022, pp. S1–S259. *Taylor & Francis Online, https://doi.org/10.1080/26895269.2022.2100644.*

[60] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 194.

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expected for the sex to which they were assigned at birth'') and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC–8 effectively recognizes transgender identification as a medical condition justifying medical interventions.'' [61]

While AMA and the AAP have not issued their own treatment guidelines, they support the ES and WPATH guidelines, as discussed previously in this proposed rule. AAP issued a policy statement in 2018 supporting the use of puberty blockers, cross-sex hormones, and surgeries for minors.[62] In support of sex-rejecting surgeries, AAP stated that while ''current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.'' The AAP reaffirmed its policy statement in 2023 but also stated that it was conducting its own review of the evidence and guideline development—which still has not been released.[63]

Regarding the AAP policy statement, the HHS Review states:

''The AAP 2018 policy statement is not technically a CPG [clinical practice guideline] but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD [gender dysphoria].[64] Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs [puberty blockers], CSH [cross-sex hormones], and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7. As noted in Chapter 2, the AAP policy statement's use of ''gender diverse'' casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.'' [65]

We solicit comment of any published peer-reviewed findings that measure the effects of restrictions similar to those in this proposed rule on insurers, providers, and patients in international settings as well as the U.S.

3. U.S. Legal Landscape Regarding Sex-Rejecting Procedures

The United States has seen a high level of activity both at the State level and within the judicial system on this topic in recent years.

a. U.S. State Laws

Several States and territories have adopted laws reflecting their views of the evidence on SRPs for children with 28 restricting and 15 protecting this treatment. As of August 2025, 27 States and one territory have laws limiting or prohibiting some or all SRPs for children.[66] These include Alabama, Arkansas, Arizona, Florida, Georgia, Iowa, Idaho, Indiana, Kansas, Kentucky, Louisiana, Missouri, Mississippi, Montana, North Carolina, New Hampshire, North Dakota, Nebraska, Ohio, Oklahoma, Puerto Rico, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. Of these, 2 States' laws or policies (Montana and Arkansas) are pending resolution of ongoing legal challenges (as of August 2025).

States with such laws or policies apply them to varying age ranges. Twenty-five States prohibit certain SRPs in individuals under the age of 18. Two States (Nebraska and Alabama) prohibit them for those under the age of 19. Puerto Rico prohibits such procedures for those under the age of 21.

Which SRPs (that is puberty blockers, hormone therapy, and surgery) are banned for children varies by State. As of August 2025, 25 States have laws that prohibit access to puberty blockers, hormone therapies, and gender dysphoria related surgeries for children. Two States (New Hampshire and Arizona) have restrictions on surgery (but permit endocrine SRPs) for this population. No State bans only medications without also banning surgical procedures.[67]

All the States and the territory with restrictions provide exceptions to the law/policies. The most common exceptions include:

- Children born with medically verifiable disorder of sex development. This allows treatment for children who are born with medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other factors that can be medically verified.
- Children who have been diagnosed with a disorder of sexual development by a physician through genetic or biochemical testing.
- Treatment for any infection, injury, disease, or disorder that has been caused or exacerbated by the performance of SPRs.
- Children suffering from physical disorders, physical injuries, or physical illnesses that would otherwise place the children in danger of death or impairment of bodily function.

We note that 12 States provide tapering off periods for patients who started puberty blockers or hormones before enactment of the restriction, with some specifying specific dates (for example, in South Carolina services cannot go beyond January 31, 2025) and others specifying a period of time from the date of enactment (ranging between 6 months and 1 year). Ten States have grandfather clauses primarily allowing children who were already receiving treatment to continue receiving it indefinitely.

Conversely, 14 States and the District of Columbia have shield laws protecting SRPs, and three other States have E.O.s protecting these procedures.[68] These

[61] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 194–195.

[62] Rafferty, Jason, et al. ''Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents.'' *Pediatrics,* vol. 142, no. 4, 1 Oct. 2018, doi:10.1542/peds.2018–2162.

[63] Wyckoff, Alyson Sulaski. ''AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update.'' *AAP News,* August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy.*

[64] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 148.

[65] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 148, 149.

[66] Dawson, L., Kates, J. ''Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions.'' *KFF,* 21 Aug. 2025 [24 Nov. 2025], *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker.*

[67] American Psychological Association. ''Navigating the legal landscape: FAQs on gender affirming care for minors.'' *American Psychological Association,* 28 Jun. 2024, *https://www.apaservices.org/practice/legal/managed/legal-landscape-gender-care-minors.*

[68] ''Equality Maps: Transgender Healthcare 'Shield' Laws.'' *Movement Advancement Project,*

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States are (not including the District of Columbia): Arizona,[69] California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. Shield laws and State E.O.s often describe SRPs broadly, including medications and procedures, and include these under broader definitions of protected healthcare activities. These laws often protect providers from adverse action by medical malpractice insurers and licensure boards and allow for their address to remain confidential. One State (Maine) has a shield law that allows children 16 and over to receive hormone therapy when the guardian has refused SRPs. Four States explicitly provide child abuse and child custody protections for parents who supported their children in receiving specified procedures. Four State shield laws and E.O.s have requirements for SRPs to be covered under health plans. Arizona requires coverage for State employee health plans. Illinois, Oregon, and Vermont require some level of SRPs coverage by all health insurance providers. Vermont includes an exception for services that do not comply with Federal law.

b. United States Supreme Court

Recently, the Supreme Court in *United States* v. *Skrmetti*, 145 S. Ct. 1816 (2025) upheld Tennessee's law (referred to as Senate Bill 1; SB 1) banning certain surgical and chemical interventions for children with gender dysphoria, in litigation challenging that law under the Equal Protection Clause of the U.S. Constitution. SB1 prohibits a healthcare provider from performing medical procedures, including surgery, and prescribing puberty blockers, for a child for the purpose of enabling the child to identify with a purported identity inconsistent with the child's sex. At the same time, SB1 allows healthcare providers to perform medical procedures for children if the procedure is to treat a child's congenital defect, precocious puberty, disease, or physical injury. On June 18, 2025, the Court found that SB1's prohibition of certain medical procedures for children with gender dysphoria incorporates classifications based on age and medical use—not the child's sex. As a result of these classifications based on age and medical use, the Court held that SB1 was not subject to heightened scrutiny under the Equal Protection Clause of the Fourteenth Amendment and the law satisfied so called ''rational basis'' review.

4. CMS Actions

The proposed rule is animated by significant child safety concerns when SRPs are used for certain medical uses—that is to align a child's physical appearance or body with an asserted identity that differs from the child's biological sex. CMS published a formal guidance letter to State Medicaid Directors regarding SRPs on April 11, 2025, reminding States of their responsibility to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interest of recipients.[70] In addition, the Administrator of CMS sent a letter issued on May 28, 2025, to a number of hospitals addressing significant issues concerning quality standards and specific procedures affecting children. The letter requested that the recipient hospitals provide CMS with copies of certain hospital policies and procedures on the adequacy for informed consent protocols for children with gender dysphoria, including how hospitals determine that children are capable of making these potentially life changing decisions and when parental consent is required; describe any changes to clinical practice guidelines and protocols that the institution plans to enact in light of the recent comprehensive review and guidance released by the Department; provide CMS with medical evidence of any adverse events related to these procedures, particularly in children who later sought to detransition; and complete financial data for all pediatric SRPs performed at the institution and paid, in whole or in part, by the Federal Government.[71]

In addition, on May 28, 2025, Secretary Kennedy wrote to hospitals, health care providers, health care risk managers, and State medical boards across the nation, asking them to read the HHS Review, and to make necessary updates to their ''treatment protocols and training for care for children and adolescents with gender dysphoria to protect them from these harmful interventions.'' [72]

These letters reaffirmed CMS' and HHS' commitment to following the highest standards of care and to adhering closely to the foundational principles of medicine, especially relating to doing no harm to America's children and in alignment with CMS's obligations to ensure baseline quality standards at institutions participating in the Medicare and Medicaid programs.

II. Provisions of the Proposed Regulations

We have undertaken a review of the current hospital health and safety standards (known as the CoPs) as well as the latest information regarding SRPs in children to ensure hospitals are best protecting the health and safety of children. The evidence as presented in the Review (see section I.B.2. of this proposed rule) indicates that SRPs lack the necessary outcomes data on safety and long-term effectiveness. CMS takes very seriously the absence of rigorous scientific data demonstrating the safety and effectiveness of SRPs and the considerable evidence regarding the risks. Based on this, we believe that certain SRPs (namely pharmaceutical and surgical interventions) are not consistent with the health and safety of children, given the risk of significant (long term) harms, known complications, and weak and uncertain evidence of benefits.

We therefore propose to add a new section to 42 CFR part 482, subpart C that would prohibit Medicare and Medicaid-participating hospitals from performing sex-rejecting procedures (SRPs) on any child (§ 482.46(a)). As set out in proposed § 482.46(a)(5), we propose to define SRPs as any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with a stated identity that differs from the individual's sex by either (1) intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits or (2) intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.

n.d., accessed 11 August 2025, *https://www.lgbtmap.org/equality-maps/healthcare/trans_shield_laws.*

[69] Arizona banned SRPs for transgender minors in 2022, but in 2023 the governor issued an executive order with ''shield'' style protections for SRPs that are still legal in the State.

[70] Department of Health & Human Servies, Centers for Medicaid & CHIP Services. ''Puberty blockers, cross-sex hormones, and surgery related to gender dysphoria.'' Received by State Medicaid Director, 7500 Security Blvd. Mail Stop S2–26–12, 11 Apr. 2025, Baltimore, Maryland, *https://www.cms.gov/files/document/letter-stm.pdf.*

[71] Department of Health & Human Services, Centers for Medicare and Medicaid Services. ''Urgent Review of Quality Standards and Gender Transition Procedures.'' 28 May 2025, Washington, DC, *www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.*

[72] U.S. Department of Health & Human Services [@HHSGov]. *X* (formerly Twitter), 28 May 2025, *https://x.com/HHSGov/status/1927791449476567043.*

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We propose at § 482.46(a)(1) through (4) to include several additional definitions critical to interpreting the proposal. We propose that the term ''child'' be defined as any individual younger than 18 years of age. We further propose that the term ''female'' be defined as an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova). We propose that the term ''male'' be defined as an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm. Finally, we propose that the term ''sex'' is defined as an individual's immutable biological classification as either male or female.

