Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

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

42 CFR Part 457

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

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

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

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

Authority: 42 U.S.C. 1302.

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

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

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

§ 441.800 Basis and purpose.

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

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

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

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

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

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

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

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

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

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

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

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

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

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

§ 441.802 General rules.

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

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

PART 457—ALLOTMENTS AND GRANTS TO STATES

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

Authority: 42 U.S.C. 1302.

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

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

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

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

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3481–P]

RIN 0938–AV87

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

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

ACTION: Proposed rule.

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

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

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

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT:

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

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

SUPPLEMENTARY INFORMATION:

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

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

I. Background

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

A. Statutory Authority

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

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

B. Sex-Rejecting Procedures for Children With Gender Dysphoria

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

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

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

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

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

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

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

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

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

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

2. Medical Evidence Regarding Sex-Rejecting Procedures in Children

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

a. The HHS Review

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. International Reviews of SRPs in Children

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

c. Medical Professional Societies Supporting SRPs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Continued

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

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

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

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

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

The HHS Review states:

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

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

Regarding the WPATH guidelines, the HHS review states:

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

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

[49] HHS Review pg. 141.

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

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

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

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

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

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

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

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

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

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

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

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

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

Regarding the AAP policy statement, the HHS Review states:

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

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

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

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

a. U.S. State Laws

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. United States Supreme Court

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

4. CMS Actions

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

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

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

II. Provisions of the Proposed Regulations

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

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

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

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

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

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

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

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

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

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

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

Practice of Medicine

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

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

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

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

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

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

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

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

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

III. Collection of Information Requirements

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

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

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

A. Hospital Notifications to Patients

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 1—NOTIFICATION LETTERS TO PATIENTS

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

B. Updating Hospital Policies and Procedures

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

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

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

TABLE 2—COST FOR UPDATING FACILITY POLICIES AND PROCEDURES

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

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

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

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

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

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

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

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

IV. Response to Comments

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

V. Regulatory Impact Analysis

A. Statement of Need

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

B. Overall Impact

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

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

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

1. Costs and Transfers

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

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

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

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

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

[92] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBll1dfQ==*. Accessed 3 Dec. 2025.

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

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

[95] Bureau of Economic Analysis. ''National Income and Product Accounts.'' *BEA Interactive Data Application, https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13#eyJhcHBpZCI6MTksInN0ZXBzIjpbMSwyLDMsM10sImRhdGEiOltbIk5JUEFfVGFibGVfTGlzdCIsIjEzIl0sWyJDYXRlZ29yaWVzIiwiU3VydmV5Il0sWyJGaXJzdF9ZZWFyIiwiMjAyMSJdLFsiTGFzdF9ZZWFyIiwiMjAyNCJdLFsiU2NhbGUiLCIwIl0sWyJTZXJpZXMiLCJBll1dfQ==*. Accessed 18 Aug. 2025.

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

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

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

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

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

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

2. Benefits

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

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

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

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

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

number of children who will stop receiving SRPs.

C. Alternatives Considered

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

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

D. Regulatory Review Cost Estimation

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

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

E. Accounting Statement

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

TABLE 4—ACCOUNTING STATEMENT

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

F. Regulatory Flexibility Act (RFA)

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

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

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

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

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

G. Unfunded Mandates Reform Act (UMRA)

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

H. Federalism

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

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

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

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

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

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

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

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

List of Subjects in 42 CFR Part 482

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

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

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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

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

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

§ 482.46 Condition of participation: Sex-rejecting procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

exacerbated by the performance of a sex-rejecting procedure.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 84

RIN 0945–AA27

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

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

ACTION: Notice of proposed rulemaking.

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

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

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

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

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

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

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Background

Statutory Framework

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