IN THE COMMONWEALTH COURT OF PENNSYLVANIA

PENN STATE HEALTH AND ST. JOSEPH REGIONAL HEALTH NETWORK D/B/A PENN STATE HEALTH ST. JOSEPH, Petitioners v. COMMONWEALTH OF PENNSYLVANIA, PENNSYLVANIA HUMAN RELATIONS COMMISSION, Respondent.	:	NO. 335 M.D. 2025

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MidPenn Legal Services
213–A North Front Street
Harrisburg, Pennsylvania 17101
Telephone Number (717) 232–0581

Dauphin County Lawyer Referral Service
Dauphin County Bar Association
213 North Front Street
Harrisburg, Pennsylvania 17101
Telephone Number (717) 232–7536

BUCHANAN INGERSOLL & ROONEY PC
Anthony (T.J.) Andrisano (Pa. I.D. No. 201231)
Alyssa K. Stouder (Pa. I.D. No. 324468)
409 N. Second St., Suite 500
Harrisburg, PA 17101
(717) 237-4856
anthony.andrisano@bipc.com
alyssa.stouder@bipc.com

Geoffrey F. Sasso, Esq. (Pa. I.D. No. 202936)
Makenzie P. Leh, Esq. (Pa. I.D. No. 333895)
50 S 16th Street, Suite 3200
Philadelphia, PA 19102
(215) 665-3918
geoffrey.sasso@bipc.com
makenzie.leh@bipc.com

Attorneys for Petitioners,
Penn State Health and St. Joseph Regional Health Network
d/b/a Penn State Health St. Joseph

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SECOND AMENDED PETITION FOR REVIEW IN THE NATURE OF A COMPLAINT

Petitioners Penn State Health ("PSH") and St. Joseph Regional Health Network d/b/a Penn State Health St. Joseph ("SJRHN") (collectively, "Petitioners"),

by and through their attorneys, Buchanan Ingersoll & Rooney PC, hereby file this Second Amended Petition for Review in the Nature of a Complaint for Declaratory Judgment against the Commonwealth of Pennsylvania, Pennsylvania Human Relations Commission (the "PHRC" or "Respondent"). In support of this Second Amended Petition for Review, Petitioners aver as follows:

INTRODUCTION

PSH is an integrated academic health system serving patients and communities across central Pennsylvania, including through its Catholic-affiliated hospital, SJRHN. Petitioners, through their dedicated employees and healthcare providers, work tirelessly to deliver the best available healthcare, while simultaneously doing their utmost to comply with robust state and federal requirements.

PSH is dedicated to providing care for transgender and gender-diverse adults aged 19 years and older in a supportive and safe environment. Primary care physicians and other health care providers at PSH are trained in gender-affirming care, and they support the comprehensive health needs of transgender and gender-diverse adult patients throughout central Pennsylvania.

PSH was recently faced with Executive Orders, memos, directives, subpoenas, and other guidance from the Executive Branch, including federal agencies, which demand that healthcare entities receiving any type of federal

funds—including PSH—cease certain gender-affirming care for patients under the age of 19, at the risk of civil liability, loss of federal funding, and even criminal prosecution of individual medical providers.

While PSH remains committed to providing excellent care to all patients, PSH is a healthcare entity that receives payments through Medicare and Medicaid, and it must comply with federal law. Accordingly, PSH seeks declaratory relief from this Honorable Court related to certain state law challenges PSH is facing as a result of it being required to comply with federal law.

Further, SJRHN is recognized by the Roman Catholic Diocese of Allentown as a Catholic hospital and is operated consistent with the moral, ethical, sacramental and social teachings of the Roman Catholic Church. The regulation at issue here ignores religious freedoms afforded by Pennsylvania Religious Freedom Protection Act to a hospital operated consistent with the moral, ethical, sacramental and social teachings of the Roman Catholic Church. SJRHN provides services to all patients, but a Catholic hospital cannot be expected to perform gender-affirming surgeries inconsistent with its religious beliefs.

Therefore, Petitioners file this action in the Court's original jurisdiction to challenge the PHRC's implementation of regulations codified at Title 16 – Community Affairs, Part II – Governor's Office, Subpart A – Human Relations Commission, Chapter 41 – Preliminary Provisions – Subchapter D – Protected

Classes, Definitions and Sex Discrimination ("PHRC regulations") (16 Pa. Code. §§ 41.204,41.206). Petitioners also challenge the construction of the Pennsylvania Human Relations Act, 43 P.S. § 951, *et seq.* ("PHRA") and the PHRC regulations as violating the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401 *et seq.* ("RFPA") and federal law.