At § 482.46(b), we are proposing exceptions to § 482.46(a) to protect the health and safety of children in certain rare and exceptional circumstances. Proposed exceptions include:

- *Procedures to treat an individual with a medically verifiable disorder of sexual development (§ 482.46(b)(1)).* This allows treatment for children who are born with certain medical conditions that affect their sexual development. These are rare conditions where a child's reproductive or sexual anatomy does not develop in typical ways due to genetic, hormonal, or other medical factors that can be medically verified and documented. Examples include a child with external biological sex characteristics that are irresolvably ambiguous, such as those born with 46 XX chromosomes with virilization, 46 XY chromosomes with under-virilization, or having both ovarian and testicular tissue.
- *Procedures for purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex (§ 482.46(b)(2)).* This permits procedures that are done for reasons entirely separate from changing a child's physical appearance to match a gender identity that differs from their biological sex, including procedures for children with a physical disorder, injury, or physical illness. In other words, the procedure must have a purpose separate from intending to change the body to not correspond to one's biological sex.
- *Treating Complications (§ 482.46(b)(3)).* This exception allows treatment for any infections, injuries, diseases, or other medical disorders that were caused by or made worse by previous SRPs. This exception allows physicians or other licensed practitioners to treat complications that arise from these procedures.

While we are proposing certain exceptions, any procedures or treatments under these exceptions must still be performed with the consent of the child's parent or legal guardian, as currently required under the patient rights CoP at § 482.13(b)(2), the medical records CoP at § 482.24 (c)(4)(v), the surgical services CoP at § 482.51(b)(2), and in compliance with applicable State law(s).

Practice of Medicine

Under Section 1801 of the Act, CMS may not ''exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, (42 U.S.C. 1395). However, we believe that providing the SRPs for children is not healthcare and hence are not subsumed under the term of ''the practice of medicine.'' Therefore, the proposed rule would not regulate the practice of medicine. As the Review notes regarding SRPs, when ''medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients.'' [73] As the Review states, ''in the domain of pediatrics, these norms limit the authority not only of patients (who in any case lack full decision-making capacity) but of parents as well.'' [74] The first obligation of the physician, under the Hippocratic Oath, originating in the fourth century BC, is to first do no harm, as the purpose of the practice of medicine is to heal. SRPs introduce a unique set of iatrogenic harms, especially, ''surgeries to remove healthy and functioning organs.'' [75] The Review states: ''to discharge their duties of nonmaleficence and beneficence, clinicians must ensure, insofar as reasonably possible, that any interventions they offer to patients have clinically favorable risk/benefit profiles relative to the set of available alternatives, which includes doing nothing.'' [76] As related previously in this proposed rule, the risk-benefit profile of these procedures for children is extremely poor. At the same time,'' the Review notes, ''there is increasing recognition of the risk and harms associated'' with pediatric sex-rejecting procedures, including ''possible outcomes, such as impaired cognitive function, greater susceptibility to hormone-sensitive cancers, cardiac disease, reduced bone density, sexual dysfunction, infection, and infertility [that] are objectively detrimental to health'' The Review concludes that''[s]uch medical harms, or plausible risks thereof, should not be imposed on children or adolescents in the absence of a reasonable expectation of proportionate medical benefit.'' [77]

There are other considerations for why the regulations proposed in this rule do not regulate the practice of medicine. A person's body (including its organs, organ systems, and processes natural to human development like puberty) are either healthy or unhealthy based on whether they are operating according to their biological functions. Organs or organ systems do not become unhealthy simply because the individual may experience psychological distress relating to his or her sexed body. For this reason, removing a patient's breasts as a treatment for breast cancer is fundamentally different from performing the same procedure solely to alleviate mental distress arising from gender dysphoria. The former procedure aims to restore bodily health and to remove cancerous tissue. In contrast, removing healthy breasts or interrupting normally occurring puberty to ''affirm'' one's ''gender identity'' involves the intentional destruction of healthy biological functions. This is not health care and hence imposing restrictions as this rule proposes does not limit the practice of medicine. The Review further notes there is lack of clarity about what SRPs' fundamental aims are, unlike the broad consensus about the purpose of medical treatments for conditions like appendicitis, diabetes, or severe depression.[78] Rather as discussed above, these procedures lack strong evidentiary foundations, and our

[73] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov, 2025. *https://opa.hhs.gov/gender-dysphoria-report* Pg. 15.

[74] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report* Pg. 225.

[75] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025. *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 128.

[76] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 226.

[77] U.S. Department of Health and Human Services (HHS) ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,* 19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report* Pg. 227–228.

[78] U.S. Department of Health and Human Services (HHS). ''Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices.'' *HHS Office of Population Affairs,*19 Nov. 2025, *https://opa.hhs.gov/gender-dysphoria-report,* Pg. 24–26.

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understanding of long-term health impacts is limited and needs to be better understood. Nothing in this proposed rule prohibits or permits the basic legality of SRPs. Rather, this proposed rule would ensure patient safety and medical integrity. CMS would no longer directly or indirectly support harm to children by allowing facilities that engage in such harmful practices to receive Medicare and Medicaid funds.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements (ICRs).

A. Hospital Notifications to Patients

Proposed § 482.46 would require that hospitals not perform sex-rejecting procedures (SRPs) on children, barring certain exceptions. We expect that hospitals that are currently performing these procedures on children would need to inform the child and their parents or legal guardian who are seeking such procedures that they no longer perform such procedures. Based on our experience, we expect that the child's physician or the licensed practitioner providing this care would spend an average of 30 minutes writing each notification. In addition, they would spend 30 minutes answering any questions from the child and their parents or legal guardian. This leads to a total burden of 1 hour per patient.

To calculate the total provider burden across all patients, we first examined State laws and found that 25 States have active laws restricting SRPs.[79] Given these State laws that already prohibit these procedures, we do not expect that physicians or licensed practitioners in these States would be writing a significant number of notifications. While acknowledging that some children living in these States may be traveling to States that permit SRPs for children, we do not expect that this is a large number of children for two reasons. First, across States with these restrictions, nearly 45 percent of children were enrolled in Medicaid or CHIP as of March 2025 and these programs would not fund SRPs outside the State.[80] Second, a recent study showed that across States with restrictions on SRPs, the average driving time to the nearest clinic in a State without restrictions was 5.3 hours, with the average time in Florida reaching 9 hours.[81] As such, we base our estimate on the number of children affected for children in States that currently do not have restrictions but seek comments on this assumption.

The second step was to identify the number of individuals under the age of 18 who live in States that allow SRPs. We combined information on State restrictions with Census Bureau population estimates[82] and found that there are approximately 8,674,717 females and 9,165,563 males between the ages of 10 and 17 living in States that do not have active laws restricting SRPs. While acknowledging that children younger than 10 may be receiving SRPs, we believe this is a reasonable estimate of the population affected by the proposed requirement.

The third step was to identify the number of individuals under 18 years of age who may be receiving SRPs. A recent study[83] found that among children between the ages of 8 and 17 covered by private insurance, males received puberty blockers and hormones at a rate of 15.22 per 100,000 and 25.34 per 100,000, respectively. Meanwhile, females received puberty blockers and hormones at a rate of 20.81 per 100,000 and 49.9 per 100,000, respectively. Applying these rates to the number of males and females in States without active laws restricting SRPs,[84] we estimate that there are approximately 6,651 individuals receiving hormones and 3,200 individuals receiving puberty blockers for a total of 9,851 individuals. As the authors note, these rates are more likely to be generalizable to patients with private insurance in large care plans and they expect lower rates for those utilizing Medicaid and in less comprehensive care plans. Another study[85] used national data to estimate the rate of sex rejecting surgical procedures and found that in 2019, there were approximately 85 sex-rejecting surgical procedures for children with a gender dysphoria diagnosis. The same as our estimates for the number of children receiving puberty blockers and hormones, this estimate is for insured patients and there may be lower rates for those utilizing Medicaid and in less comprehensive care plans. Given the overlap in treatment for some patients who may receive both surgical procedures and hormones, we estimate that a maximum of 9,851 individuals under the age of 18 are receiving SRPs.

While hospitals often prescribed puberty blockers and hormone replacement therapy as part of sex-rejecting procedures, primary care providers and endocrinologists outside of hospitals, who would not be affected by these requirements, can also prescribe these treatments. A recent analysis found that approximately 52 percent of primary care physicians were not affiliated with a hospital.[86] We do not know the share of children receiving puberty blockers or hormone replacement therapy outside the hospital setting and, therefore, would not need to receive notification that

[79] Dawson, L., Kates, J. ''KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming Care.'' *KFF,* 24 Nov. 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/.*

[80] Centers for Medicare & Medicaid Servies. ''State Medicaid and CHIP Applications, Eligibility Determinations, and Enrollment Data.'' *Data.Medicaid.gov, https://data.medicaid.gov/dataset/6165f45b-ca93-5bb5-9d06-0db29c692a360/data.* Accessed 6 Aug.2025.

[81] Borah, Luca et. al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA,* vol. 330,4 (2023): 375–378. doi: 10.1001/jama.2023.11299.

[82] U.S. Census Bureau, U.S. Department of Commerce. ''Age and Sex.'' American Community Survey, ACS 1-Year Estimates Subject Tables, Table S0101, *https://data.census.gov/table/ACSST1Y2023.S0101?q=population+by+age+by+state.* (Accessed 26 Jul. 2025).

[83] Hughes Landon D. et al. ''Gender-Affirming Medications Among Transgender Adolescents in the US, 2018–2022.'' *JAMA Pediatrics,* vol. 179, 3, (2025): p.342–344. doi:10.1001/jamapediatrics.2024.6081.

[84] Dawson, L., Kates, J. ''KFF Analysis of State Laws and Policies Restricting Minor Access to Gender Affirming *Care.*'' *KFF,* 24 Nov. 2025, *https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/.*

[85] Dai Dannie, et al. ''Prevalence of Gender-Affirming Surgical Procedures Among Minors and Adults in the US.'' *JAMA Network Open,* vol. 7, 6, 27 Jun. 2024, doi:10.1001/jamanetworkopen.2024.18814.

