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.

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.''

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/.*

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.*

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*.

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.

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,

Continued

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.

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.

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

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 . . .''

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.*

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.*

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.*

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.*

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.

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

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,

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

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.*

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

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.

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.