Petitioners seek review of the PHRC regulations and the construction of the PHRA and the PHRC regulations on three (3) primary grounds:

1) they are invalid because they constitute an unconstitutional exercise of lawmaking power by an administrative agency that exceeds the scope of the PHRC's granted power and are not reasonable;

2) they substantially burden Petitioner SJRHN's free exercise of religion in violation of the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401 *et seq.* ("RFPA");

3) they are at least partially preempted by federal law—specifically, by Executive Order 14187, which required the head of each department or agency that provides research or education grants to medical institutions to immediately take steps to ensure that institutions receiving Federal research or education grants cease providing gender-affirming care to children under the age of nineteen (19), and by the laws, programs, issues, and documents that were subsequently issued in accordance with Executive Order 14187. *See* FR Doc. 2025-02194.

Petitioners now file this action seeking declaratory relief, including a declaration that the PHRC regulations as well as the construction of the PHRA and

the PHRC regulations are unlawful, unconstitutional, invalid, and preempted by federal law.

JURISDICTIONAL STATEMENT

1. This Honorable Court has original jurisdiction over this Petition for Review pursuant to 42 Pa. C.S. § 761(a). This Petition for Review is addressed to the Court's original jurisdiction and is in the nature of a Complaint for Declaratory Judgment.

2. Under the Declaratory Judgments Act, 42 Pa. C.S. §§ 7531-7541, this Court has the authority "to declare rights, status, and other legal relations whether or not further relief is or could be claimed . . . The declaration may be either affirmative or negative in form and effect, and such declarations shall have the force and effect of a final judgment or decree." 42 Pa. C.S. § 7532.

3. "[T]he propriety of invoking the original equitable jurisdiction of the Commonwealth Court in a case seeking preenforcement review of a substantial challenge to the validity of regulations promulgated by an administrative agency is clear." *Arsenal Coal Co. v. Commonwealth, Dep't of Env't Res.*, 477 A.2d 1333, 1338 (Pa. 1984).

THE PARTIES

4. Petitioners are Pennsylvania nonprofit corporations offering a full range of outpatient and inpatient diagnostic, medical, and surgical services, which have a registered business address at 100 Crystal A Drive MC CA210, Hershey, Pennsylvania 17033, and which operate the SJRHN as a Catholic identified acute care hospital located at 2500 Bernville Road, Reading, Pennsylvania 19605.

5. As a provider of healthcare, Petitioners receive federal reimbursement payments, such as Medicare/Medicaid, from the federal government of the United States of America.

6. PSH is a Pennsylvania non-profit corporation with its own 501(c)(3) designation by the Internal Revenue Service ("IRS").

7. SJRHN is a Pennsylvania non-profit corporation with its own 501(c)(3) designation by the IRS.

8. The sole member of SJRHN is PSH; SJRHN is one (1) of ten (10) direct subsidiaries of PSH.

9. SJRHN is recognized by the Roman Catholic Diocese of Allentown (the "Diocese") as a Catholic hospital and is operated consistent with the moral, ethical, sacramental and social teachings of the Roman Catholic Church.

10. SJRHN is operated as a Catholic hospital and it is authorized by the Roman Catholic Diocese of Allentown (the "Diocese") to be identified as a Catholic hospital.

11. SJRHN, in operating as a Catholic hospital, holds a sincerely held religious belief that God created humans as male and female.

12. SJRHN, in operating as a Catholic hospital, also holds a sincerely held religious belief that technological interventions on the human body that do not aim to repair some defect in the body or sacrifice a part of the body for the sake of the whole—including gender-affirming procedures[1]—should not be performed on patients.

13. Respondent the PHRC is an independent agency of the Commonwealth of Pennsylvania, organized and existing pursuant to the PHRA, with an office located at 333 Market Street, 8th Floor, Harrisburg, Pennsylvania 17101.

GENERAL STATEMENT OF MATERIAL FACTS

14. The PHRA guarantees individuals the right to obtain all accommodations, advantages, facilities, and privileges of any public accommodation without discrimination because of sex. 43 P.S. § 953.

[1] Petitioners utilize the term "gender-affirming" procedures or care throughout this Petition, as this is the term utilized by several complainants in administrative complaints filed with the PHRC against Petitioners, and alleging violations of the PHRA related to these procedures/care.