[86] Singh, Yashaswini et al. ''Growth of Private Equity and Hospital Consolidation in Primary Care and Price Implications.'' *JAMA Health Forum* vol. 6,1 e244935. 3 Jan. 2025, doi:10.1001/jamahealthforum.2024.4935.

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SRPs were no longer offered. Assuming that 25 percent of children are receiving care from primary care physicians or endocrinologists and that 52 percent of these providers are outside the hospital system, then 8,570 of the 9,851 children receiving treatment as identified above would need to receive notices and have discussions with their treating physician or licensed practitioner. We seek comments on data sources on the number of children receiving puberty blockers or hormone replacement therapy outside the hospital setting who would not be affected by the proposed requirement.

To estimate the total cost for this requirement, we assumed that a physician would write these notices. We calculated the physician's hourly rate by doubling the national mean salary for physicians (occupation code 29–1210) using the BLS' May 2024 National Occupational Employment and Wage Estimates for hospitals (NAICS code 622000),[87] leading to an hourly cost of $226.18 ($113.09 × 2). We doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. The HHS wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs. Utilizing these data, in Table 1, we estimate that this requirement would cost $1,938,363. We seek comments on the estimated time burden for physicians to provide written notices to their patients that the hospital is no longer providing SRPs.

TABLE 1—NOTIFICATION LETTERS TO PATIENTS

Employee type	Average hourly rate (a)	Hours per patient (b)	Number of patients (c)	Total cost (d = a × b × c)	Total hourly cost (e = b × c)
Physician	$226.18	1	8,570	$1,938,363	8,570

B. Updating Hospital Policies and Procedures

In addition to sending out notices to patients that they are no longer providing SRPs, hospitals will need to update their policies and procedures to ensure that they align with the proposed requirements.

To estimate the cost for hospitals to update their policies and procedures, we used data from the BLS' May 2024 National Occupational Employment and Wage Estimates for hospitals (NAICS code 622000),[88] and doubled the mean salary since the BLS data do not include overhead costs and fringe benefits. Based on our experience, we estimate that updating the hospital's policies and procedures related to SRPs for children would take 3 hours of work from a physician (occupation code 29–1210) at $678.54 ($226.18 × 3 hours) and a member of the clerical staff (occupation code 43–6010) at $143.40 ($47.80 × 3 hours), and 3 hours of work from a lawyer (occupation code 23–1010) at $650.16 ($216.72 × 3 hours) to review the updated policies and procedures to ensure that they meet the legal guidelines. This leads to a total per facility cost of $1472.10.

To estimate the number of hospitals that would need to update their policies and procedures, we first used the CMS' Q2 2025 Provider of Services File—Hospitals & Non-Hospital Facilities dataset and identified a total of 4,832 Medicare/Medicaid certified hospitals.[89] We expect that even in States that have active bans on SRPs, some hospitals would still need to update their policies and procedures since many of these States have exceptions that conflict with the requirements in this proposed rule. We recognize, however, that not all hospitals offer SRPs for children, and increasingly more hospitals nationwide are ending these services.[90] Given these uncertainties, we assume that 75 percent, or 3,624 hospitals would need to update their policies and procedures. Using this estimate, we expect that hospitals would spend $5,334,890 updating their policies and procedures. We seek comments on this estimate, specifically whether there are data sources to more accurately estimate the number of hospitals nationwide that currently offer SRPs for children.

TABLE 2—COST FOR UPDATING FACILITY POLICIES AND PROCEDURES

Per hospital cost (a)	Hospitals (b)	Per hospital hourly cost (c)	Total cost (a × b)	Total hourly cost (b × c)
$1,472.10	3,624	9	$5,334,890	32,616

The information collections will be sent to OMB for approval under the OMB Control number: 0938–NEW.

If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this proposed rule.

[87] U.S. Bureau of Labor Statistics. ''Occupational Employment and Wage Statistics (OEWS) Tables.'' *Occupational Employment and Wage Statistics,* BLS.gov, May 2024, *https://www.bls.gov/oes/tables.htm.* Accessed 23 Jul. 2025.

[88] U.S. Bureau of Labor Statistics. ''Occupational Employment and Wage Statistics (OEWS) Tables.'' *Occupational Employment and Wage Statistics,* BLS.gov, May 2024, *https://www.bls.gov/oes/tables.htm.* Accessed 23 Jul. 2025.

[89] Centers for Medicare and Medicaid Services. ''Provider of Services File—Hospital & Non-Hospital Facilities, Q2 2025.'' *Data.CMS.gov, https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data.* Accessed 13 Aug. 2025.

[90] Cowan, Jill Cowan. ''Hospitals Are Limiting Gender Treatment for Trans Minors, Even in Blue States.'' *The New York Times,* 22 Jul. 2025, *https://www.nytimes.com/2025/07/22/us/trump-transgender-healthcare-california-hospitals.html.* Accessed 6 Aug. 2025.

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IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

Throughout the United States, thousands of children are receiving sex-rejecting procedures (SRPs), specifically pharmacological and surgical interventions, for gender dysphoria. As outlined in section I. and II. of this proposed rule, however, recent HHS and international analyses question the efficacy and safety of SRPs in children. To protect children's health and safety, we are proposing to prohibit hospitals subject to part 482 from performing SRPs on any child with certain exceptions to best protect children's health and safety.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96 354); section 1102(b) of the statute; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities. The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f) of Executive Order 12866.

As noted above in Table 1 and Table 2, estimated costs of approximately $7.3 million are due to the time that a physician or licensed practitioner would spend providing patients with notification that the hospital no longer provides these procedures and for hospitals to update their policies and procedures related to SRPs for children. Below, we estimate additional impacts from the proposed requirement.

1. Costs and Transfers

We estimated the value of treatments in hospitals that would change in response to the proposed requirements using data from a study analyzing the per person cost of these treatments based on commercial claims data from 1993 to 2019.[91] This study estimated that for SRPs that included testosterone, estrogens and anti-androgens, and GnRH, there was an average combined cost to payors of $755 per person in 2019 dollars. Adjusting for inflation,[92] this leads to an average cost of approximately $909 per patient in 2024 dollars. For surgical procedures, there was an average per procedure cost of $28,367 in 2019 dollars. Adjusting for inflation, this leads to an average cost of approximately $34,165 in 2024 dollars. Utilizing our estimate in the collection of information section that 8,570 children would be affected by our rule and that there are 85 surgical SRPs on children annually, we estimate an annual value of $7,790,130 (8,570 patients × $909) for non-surgical SRPs and $2,904,025 (85 patients × $34,165) for surgical SRPs, for a total annual value of $10,694,155.

For children who are currently receiving SRPs at hospitals, there is likely to be bifurcation in their response to the proposed requirement. Some of these children may no longer receive SRPs at non-hospital providers that are not covered by the proposed requirement due to factors, such as difficulty in identifying in-network providers that have available space and longer commute times to these providers.[93] [94] The end of SRPs for these children would result in a reduced payments from payors, including insurance companies and private persons, to hospitals. Other children, however, are likely to switch to other provider types that are not affected by this proposed requirement. For these children, the proposed requirement would result in a change in transfers from Medicare-certified hospitals to other providers.

In the absence of data showing the likely share of patients in each category, we assumed that 50 percent of affected children would fall into each of the categories described above. Using this percentage, we estimate that the proposed requirements would result in $5,347,077 in reduced costs for payors and a $5,347,077 change in transfers from hospitals to other provider types annually. We seek comments on our assumption regarding the share of patients in each group.

For children who continue receiving SRPs, there are the costs associated with switching providers. Dahl and Forbes (2023) estimate that 46-percent of individuals are willing to pay over $600 per person (in 2011 dollars, or approximately $821 when updated for inflation) to avoid switching medical providers.[95] [96] The full willingness-to-pay (WTP) distribution is not reported, but for purposes of this regulatory

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[91] Baker, Kellan, and Arjee Restar. ''Utilization and Costs of Gender-Affirming Care in a Commercially Insured Transgender Population.'' *The Journal of Law, Medicine & Ethics,* vol. 50,3 (2022): 456–470. doi:10.1017/jme.2022.87

[92] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBIl1dfQ==*. Accessed 3 Dec. 2025.

[93] Borah, Luca et al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA* vol. 330,4 (2023): 375–378. doi:10.1001/jama.2023.11299.

[94] Gridley, Samantha J et al. ''Youth and Caregiver Perspectives on Barriers to Gender-Affirming Health Care for Transgender Youth.'' *The Journal of Adolescent Health,* vol. 59,3 (2016): 254–261. doi:10.1016/j.jadohealth.2016.03.017.

[95] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBIl1dfQ==*. Accessed 18 Aug. 2025.

[96] Dahl, Gordon B., and Forbes, Silke J. ''Doctor switching costs.'' *Journal of Public Economics* vol. 221, May (2023): pp. 104858.

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impact analysis, it is assumed that $821 is a reasonable estimate of an average that includes the 46-percent of WTP amounts above it and the 54-percent below. Applying this $821 amount to the above-estimated 8,570 affected patients (including 4,285 patients who would switch providers and 4,285 patients for whom the switching-cost estimate is a lower bound on the WTP to avoid the experience of being unable to switch [97] yields a cost estimate of $7,035,970 that declines over several years to an annual $3,517,985. Because the Dahl and Forbes estimate is derived from a choice between retaining or switching primary-care physicians—where finding substitute providers may be relatively easy as compared with finding, and maintaining patient-provider relationship with facilities offering the specialized treatment associated with adolescent gender dysphoria—this estimate may have a tendency toward understatement of the proposed rule's cost to patients for switching providers.

In Table 3, we estimate the costs and transfers associated with the proposed requirement over 10 years. Overall, we expect that this proposed rule would result in approximately $53.5 million in savings for payors due to some patients ending SRPs, with a cost of $44 million to patients who continue treatment at new providers for finding a new provider and for patients who would have paid to avoid the experience of being unable to switch providers. We also expect a change in transfers of $53.5 million from hospitals to other provider types as patients seek alternative sources of care. The effect attributable to this proposed rule might be lower in magnitude than the aggregate presented here if other actions, such as the HHS/CMS proposal titled ''Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children'' are finalized before finalization of *this* proposal.

TABLE 3—COSTS AND TRANSFERS FOR CHANGING PATIENT BEHAVIOR RELATED TO SEX-REJECTING PROCEDURES

Year	Costs		Transfers ($)
	Ending sex-rejection procedures ($)	Switching providers (probably tending toward cost under-estimation) ($)	
1	−5,347,077	7,035,970	5,347,077
2	−5,347,077	6,156,474	5,347,077
3	−5,347,077	5,276,978	5,347,077
4	−5,347,077	4,397,481	5,347,077
5	−5,347,077	3,517,985	5,347,077
6	−5,347,077	3,517,985	5,347,077
7	−5,347,077	3,517,985	5,347,077
8	−5,347,077	3,517,985	5,347,077
9	−5,347,077	3,517,985	5,347,077
10	−5,347,077	3,517,985	5,347,077
10 Year Total	−53,470,770	43,974,813	53,470,770

In developing our estimate, we acknowledge that this quantitative approach may fail to capture a societal cost pattern that may be somewhat concentrated in *upfront* transition activity—for example, the potential establishment of free-standing clinics to provide SRPs that would newly be prohibited at hospitals participating in Medicare.[98] There may also be costs for clinicians who provide SRPs for children at hospitals who would incur costs to move to other provider types where these procedures are allowed. We also acknowledge that some patients may choose new forms of treatment such as psychotherapy. Given these various uncertainties, we request comment on how to refine the estimation of regulatory costs.

2. Benefits

As we have noted throughout the proposed rule in Sections I and II, the proposed requirement is designed to ensure the health and safety of children by limiting SRPs given recent research that questions its efficacy and safety. Although we do not have quantitative financial data on the impact of the proposed rule's provision, we estimate the number of children who this proposed rule would positively affect using the same strategy used when estimating the rule's collection of information costs. Specifically, we expect that due to factors such as difficulty in identifying in-network providers that have available space and longer commute times to these providers [99] [100], half of the 8,570 (or 4,285) children who are receiving SRPs in hospitals would stop receiving these procedures leading to the avoidance of unnecessary health complications. As noted in the collection of information section, we assumed this percentage in the absence of quantitative data showing the number of children who will no longer seek SRPs. We seek comments on additional benefits that could emerge from these proposed requirements and sources of data to provide a quantitative estimate of the proposed rule's benefits. We also seek comments on sources of data to more accurately estimate the

[97] The latter portion of the estimate persists in any year when SRPs are estimated to occur at a reduced level due to the proposed rule. By contrast, the former effect is assumed to decline over the first several years of the analytic time horizon, as provider-switching patients age out of childhood.

[98] The cost of setting up separate specialty facilities (a process encompassing managerial, legal, and physical tasks) would exceed the cost of achieving only physical separation—estimated previously by the Department to be at least $20,000 to $40,000 per entity undertaking such actions. Please see *Compliance With Statutory Program Integrity Requirements,* 84 FR 7714, *https://www.federalregister.gov/d/2019-03461/* page-7782.

[99] Borah, Luca et al. ''State Restrictions and Geographic Access to Gender-Affirming Care for Transgender Youth.'' *JAMA* vol. 330,4 (2023): 375–378. doi:10.1001/jama.2023.11299.

[100] Gridley, Samantha J et al. ''Youth and Caregiver Perspectives on Barriers to Gender-Affirming Health Care for Transgender Youth.'' *The Journal of Adolescent Health,* vol. 59,3 (2016): 254–261. doi: 10.1016/j.jadohealth.2016.03.017.

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number of children who will stop receiving SRPs.

C. Alternatives Considered

As we detailed earlier in this proposed rule, the growth in SRPs in children is a growing concern given recent research that questions its efficacy and safety. We believe that the changes we are proposing are necessary to ensure the health and safety of children throughout the United States and align with the best available scientific evidence. We acknowledge, however, that there are different standards that we could have used in developing these proposed requirements.

In developing this proposed rule, we considered aligning our requirements with those States that already have restrictions on SRPs but with a variety of exceptions they provide as outlined in Section 1.B of this proposed rule. For example, we could have allowed those currently receiving these procedures to continue receiving them. Ultimately, however, we have decided to adopt the proposed provisions with fewer exceptions than are allowed in these States to maximize health and safety for all children. We seek comments, however, on whether we should adopt one or more of the additional State exceptions related to SRPs.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the proposed rule when finalized, we assume that all hospitals will review this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is also possible that other individuals and providers will review this proposed rule. For these reasons we thought that doubling the number of Medicare or Medicaid certified hospitals (n = 4,832) would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 75 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this proposed rule is $132.44 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately ([9,500 words/250 words per minute] × 75 percent) 28.5 minutes for the staff to review 75 percent of this proposed rule. For each entity that reviews the rule, the estimated cost is $62.91 (0.475 hours × $132.44). Therefore, we estimate that the total cost of reviewing this regulation is $607,962 ($[62.91] × [9,664]).

E. Accounting Statement

As required by OMB Circular A–4 (available online at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 4 showing classification of the costs and benefits associated with the provisions of this proposed rule. This includes the total costs for hospitals providing notices to children and their parents that they are no longer providing SRPs as identified in Table 1, the cost for hospitals to update their policies and procedures in Table 2, the reduction in costs due to the ending of SRPs for some patients as well as an increase in cost for patients who seek new providers in Table 3, as well as the regulatory review costs. There are also transfer costs for patients seeking care at other providers as outlined in Table 3. There are $0 benefit estimates in the statement. This statement provides our best estimate for the Medicare and Medicaid provisions of this proposed rule.

TABLE 4—ACCOUNTING STATEMENT

Category	Estimate	Units		
		Year dollar	Discount rate (%)	Period covered
Annualized Monetized Costs ($million/year)	0.32–0.04	2024	7 or 3	2026–2035
Annualized Monetized Transfers ($million/year)	5.3	2024	7 or 3	2026–2035

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals (NAICS 6221) are considered small businesses either by the Small Business Administration's size standards with total revenues of $47.0 million or less in any single year or by the hospital's not for profit status. According to the 2022 Economic Census,[101] general medical and surgical hospitals (NAICS 6221) have revenues of $1.27 trillion.

Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. With estimated annual costs and reduction in transfers resulting in the loss of approximately $11.4 million in annual revenues for hospitals, which is approximately 0.0008 percent of revenues, this proposed rule would not have a significant economic impact as measured on a substantial number of small businesses or other small entities as measured by a change in revenue of 3 to 5 percent. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the statute requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the statute, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. With total requirement costs and the loss of transfers reducing hospital revenues by approximately $11.4 million annually for all 4,832 hospitals, or $2,194 per hospital, we expect that

[101] U.S. Census Bureau. ''All Sectors: Summary Statistics for the U.S., States, and Selected Geographies: 2022.'' *Economic Census, United States Census Bureau,* 2022, *data.census.gov/table/EC2200BASIC?q=EC2200BASIC.* Accessed 15 Dec. 2025.

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this proposed rule would have a negligible impact on small rural hospitals. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This proposed rule does not mandate any spending requirements for State, local, or tribal governments, or for the private sector.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, pre-empts State law, or otherwise has federalism implications. This proposed rule would pre-empt State laws that prohibit SRPs for children that include exceptions for reasons beyond those exceptions provided in this proposed rule, including for children who are already undergoing these procedures. It would also pre-empt State laws requiring hospitals to provide SRPs.

Consistent with the Executive Order, we find that State and local laws that provide exceptions from the prohibition beyond those listed in this proposed rule, as well as State and local laws that require hospitals to provide SRPs for children, directly conflict with this exercise of CMS' statutory health and safety authority to prohibit providers subject to this proposed rule from providing these procedures.

Similarly, to the extent that State-run hospitals that receive Medicare and Medicaid funding are required by State or local law to provide SRPs for children except in those cases covered by our exceptions, there is direct conflict between the provisions of this proposed rule (prohibiting such procedures) and the State or local law (allowing them).

As is relevant here, this proposed rule preempts the applicability of any State or local law providing for SRPs to the extent such law provides broader grounds for these procedures than provided for by Federal law and are inconsistent with this proposed rule. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this proposed rule preempts State and local laws to the extent the State and local laws conflict with this proposed rule. The agency has considered other alternatives (for example, relying entirely on State laws prohibiting SRPs) and has concluded that the requirements established by this proposed rule are the minimum regulatory action necessary to achieve the objectives of the statute.

Given the growth in SRPs among children in recent years, we believe that the prohibition of these procedures for children is necessary to promote and protect patient health and safety. The agency has examined research on SRPs for children and concludes that it can cause permanent harm with uncertain benefits. We are inviting State and local comments on the substance as well as legal issues presented by this proposed rule, and its impact on them.

I. E.O. 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' We followed the implementation guidance from OMB–M–25–20 (*https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf*) when estimating the proposed rule's impact related to the executive order. Specifically, we used a 7 percent discount rate when estimating the cost for the purposes of Executive Order 14192. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 17, 2025.

List of Subjects in 42 CFR Part 482

Grant programs health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 2. Section 482.46 is added to subpart C to read as follows:

§ 482.46 Condition of participation: Sex-rejecting procedures.

The hospital must not perform sex-rejecting procedures on any child.

(a) *Definitions.* As used in this section:

(1) ''Child'' means any individual younger than 18 years of age.

(2) ''Female'' means an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing eggs (ova).

(3) ''Male'' means an individual of the sex characterized by a reproductive system with the biological function of (at maturity, absent disruption or congenital anomaly) producing sperm.

(4) ''Sex'' means an individual's immutable biological classification as either male or female.

(5) ''Sex-rejecting procedure'' means any pharmaceutical or surgical intervention that attempts to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex either by:

(i) Intentionally disrupting or suppressing the development of biological functions, including primary or secondary sex-based traits; or

(ii) Intentionally altering an individual's physical appearance or body, including removing, minimizing, or permanently impairing the function of primary or secondary sex-based traits such as the sexual and reproductive organs.

(b) Exceptions. The definition at paragraph (a)(5) of this section does not include procedures:

(1) To treat an individual with a medically verifiable disorder of sexual development;

(2) For purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex; or

(3) To treat complications, including any infection, injury, disease, or disorder that has been caused by or

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exacerbated by the performance of a sex-rejecting procedure.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23465 Filed 12–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 84

RIN 0945–AA27

Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department) issues this Notice of Proposed Rulemaking (NPRM) to revise 45 CFR 84.4(g) in the regulation implementing section 504 of the Rehabilitation Act of 1973 (section 504) as it applies to recipients of HHS funding (entitled ''Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance,'' 89 FR 40066 (''2024 Final Rule'')), published on May 9, 2024. This rule clarifies that the Department interprets the statutory exclusion of ''gender identity disorders not resulting from physical impairments'' from the definitions of ''individual with a disability'' and ''disability'' set forth at 29 U.S.C. 705(9) & (20)(F)(i), 42 U.S.C. 12211(b), to encompass ''gender dysphoria not resulting from a physical impairment'' for purposes of part 84. This clarification is necessary to resolve ambiguity introduced in the preamble to the 2024 Final Rule and to ensure compliance with the best reading of the plain language of the governing statute.