15. A "public accommodation, resort or amusement" includes clinics and hospitals. 43 P.S. § 954.

16. On or about August 16, 2023, Respondent issued regulations, 16 Pa. Code §§ 41.201 – 41.207, which define "sex" as used in the PHRA and the Pennsylvania Fair Educational Opportunities Act ("PFEOA"), as inclusive of "gender, including a person's gender identity or gender expression." 16 Pa. Code § 41.206.

17. The PHRC regulations further define "gender identity or expression" as "[h]aving or being perceived as having a gender-related identity, appearance, expression or behavior, which may or may not be stereotypically associated with the person's sex assigned at birth. Gender identity or expression may be demonstrated by consistent and uniform assertion of the gender identity or any other evidence that the gender identity is part of a person's core identity." 16 Pa. Code § 41.204.

18. These regulations purport to "ensure that all unlawful discriminatory practices proscribed by the PHRA ... are interpreted and applied consistently … also ensures that all complaints filed with the PHRC are investigated consistent with the rules outlined in this subchapter." 16 Pa. Code § 41.201.

19. Prior to the issuance of the PHRC regulations, the PHRA did not contain a definition of "sex" for purposes of the prohibition of sex discrimination,

nor did the General Assembly explicitly grant the PHRC the authority to promulgate a regulation including such a broad and expansive definition[2].

20. Even after the issuance of the PHRC regulations, the Pennsylvania Supreme Court clearly defined "sex" as "either the male or female division of a species …" for purposes of the Equal Rights Amendment to the Pennsylvania Constitution, Pa. Const. art. I, § 28. *Allegheny Reprod. Health Ctr. v. Pa. Dep't of Hum. Servs.*, 309 A.3d 808, 868-869 (Pa. 2024).

21. The Pennsylvania Supreme Court further explained: "There is no reason to conclude, based on the text of Section 28, that there was an intention to give a different meaning to sex than the meaning given to it in the PHRA that preceded it." *Allegheny*, 309 A.3d at 876.

22. The PHRA affords the PHRC the power to "adopt, promulgate, amend and rescind rules and regulations to effectuate the policies and provisions of [the PHRA]." 43 P.S. § 957(d).

23. However, Article II, Section 1 of the Pennsylvania Constitution provides:

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[2] During its 2023-2024 session, the Pennsylvania House of Representatives introduced HB 300, an Act amending the PHRA to explicitly include gender identity and expression as included in the protections of the PHRA. After at least three (3) considerations by committees, on October 8, 2024, a resolution was presented to discharge the committee from further consideration of HB 300. To be clear, HB 300 was never passed into law by the Pennsylvania legislature. The PHRA does not include gender identity and expression in its protections; nor does it define "sex" to include gender identity and expression.

> The legislative power of this Commonwealth shall be vested in a General Assembly, which shall consist of a Senate and a House of Representatives.

Pa. Const., art. II, § 1.

24. The non-delegation doctrine, derived from Article II, Section 1 of the Pennsylvania Constitution, "requires that the basic policy choices involved in 'legislative power' actually be made by the [l]egislature as constitutionally mandated." *City of Lancaster v. Pa. Pub. Util. Comm'n*, 313 A.3d 1020, 1027-1028 (Pa. 2024).

25. The Pennsylvania General Assembly has not delegated any authority to the PHRC to amend the PHRA to include a new definition of "sex;" nor has it delegated any authority to the PHRC to amend and expand the definition of "sex" for purposes of Pennsylvania statutes.

26. Article III, Section 1 of the Pennsylvania Constitution provides:

> No law shall be passed except by bill, and no bill shall be so altered or amended, on its passage through either House, as to change its original purpose.

Pa. Const., art. III, § 1.

27. The PHRC regulations were not passed by bill through the Pennsylvania General Assembly.

28. Article III, Section 6 of the Pennsylvania Constitution provides:

> No law shall be revived, amended, or the provisions thereof extended or conferred, by reference to its title only, but so much thereof as is

> revived, amended, extended or conferred shall be re-enacted and published at length.

Pa. Const., art. III, § 6.

29. Regulations promulgated under an agency's grant of legislative power by the General Assembly must be: a) adopted within the agency's granted power; b) issued pursuant to proper procedure; and c) reasonable. *Tire Jockey Serv., Inc. v. Commonwealth, Dep't of Env't Prot.*, 915 A.2d 1165, 1186 (2007).