DATES: *Comments:* Submit comments on or before January 20, 2026.

ADDRESSES: You may submit comments to this proposed rule, identified by RIN Number 0945–AA27, by any of the following methods. Please do not submit duplicate comments.

Federal eRulemaking Portal: You may submit electronic comments at *https://regulations.gov* by searching for the Docket ID number XXXXX. Follow the instructions for submitting electronic comments. If you are submitting comments electronically, the department strongly encourages you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Adobe Portable Document Format (PDF), the Department strongly encourages you to convert the PDF to ''print-to-PDF'' format, or to use some other commonly used searchable text format. Please do not submit the PDF in scanned format. Using a print-to-PDF allows the Department to electronically search and copy certain portions of your submissions to assist in the rulemaking process.

Regular, Express, or Overnight Mail: You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Disability NPRM, RIN 0945–AA27, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington, DC 20201.

All comments received by the methods and due date specified above, or officially post marked by the due date above, will be posted without change to content to *https://www.regulations.gov,* including any personal information provided, and such posting may occur after the closing of the comment period.

However, the Department may redact certain non-substantive content from comments before posting, including threats, hate speech, profanity, graphic images, or individually identifiable information about an individual third-party other than the commenter. In addition, comments or material designated as confidential or not to be disclosed to the public will not be accepted. Comments may be redacted or rejected as described above without notice to the commenter, and the Department will not consider in rulemaking any redacted or rejected content that would not be made available to the public as part of the administrative record. Because of the large number of public comments normally received on **Federal Register** documents, the Office for Civil Rights is not able to provide individual acknowledgements of receipt.

Please allow sufficient time for mailed comments to be timely received in the event of delivery or security delays.

Please note that comments submitted by fax or email and those submitted or postmarked after the comment period will not be accepted.

Docket: For a plain language summary of the proposed rule and complete access to background documents or posted comments, go to *https://www.regulations.gov* and search for Docket ID number XXXXX.

FOR FURTHER INFORMATION CONTACT: John Thompson, Office for Civil Rights, Department of Health and Human Services at (202) 545–4884 or (800) 537–7697 (TDD), or via email at *504@hhs.gov.*

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Background

Statutory Framework

Section 504 of the Rehabilitation Act of 1973, codified at 29 U.S.C. 794, prohibits discrimination on the basis of disability in federally assisted and federally conducted programs and activities. Specifically, 29 U.S.C. 794(a) provides: ''No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency[.]'' The HHS Office for Civil Rights (OCR) enforces section 504 as well as other statutes that prohibit discrimination on the basis of disability. Although the Rehabilitation Act predates the Americans with Disabilities Act of 1990 (ADA), Congress subsequently amended the Rehabilitation Act, through the Rehabilitation Act Amendments of 1992 (Pub. L. 102–569, sec. 102, 106 Stat 4344), to align key definitions in the Rehabilitation Act with key definitions in the ADA. Under these amendments, the term ''individual with a disability'' ''does not include an individual on the basis of . . . transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender

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STATE OF ALABAMA
OFFICE OF THE ATTORNEY GENERAL

STEVE MARSHALL
ATTORNEY GENERAL

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February 17, 2026

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

Submitted electronically via http://www.regulations.gov

Re: Comments on proposed rulemakings: (1) "Medicare and Medicaid Programs: Hospital Condition of Participation: Prohibiting Sex Rejecting Procedures for Children" (Docket No. CMS-2025-1822-0001), and (2)"Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children" (Docket No. CMS-2025-1823-0001).

Dear Secretary Kennedy:

On behalf of the States of Alabama, XX, and XX, we write to comment on two proposed rules to restrict federal funding from subsidizing sex-change procedures for minors. Because those procedures have not been shown to be safe or effective for treating gender dysphoria in minors—and, in fact, have been shown to carry a great risk of harm—we agree that the federal government should stop paying for them. It should also stop subsidizing hospitals that provide the treatments. We support the proposed rules.

We write to provide additional information regarding the purported "standards of care" used by some providers to justify providing sex-change procedures to minors. As the proposed rules note, the organization that authors the primary treatment guideline is the World Professional Association for Transgender Health (WPATH). *See* 90 Fed. Reg. 59441, 59444-45. And as the proposed rules also note, those guidelines "are not trustworthy according to accepted standards for evaluating guideline quality," *id.* at 59445—or, frankly, any other standard.

Many of our States have learned this firsthand through litigating to defend our laws prohibiting the provision of sex-change procedures to minors. For instance, in 2022, shortly after the Alabama legislature passed a law prohibiting

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pediatric sex-change procedures, plaintiffs there sought a preliminary injunction based on the promise that WPATH used the "best available science" to develop its "standard of care." *See* Plaintiffs' PI Mem., *Boe v. Marshall*, No. 2:22-cv-184 (M.D. Ala. 2022), Doc. 8 at 12-13, 16. The district court believed them. While acknowledging that "[k]nown risks" of transitioning treatments "include loss of fertility and sexual function," the court preliminarily enjoined enforcement of Alabama's law because "WPATH recognizes transitioning medications as established medical treatments and publishes a set of guidelines for treating gender dysphoria in minors with these medications." *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1139, 1151 (M.D. Ala. 2022), *rev'd sub nom. Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), *reh'g en banc denied*, 114 F.4th 1241 (11th Cir. 2024).

Alabama then sought and obtained discovery from WPATH to test the court's deference.[1] Doing so unveiled a tragic medical scandal. Internal documents from WPATH showed that the organization crafted its latest Standards of Care—SOC-8, published in 2022—as "a tool for our attorneys to use in defending access to care."[2] Its evidence-review team "found little to no evidence about children and adolescents."[3] Some SOC-8 authors opted *out* of the evidence-review process entirely due to "concerns, echoed by the social justice lawyers we spoke with, … that evidence-based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits."[4] And Admiral Rachel Levine, the former Assistant Secretary for Health at HHS, demanded that WPATH remove from SOC-8 *all* age limits for chemical treatments, chest surgeries, and even surgeries to remove children's genitals. After some initial consternation "about allowing US politics to dictate international professional clinical guidelines,"[5] WPATH obliged. This evidence became public in 2024 and has been covered in—and substantiated by—deeply reported pieces in the *New York Times*, *The Economist*, *The Atlantic*, and elsewhere.[6]

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[1] *See* Order, *Boe*, 2:22-cv-184 (M.D. Ala. Mar. 27, 2023), Doc. 263.

[2] Defendants' Ex. 181 at 75, *Boe*, 2:22-cv-184 (M.D. Ala.), Doc. 700-10. Throughout this letter, the undersigned will reference evidence that Alabama submitted to the court in *Boe*. Citations will be by exhibit number followed by the docket entry in parenthesis and the internal page number following the colon. *E.g.*, Ex.181 (Doc.700-10):75. Exhibits are available online: https://www.alabamaag.gov/boe-v-marshall/.

[3] Ex.173(Doc.560-23):22.

[4] Ex.174(Doc.560-24):1-2.

[5] Ex.186 (Doc.700-15):32.

[6] *See, e.g.*, Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. TIMES (June 25, 2024), https://perma.cc/RP5L-QFD9; Nicholas Confessore, *How the Transgender Rights Movement Bet on the Supreme Court and Lost*, N.Y. TIMES (June 19, 2025), https://perma.cc/L5A6-ZVAW; *Research into Trans Medicine Has Been Manipulated*, THE ECONOMIST (June 27, 2024), https://perma.cc/A942-J2DY; Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://perma.cc/R4TZ-LS32; Leor Sapir, *"We're All Just Winging It": What The Gender*

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The Services should have this additional information as it considers finalizing the proposed rules.

* * *

WPATH published Standards of Care 8 (SOC-8) in September 2022.[7] Dr. Eli Coleman, a sexologist at the University of Minnesota, chaired the guideline committee, and WPATH hired an outside evidence-review team, led by Dr. Karen Robinson at Johns Hopkins University, to conduct systematic evidence reviews for authors to use in formulating their recommendations.[8] Two WPATH presidents, Dr. Walter Bouman, a clinician at the Nottingham Centre for Transgender Health in England, and Dr. Marci Bowers, a surgeon in California who has performed over 2,000 transitioning vaginoplasties, oversaw development and publication of the guideline.

A. WPATH Intentionally Used SOC-8 to Advance Political and Legal Goals.

WPATH selected 119 authors—all existing WPATH members—to contribute to SOC-8.[9] According to Dr. Bowers, it was "important" for each author "to be an advocate for [transitioning] treatments before the guidelines were created."[10] Many authors regularly served as expert witnesses to advocate for sex-change procedures in court; Dr. Coleman testified that he thought it was "ethically justifiable" for those authors to "advocate for language changes [in SOC-8] to strengthen [their] position in court."[11] Other contributors seemed to concur. One wrote: "My hope with these SoC is that they land in such a way as to have serious effect in the law and policy settings that have affected us so much recently; even if the wording isn't quite correct for people who have the background you and I have."[12] Another chimed in: "It is abundantly clear to me when I go to court on behalf of TGD [transgender and gender-diverse] individuals" that "[t]he wording of our section for Version 7 has been critical to our successes, and I hope the same will hold for Version 8."[13]

Perhaps for this reason—and because it knew that "we will have to argue it in court at some point"[14]—WPATH commissioned a legal review of SOC-8 and

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Doctors Say in Private, THE FREE PRESS (Dec. 3, 2025), https://www.thefp.com/p/were-all-just-winging-it-what-the; *see also* Steve Marshall, *WPATH, 'Transgender Healthcare,' and the Supreme Court*, WALL STREET J. (Dec. 2, 2024), https://perma.cc/S74A-AFAM.

[7] *See* Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH (2022), https://perma.cc/Y9G6-TP3M.

[8] *Id.* at S248-49.

[9] *Id.* at S248-49; *see* Ex.21(Doc.700-3):201:2–223:24.

[10] Ex.18(Doc.564-8):121:7-11.

[11] Ex.21(Doc.700-3):158:17-25.

[12] Ex.184(Doc.700-13):24.

[13] Ex.184(Doc.700-13):15.

[14] Ex.182(Doc.700-11):152.

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was in regular contact with movement attorneys.[15] Dr. Bouman noted the oddity: "The SOC8 are clinical guidelines, based on clinical consensus and the latest evidence based medicine; [I] don't recall the Endocrine Guidelines going through legal reviews before publication, or indeed the current SOC?"[16] The WPATH Executive Committee discussed various options for the review—"ideas; ACLU, TLDEF, Lambda Legal…"[17]—before apparently settling on the senior director of transgender and queer rights at GLAD (and counsel for plaintiffs in Alabama's case) to conduct the review.[18]

Authors were explicit in their desire to tailor SOC-8 to ensure coverage for an "individual's embodiment goals,"[19] whatever they might be. As Dr. Dan Karasic, one of the plaintiffs' experts in Alabama's case, explained to other contributors: "Medical necessity is at the center of dozens of lawsuits in the US right now";[20] "I cannot overstate the importance of SOC 8 getting this right at this important time."[21] Another author was more succinct: "[W]e need[] a tool for our attorneys to use in defending access to care."[22]

At Dr. Karasic's urging, WPATH included a whole section in SOC-8 on "medical necessity" and took to heart his advice to list the "treatments in an expansive way."[23] It assigned the designation to a whole host of interventions, including but "not limited to hysterectomy," with or without "bilateral salpingo-oophorectomy"; "bilateral mastectomy, chest reconstruction or feminizing mammoplasty"; "phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty"; "gender-affirming facial surgery and body contouring"; and "puberty blocking medication and gender-affirming hormones."[24]

One author aptly concluded of the statement: "I think it is clear as a bell that the SOC8 refers to the necessity of treatment (in its broadest sense) for their gender dysphoria (small 'd'); because it refers to the symptom of distress—which is a very very very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians are stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO)."[25]

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[15] Ex.4(Doc.557-4):vi.
[16] Ex.182(Doc.700-11):151.
[17] Ex.184(Doc.700-13):14.
[18] SOC-8, *supra* note 12, at S177.
[19] Ex.180(Doc.700-9):11.
[20] *Id.* at 64.
[21] Ex.181(Doc.700-10):43.
[22] *Id.* at 75.
[23] SOC-8, *supra* note 12, at S18.
[24] *Id.*
[25] Ex.181(Doc.700-10):36 (second closed parenthesis added).

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WPATH also made sure to sprinkle the "medically necessary" moniker throughout the guideline, even when doing so revealed it had put the cart before the horse. The adolescent chapter, for instance, notes that "[a] key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical and surgical treatments,"[26] but WPATH never paused to ask (or answer) how such treatments can be considered "medically necessary" if the "quality of evidence" supporting their use is so deficient. At least some authors tacitly acknowledged the question and made sure they wouldn't have to answer it—by following the advice of "social justice lawyers" to avoid conducting systematic evidence reviews lest they "reveal[] little or no evidence and put[] us in an untenable position in terms of affecting policy or winning lawsuits."[27] Others just sought to massage the guideline's language to avoid "empower[ing]" those concerned that the evidence did not support transitioning treatments,[28] all while authors and WPATH leaders raised such concerns internally.[29]

B. WPATH Changed Its Treatment Recommendations Based on Politics.

Outside political actors also influenced SOC-8. Most notably, Admiral Levine, the former Assistant Secretary for Health, met regularly with WPATH leaders, "eager to learn when SOC 8 might be published."[30] A few months before SOC-8 was to be published in September 2022 (and long after the public comment period had closed that January[31]), WPATH sent Levine an "Embargoed Copy – For Your Eyes Only" draft of SOC-8 that had been "completed" and sent to the publisher for proofreading and typesetting.[32] The draft included a departure from Standards of Care 7, which, except for so-called "top surgeries," restricted transitioning surgeries to patients who had reached the "[a]ge of majority in a given country."[33] The draft SOC-8 relaxed the age minimums: 14 for cross-sex hormones, 15 for "chest masculinization" (i.e., mastectomy), 16 for "breast augmentation, facial surgery (including rhinoplasty, tracheal shave, and genioplasty)," 17 for "metoidioplasty, orchiectomy, vaginoplasty, hysterectomy and fronto-orbital remodeling," and 18 for "phalloplasty."[34]

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[26] SOC-8, *supra* note 12, at S45-46.

[27] Ex.174(Doc.560-24):1-2.

[28] Ex.184(Doc.700-13):55.

[29] *E.g.*, Ex.176(Doc.700-5):67-68 (Dr. Bowers admitting that "no long-term studies" exist for puberty blockers); Ex.180(Doc.700-9):21 (author admitting that "most of the recommendation statements in SOC8 are not PICO format"—meaning were not supported by systematic evidence reviews—"but consensus based or based on weak evidence"); Ex.180(Doc.700-9):63 (WPATH leader: "My understanding is that a global consensus on 'puberty blockers' does not exist"); *see generally* Ex.4(Doc.557-4):i-iv.

[30] Ex.184(Doc.700-13):54.

[31] *See* Ex.187(Doc.700-16):4-5.

[32] Ex.170(Doc.700-4):61-64.

[33] E. Coleman, *Standards of Care, Version 7*, 13 INT'L J. TRANSGENDERISM 1, 25-27 (2012), https://perma.cc/T8J7-W3WC.

[34] Ex.170(Doc.700-4):143.

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After reviewing the draft, Levine's office contacted WPATH with a political concern: that the listing of "specific minimum ages for treatment," "under 18, will result in devastating legislation for trans care."[35] WPATH leaders met with Levine to discuss the age recommendations.[36] Levine's solution was simple: "She asked us to remove them."[37]

The authors of the adolescent chapter wrestled with how to respond to the request:

- "I really think the main argument for ages is access/insurance. So the irony is that the fear is that ages will spark political attacks on access. I don't know how I feel about allowing US politics to dictate international professional clinical guidelines that went through Delphi."[38]

- "I'm also curious how the group feels about us making changes based on current US politics.... I agree about listening to Levine."[39]

- "I think it's safe to say that we all agree and feel frustrated (at minimum) that these political issues are even a thing and are impacting our own discussions and strategies."[40]

WPATH initially told Levine that it "could not remove [the age minimums] from the document" because the recommendations had already been approved by SOC-8's "Delphi" consensus process.[41] (Indeed, Dr. Coleman said that consensus was "[t]he only evidence we had" for the recommendations.[42]) But, WPATH continued, "we heard your comments regarding the minimal age criteria" and, "[c]onsequently, we have made changes to the SOC8" by downgrading the age "recommendation" to a "suggestion."[43] Unsatisfied, Levine immediately requested—and received—more meetings with WPATH.[44]

Following Levine's intervention, and days before SOC-8 was to be published, pressure from the American Academy of Pediatrics (AAP) tipped the scales when it threatened to oppose SOC-8 if WPATH did not remove the age minimums.[45] WPATH leaders initially balked. One of the co-chairs of SOC-8 complained that "[t]he AAP guidelines ... have a very weak methodology, written

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[35] Ex.186 (Doc.700-15):28.
[36] *See* Ex.186 (Doc.700-15):11, 17; Ex.21(Doc.700-3):287:5–288:6.
[37] Ex.186 (Doc.700-15):11.
[38] *Id.* at 32.
[39] *Id.*
[40] *Id.* at 33.
[41] *Id.* at 17.
[42] *Id.* at 57.
[43] *Id.* at 17.
[44] *See* Ex.18(Doc.564-8):226:8–229:18; Ex.186 (Doc.700-15):73, 88-91.
[45] Ex.187(Doc.700-16):13-14, 109.

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by few friends who think the same."[46] But the political reality soon set in: AAP was "a MAJOR organization," and "it would be a major challenge for WPATH" if AAP opposed SOC-8.[47] WPATH thus "remove[d] the ages."[48]

That is concerning enough. But perhaps even more worrisome is what the episode reveals. *First*, it shows that politicians and AAP sought, and WPATH agreed, to make changes in a clinical guideline recommending irreversible sex-change procedures *for kids* based purely on political considerations. Dr. Coleman was clear in his deposition that WPATH removed the age minimums without allowing authors to vote on the change and "without being presented any new science of which the committee was previously unaware."[49]

Second, as soon as WPATH made the change, it treated the decision as "highly, highly confidential."[50] Dr. Bowers encouraged contributors to submit to "centralized authority" so there would not be "differences that can be exposed."[51] "[O]nce we get out in front of our message," Bowers urged, "we all need to support and reverberate that message so that the misinformation drone is drowned out."[52]

Having decided the strategy, Bowers then crafted the message, circulating internally the "gist of my[] response to Reuters" about the missing age minimums: "[S]ince the open comment period, a great deal of input has been received and continued to be received until the final release. [I] feel the final document puts the emphasis back on individualized patient care rather than some sort of minimal final hurdle that could encourage superficial evaluations and treatments."[53] Another leader responded: "I like this. Exactly—individualized care is the best care—that's a positive message and a strong rationale for the age change."[54] Apparently, it didn't matter that the explanation itself was "misinformation"; as Dr. Bowers explained in a similar exchange, "it is a balancing act between what i feel to be true and what we need to say."[55]

C. WPATH Failed to Properly Manage Conflicts of Interest.

At the back of SOC-8 is an appendix with the methodology WPATH said it employed.[56] Among other things, it boasts that WPATH managed conflicts of

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[46] *Id.* at 100.
[47] *Id.* at 191.
[48] *Id.* at 338.
[49] Ex.21(Doc.700-3):293:25–295:16.
[50] Ex.188(Doc.700-17):152.
[51] Ex.177(Doc.700-6):124.
[52] *Id.* at 119.
[53] Ex.188(Doc.700-17):113.
[54] *Id.*
[55] Ex.177(Doc.700-6):102.
[56] *See* SOC-8, *supra* note 12, at S247-51.

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interest and engaged an evidence-review team to conduct systematic literature reviews.[57] Discovery revealed a different story.

WPATH cites two standards it said it used to manage conflicts of interest: one from the National Academies of Medicine and the other from the World Health Organization.[58] Both standards generally recognize that the experts best equipped for creating practice guidelines are those at arm's length from the services at issue—sufficiently familiar with the topic, but *not* professionally engaged in performing, researching, or advocating for the practices under review.[59]

At the same time, the standards recognize that a guideline committee typically benefits from *some* involvement by clinicians who provide the services at issue.[60] Accordingly, they suggest ways for committees to benefit from conflicted clinicians while limiting their involvement. The standard from the National Academies recommends that "[m]embers with [conflicts of interest] should represent *not more than a minority* of the [guideline development group]."[61]

WPATH largely ignored these standards. From the get-go, it expressly limited SOC-8 authorship to existing WPATH members—clinicians and other professionals (and non) who were *already* enthusiastic about transitioning treatments.[62] As Dr. Bowers testified, it was "important for someone to be an advocate for [transitioning] treatments before the guidelines were created."[63]

Dr. Bowers's involvement in SOC-8 offers a good illustration of the lack of real conflict checks. According to the National Academies, a "conflict of interest" is "[a] divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing."[64] Bowers should have been subject to that standard, serving not only as a member of the Board that oversaw and approved SOC-8 but as an author of the chapter tasked with evaluating the evidence for transitioning surgeries.

So it is notable that Bowers made "more than a million dollars" in 2023 from providing transitioning surgeries, but said it would be "absurd" to consider

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[57] *Id.*

[58] *Id.* at S247.

[59] *Id.*; Institute of Medicine (National Academies of Medicine), *Clinical Practice Guidelines We Can Trust* 81-93 (2011), https://perma.cc/7SA9-DAUM; World Health Organization, *Handbook for Guideline Development* 19-23 (2012).

[60] Institute of Medicine, *supra* note 64, at 83.

[61] *Id.* (emphasis added).

[62] SOC-8, *supra* note 12, at S248; *see* Ex.21(Doc.700-3):201:2–223:24.

[63] Ex.18(Doc.564-8):121:7-11.

[64] Institute of Medicine, *supra* note 64, at 78.

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that a conflict worth disclosing or otherwise accounting for as part of SOC-8.[65] That was WPATH's public position as well: It assured readers that "[n]o conflicts of interest were deemed significant or consequential" in crafting SOC-8.[66]

Privately, WPATH leaders knew everything was not up to par. Dr. Coleman admitted that "most participants in the SOC-8 process had financial and/or nonfinancial conflicts of interest."[67] Another author agreed: "Everyone involved in the SOC process has a non-financial interest."[68] Dr. Robinson, the chair of the evidence-review team, said the same: She "expect[ed] many, if not most, SOC-8 members to have competing interests."[69] She even had to inform WPATH—belatedly—that "[d]isclosure, and any necessary management of potential conflicts, should take place *prior* to the selection of guideline members."[70] "Unfortunately," she lamented, "this was not done here."[71] No matter: SOC-8 proclaims the opposite ("Conflict of interests were reviewed as part of the selection process"[72]), and Dr. Coleman testified that he did not know of any author removed from SOC-8 due to a conflict.[73]

D. WPATH Was Not Transparent in How It Used GRADE.

WPATH boasted that it used a process "adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework" for "developing and presenting summaries of evidence" using a "systematic approach for making clinical practice recommendations."[74] According to WPATH, Dr. Robinson's evidence-review team was to conduct systematic evidence reviews, "assign[] evidence grades using the GRADE methodology," and "present[] evidence tables and other results of the systematic review" to SOC-8 authors.[75]

Chapter authors were then to grade the recommendation statements based on the evidence.[76] Per WPATH, "strong recommendations"—"we recommend"—were only for situations where "the evidence is high quality," "a high degree of certainty [that] effects will be achieved," "few downsides," and "a high degree of acceptance among providers."[77] On the other hand, "[w]eak recommendations"—"we suggest"—were for when "there are weaknesses in the evidence base," "a

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[65] Ex.18(Doc.564-8):37:1-13, 185:25–186:9.
[66] SOC-8, *supra* note 12, at S177.
[67] Ex.21(Doc.700-3):230:17-23.
[68] Ex.174(Doc.560-24):7.
[69] Ex.166(Doc.560-16):1.
[70] *Id.* (emphasis added).
[71] *Id.*
[72] SOC-8, *supra* note 12, at S177.
[73] Ex.21(Doc.700-3):232:13-15.
[74] SOC-8, *supra* note 12, at S250.
[75] *Id.* at S249-50.
[76] *Id.* at S250.
[77] *Id.*

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degree of doubt about the size of the effect that can be expected," and "varying degrees of acceptance among providers."[78] To "help readers distinguish between recommendations informed by systematic reviews and those not," recommendations were to "be followed by certainty of evidence for those informed by systematic literature reviews":

++++	strong certainty of evidence
+++	moderate certainty of evidence
++	low certainty of evidence
+	very low certainty of evidence[79]

The reality did not match the promise. To begin, as Dr. Coleman wrote, "we were not able to be as systematic as we could have been (e.g., we did not use GRADE explicitly)."[80] Dr. Karasic, the chair of the mental health chapter, testified that rather than relying on systematic reviews, some drafters simply "used authors … we were familiar with."[81]

WPATH also decided not to differentiate "between statements based on [literature reviews] and the rest,"[82] and ordered the removal of all notations disclosing the quality of evidence for each recommendation. A draft of the hormone chapter illustrates the change. The chapter had initially offered a "weak recommendation" ("we suggest") based on low-quality evidence ("++") that clinicians prescribe cross-sex hormones to gender dysphoric adolescents, "preferably with parental/guardian consent."[83]

At first, WPATH seemed to just remove the evidence notations. But then the recommendations themselves appeared to morph from weak ("we suggest") to strong ("we recommend"). So it was in the adolescent chapter, where all but one recommendation is now "strong"[84]—even as those recommendations are surrounded by admissions that "[a] key challenge in adolescent transgender care is the quality of evidence," with "the numbers of studies … still [so] low" that "a systematic review regarding outcomes of treatment in adolescents" is purportedly "not possible."[85] And so it was in the hormone chapter, where the final version of the above statement transformed into a strong "we recommend."[86]

While this mismatch may not seem like a big deal, the difference between a "strong" and "weak" recommendation is important, particularly when it comes to life-altering interventions like cross-sex hormones. Under GRADE, "low" or

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[78] *Id.*

[79] WPATH, *Methodology for the Development of SOC8*, https://perma.cc/QD95-754H.

[80] Ex.190(Doc.700-18):8; *see* Ex.182(Doc.700-11):157-58.

[81] Ex.39(Doc.592-39):66:2–67:5.

[82] Ex.182(Doc.700-11):62; *see* Ex.9(Doc.700-2):¶¶29-36, 43-47.

[83] Ex.182(Doc.700-11):5; *see id.* at 1-40; Ex.9(Doc.700-2):¶¶29-36, 43-47.

[84] SOC-8, *supra* note 12, at S48.

[85] *Id.* at S46-47.

[86] *Id.* at S111.

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"very-low" quality evidence means, respectively, that the true effect of the medical intervention may, or is likely to be, "substantially different" from the estimate of the effect based on the available evidence.[87] Thus, given that the estimated effect is therefore likely to be *wrong* for very low-quality evidence, it is imperative for clinicians to know the quality of evidence supporting a treatment recommendation—and why, with certain exceptions not applicable here, evidence-based medicine warns against "strong" recommendations based on low-quality evidence.[88] So it is a big deal indeed that WPATH promised clinicians that it followed this system when it actually eschewed transparency and made "strong" recommendations no matter what the evidence said.

E. WPATH Hindered Publication of Evidence Reviews.

Though the SOC-8 authors and their advocacy allies didn't seem to have much use for them, the Johns Hopkins evidence-review team "completed and submitted reports of reviews (dozens!) to WPATH" for SOC-8.[89] The results were concerning. In August 2020, the head of the team, Dr. Robinson, wrote to the Agency for Healthcare Research and Quality at HHS about their research into "multiple types of interventions (surgical, hormone, voice therapy…)."[90] She reported: "[W]e found little to no evidence about children and adolescents."[91]

Dr. Robinson also informed HHS that she was "having issues with this sponsor"—WPATH—"trying to restrict our ability to publish."[92] Days earlier, WPATH had rejected Robinson's request to publish two manuscripts because her team failed to comply with WPATH's policy for using SOC-8 data.[93] Among other things, that policy required the team to seek "final approval" of any article from an SOC-8 leader and then from the WPATH Board of Directors.[94] It also mandated that authors "use the Data for the benefit of advancing transgender health in a positive manner" (as defined by WPATH) and "involve[] at least one member of the transgender community in the design, drafting of the article, and the *final approval* of the article."[95] Once those boxes were checked, the WPATH Board of Directors had final authority on whether the manuscript could be published.[96]

This is an alarming amount of editorial control over publication of a systematic review, the entire purpose of which is to provide an objective and

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[87] Howard Balshem *et al.*, *GRADE Guidelines*, 64 J. CLINICAL EPIDEMIOL. 401, 404 (2011), https://perma.cc/2KDY-6BW5.

[88] Liang Yao *et al.*, *Discordant and Inappropriate Discordant Recommendations*, BMJ (2021), https://perma.cc/W7XN-ZELX.

[89] Ex.173 (Doc.560-23):22-25.

[90] *Id.* at 24.

[91] *Id.* at 22.

[92] *Id.*

[93] Ex.167(Doc.560-17):86-88.

[94] *Id.* at 37-38, 75-81.

[95] *Id.* at 37 (emphasis added).

[96] *Id.* at 38.

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neutral review of the evidence. But WPATH justified its oversight by reasoning that it was of "paramount" importance "that any publication based on WPATH SOC8 data [be] thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense" (as WPATH defined it).[97] But to make the process *appear* neutral, WPATH imposed one last requirement: Authors had to "acknowledge[]" in their manuscript that they were "solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[98]

WPATH eventually allowed the Johns Hopkins team to publish two of its manuscripts. (It's still unclear what happened to the others.[99]) The team dutifully reported that the "authors"—not WPATH—were "responsible for all content."[100]

F. WPATH Recommends Castration as "Medically Necessary" for "Eunuchs."

As if to drive home how unscientific the SOC-8 enterprise was, WPATH included an entire chapter on "eunuchs"—"individuals assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning."[101] Because eunuchs "wish for a body that is compatible with their eunuch identity," WPATH recommends "castration to better align their bodies with their gender identity."[102] That's not an exaggeration. When asked at his deposition whether "in the case of a physically healthy man with no recognized mental health conditions and who presents as a eunuch seeking castration, but no finding is made that he's actually at high risk of self-castration, nevertheless, WPATH's official position is that that castration may be a medically necessary procedure?", Dr. Coleman confirmed: "That's correct."[103]

Dr. Coleman also admitted that no diagnostic manual recognizes "eunuch" as a medical or psychiatric diagnosis.[104] And other SOC-8 authors criticized the chapter as "very high on speculation and assumptions, whilst a robust evidence base is largely absent."[105] Dr. Bowers even admitted that not every board member read the chapter before approving it for publication.[106] No matter: The guideline that Plaintiffs rely on to ask this Court to reverse the trial court's factual findings recommends castration for men and boys who identify as "eunuch."

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[97] *Id.* at 91.

[98] *Id.* at 38.

[99] *Cf.* Ex.167(Doc.560-17):91.

[100] Kellan Baker *et al.*, *Hormone Therapy, Mental Health, and Quality of Life*, 5 J. ENDOCRINE SOC'Y 1, 3 (2021); L. Wilson, *Effects of Antiandrogens on Prolactin Levels Among Transgender Women*, 21 INT'L J. TRANSGENDER HEALTH 391, 392 (2020).

[101] SOC-8, *supra* note 12, at S88.

[102] *Id.* at S88-89.

[103] Ex.21(Doc.700-3):172:19–173:25.

[104] *Id.*

[105] Ex.182(Doc.700-11):96.

[106] Ex.18(Doc.564-8):147:9–148:4; *Boe*.MSJ(Doc.619):16.

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And how did WPATH learn that castration constitutes "medically necessary gender-affirming care"?[107] From the internet—specifically a "large online peer-support community" called the "Eunuch Archive."[108] According to SOC-8 itself, the "Archive" contains "the greatest wealth of information about contemporary eunuch-identified people."[109] The guideline does not disclose that part of the "wealth" comes in the form of the Archive's fiction repository, which hosts thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children."[110] "The fictional pornography" "includes themes such as Nazi doctors castrating children, baby boys being fed milk with estrogen in order to be violently sex trafficked as adolescents, and pedophilic fantasies of children who have been castrated to halt their puberty."[111]

Despite all this, advocates regularly promise that the WPATH Standards were developed using well-accepted processes and similar to other treatment guidelines. Let's hope not.

G. WPATH Acts Like an Advocacy Organization, Not a Medical One.

As is clear by now, though WPATH cloaks itself in the garb of evidence-based medicine, its heart is in advocacy. (Indeed, in its attempt to avoid discovery into its "evidence-based" guideline, WPATH told the district court in Alabama it was just a "nonparty advocacy organization[]."[112]) That was evident after SOC-8 was published, when Dr. Coleman circulated an internal "12-point strategic plan to advance gender affirming care."[113] He began by identifying "attacks on access to trans health care," which included (1) "academics and scientists who are naturally skeptical," (2) "parents of youth who are caught in the middle of this controversy," (3) "continuing pressure in health care to provide evidence-based care," and (4) "increasing number of regret cases and individuals who are vocal in their retransition who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[114]

To combat these "attacks" from "evidence-based medicine" and aggrieved patients, Dr. Coleman encouraged WPATH to ask other medical organizations to formally endorse SOC-8. He noted that the statement "that the SOC has so many endorsements has been an extremely powerful argument" in court, particularly given that "[a]ll of us are painfully aware that there are many gaps in research to back up our recommendations."[115] Problem was, Dr. Coleman "ha[d] no idea how

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[107] SOC-8, *supra* note 12, at S88.

[108] *Id.*

[109] *Id.*

[110] Genevieve Gluck, *Top Trans Medical Association Collaborated with Castration, Child Abuse Fetishists*, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

[111] *Id.*

[112] Mot. to Quash at 3, *Boe*, 2:22-cv-184 (M.D. Ala. Dec. 27, 2022), Doc.208.

[113] Ex.190(Doc.700-18):5 (capitalization altered).

[114] *Id.*; *see* Ex.16(Doc.557-16):¶103.

[115] Ex.190(Doc.700-18):5-6.

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it was ever said that so many medical organizations ha[d] endorsed" the standards.[116] He suspected that organizations had only "referenced" the guideline but "never formally endorsed" it.[117]

So Dr. Coleman and other WPATH leaders made a concerted effort to obtain formal endorsements from other organizations. At his deposition in May 2024, Dr. Coleman knew of only two organizations that had endorsed SOC-8: the World Association for Sexual Health and the International Society for Sexual Medicine.[118] The AAP, Dr. Coleman said, rejected WPATH's request.[119] So did the American Medical Association, which told WPATH that it "does not endorse or support standards of care—that falls outside of our expertise."[120] The response caused Dr. Bouman to complain that the AMA is run by "white cisgender heterosexual hillbillies from nowhere."[121]

Then there is WPATH's response to the Cass Review. Rather than embracing one of "the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations" in the UK,[122] WPATH seems to view NHS England and the Cass Review as simply more "attacks on access to trans health care." In its public "comment on the Cass Review," for instance, WPATH defends SOC-8 against the Review's harsh assessment by boasting that its guideline was "based on far more systematic reviews tha[n] the Cass Review."[123] That may or may not be true—Dr. Robinson did say her team had conducted "dozens!" of reviews—but it's a rich claim for WPATH to make given that it went to such great lengths to restrict its own evidence review team from publishing its findings, WPATH did not otherwise make a *single* review or evidence table from SOC-8 available to the public, and SOC-8 states that WPATH found insufficient evidence to even conduct a systematic review for the adolescent chapter. By contrast, the six systematic evidence reviews and two appraisals of international clinical guidelines conducted through an open procurement process by the University of York for the Cass Review are freely available in the peer-reviewed *Archives of Disease in Childhood*.[124] WPATH's critique of the Cass Review is simply not serious.

It is also not unusual. WPATH has long sought to ensure that only one side of the story is told, and it critiques or silences those who offer opposing

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[116] *Id.*

[117] *Id.* at 6 (spelling corrected).

[118] Ex.21(Doc.700-3):261:5-12, 262:4-8; *see* Ex.190(Doc.700-18):6.

[119] Ex.21(Doc.700-3):261:20-23; Ex.188(Doc.700-17):152.

[120] Ex.189(Doc.560-39):15.

[121] *Id.* at 13; Ex.21(Doc.700-3):259:4-10.

[122] C. Ronny Cheung et al., *Gender Medicine and the Cass Review: Why Medicine and the Law Make Poor Bedfellows*, ARCH. DIS. CHILD 1-2 (Oct. 2024), https://perma.cc/X7CH-NM7U.

[123] WPATH and USPATH Comment on the Cass Review (May 17, 2024), https://perma.cc/B2TU-ALSR.

[124] And online: https://adc.bmj.com/pages/gender-identity-service-series.

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viewpoints to the public.[125] For instance, at its inaugural conference in 2017, USPATH—WPATH's U.S. affiliate—bowed to the demands of trans-activist protestors and cancelled a panel presentation by a respected researcher, Dr. Ken Zucker, who attempted to present research showing that most children with gender dysphoria will have the dysphoria "desist" by adulthood.[126] A few years later, USPATH formally censured its president, Dr. Erica Anderson, for publicly discussing concerns about "sloppy" care resulting from gender dysphoric youth being "[r]ushed through the medicalization" of transitioning treatments.[127] WPATH even issued a formal statement "oppos[ing] the use of the lay press … as a forum for the scientific debate" over "the use of puberty delay and hormone therapy for transgender and gender diverse youth."[128] As Dr. Bowers explained it: "[T]he public … doesn't need to sort through all of that."[129]

The result of WPATH's flavor of advocacy has been predictable. One of the authors of SOC-8's adolescent chapter was prescient in her concern: "My fear is that if WPATH continues to muzzle clinicians and relay the message to the public that they have no right to know about the debate, WPATH will become the bad guy and not the trusted source."[130]

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Much more could be said about how untrustworthy WPATH is. But it is worth emphasizing that WPATH's insistence on advocacy over patient welfare has a human cost that its own leaders have seen firsthand. As Dr. Bowers recounted in a private email to other WPATH leaders (apologizing for going public with concerns about puberty blockers):

> Like my [female genital mutilation] patients who had never experienced orgasm, the puberty blockaded kids did not know what orgasm might feel like and most experienced sensation to their genitalia no differently than if it had been a finger or a portion of their thigh.... My concern culminated during a pre-surgical evaluation on a young trans girl from a highly educated family whose daughter responded when I asked about orgasm, "what is that?" The parents countered with, "oh honey, didn't they teach you that in school?" I felt that our informed consent process might not be enough.... It occurred to me that how could anyone truly know how

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[125] *See generally* Ex.16(Doc.557-16).

[126] *See* Ex.16(Doc.557-16):¶¶9-13; Ex.39(Doc.592-39):187:23–188:5; Ex.178(Doc.700-7):5.

[127] Ex.176(Doc.700-5):107, 113-14; Ex.16(Doc.557-16):¶¶14-17; Abigail Shrier, *Top Trans Doctors Blow the Whistle on "Sloppy" Care*, THE FREE PRESS (Oct. 4, 2021), https://perma.cc/R7M3-XTQ3.

[128] Joint Letter from USPATH and WPATH (Oct. 12, 2022), https://perma.cc/X7ZN-G6FS.

[129] Ex.18(Doc.564-8):287:18-22; *Boe*.MSJ(Doc.619):22.

[130] Ex.176(Doc.700-5):152.

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> important sexual function was to a relationship, to happiness? It isn't an easy question to answer....[131]

So it isn't. That is why States routinely set age limits on risky endeavors, be it driving a car, buying a beer, or consenting to a hysterectomy. Undergoing sex-change procedures is no different. As Dr. Coleman privately recognized, "at their age – they would not know what they want."[132]

We thus commend the Services work in this area and support the proposed rules that would stop subsidizing sex-change procedures for minors.

Respectfully submitted,



Steve Marshall
Attorney General of Alabama

[131] Ex.176(Doc.700-5):68.
[132] Ex.180(Doc.700-9):59.

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