30. The PHRC regulations amend the PHRA without the granted authority to do so.

31. The PHRC regulations are not reasonable and are not based on a permissible construction of the PHRA.

32. The Pennsylvania Religious Freedom Protection Act ("RFPA") provides, in relevant part:

> (a) General Rule.—Except as provided in subsection (b), an agency shall not substantially burden a person's free exercise of religion, including any burden which results from a rule of general applicability.
>
> (b) Exceptions.—An agency may substantially burden a person's free exercise of religion if the agency proves, by a preponderance of the evidence, that the burden is all of the following:
>
> (1) In furtherance of a compelling interest of the agency
>
> (2) The least restrictive means of furthering the compelling interest.

71 P.S. § 2404.

33. The definition of "person" under RFPA includes an individual or a church, association of churches or other religious order, body or institution which qualifies for exemption from taxation under section 501(c)(3) or (d) of the Internal Revenue Code of 1986 (26 U.S.C. § 501). 71 P.S. § 2403.

34. Petitioners qualify for exemption from taxation under section 501(c)(3) of the Internal Revenue Code of 1986, and they operate SJRHN consistent with the moral, ethical, sacramental, and social teachings of the Roman Catholic Church.

35. The definition of "substantially burden" under RFPA is an agency action which does any of the following:

> (1) Significantly constrains or inhibits conduct or expression mandated by a person's sincerely held religious beliefs.
>
> (2) Significantly curtails a person's ability to express adherence to the person's religious faith.
>
> (3) Denies a person a reasonable opportunity to engage in activities which are fundamental to the person's religion.
>
> (4) Compels conduct or expression which violates a specific tenet of a person's religious faith.

71 P.S. §2403.

36. The RFPA also provides: "The General Assembly intends that all laws which it has heretofore enacted or will hereafter enact and all ordinances and regulations which have been or will be adopted by political subdivisions or executive

agencies shall be construed so as to avoid the imposition of substantial burdens upon the free exercise of religion without compelling justification." 71 P.S. §2402.

37. On or about January 22, 2025, E.S.[3] filed a Complaint with the PHRC, captioned *E.S. v. SJRHN et al.*, PHRC Case No. 202401365 ("E.S.'s Complaint") alleging that Petitioners discriminated against E.S. based on E.S.'s sex, "non-binary." A redacted copy of E.S.'s Complaint is attached hereto as **Exhibit A**.

38. E.S. did not allege that Petitioners discriminated against E.S. because E.S. is male or because E.S. is female.

39. E.S. specifically alleged that, in 2024, Petitioners refused to perform a gender-affirming mastectomy at SJRHN on the basis that performing gender-affirming surgeries would be against SJRHN's religious beliefs; E.S. claimed this was discrimination on the basis of sex, i.e., non-binary, because Petitioner SJRHN performs mastectomies on patients for non-gender-affirming reasons[4].

40. On or about March 31, 2025, Petitioners filed an Answer with New Matter to E.S's Complaint. A redacted copy of Petitioners' Answer with New Matter to E.S.'s Complaint is attached hereto as **Exhibit B**.

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[3] Petitioners utilize PHRC Complainants' initials rather than full names to protect the privacy of the Complainants and will likewise redact the full names of the Complainants on any attached materials.

[4] E.S. has confirmed that PSH provided E.S. the gender-affirming procedure E.S. sought at PSH's Hampden Medical Center location. *See* **Exhibit A** at pg. 4.

41. Petitioners' Answer with New Matter asserted its RFPA claim as part of its New Matter; it asserted the following: "Complainant's claims and/or the PHRC's regulations are barred by and/or are inapplicable due to the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401-2408." *See* **Exhibit B** at pg. 6.

42. Petitioner SJRHN's free exercise of religion is substantially burdened by the PHRC regulations' new and expansive definition of "sex" for purposes of sex discrimination under the PHRA.

43. On March 20, 2023, the United States Conference of Catholic Bishops' ("USCCB") Committee on Doctrine issued a Doctrinal Note entitled Doctrinal Note on the Moral Limits to Technological Manipulation of the Human Body ("Doctrinal Note"). A copy of the Doctrinal Note is attached hereto as **Exhibit C**.

44. The Doctrinal Note specifically references an integral tenet of the Catholic faith—that God created Man as *male and female*, stating as follows:

5. Human bodiliness is, in turn, intrinsically connected with human sexual differentiation. Just as every human person necessarily has a body, so also human bodies, like those of other mammals, are sexually differentiated as male or female: "Male and female he created them" (Gen 1:27).[8] Saint John Paul II reminded us that, in the Book of Genesis, we learn that "Man is created 'from the very beginning' as male and female: the life of all humanity—whether of small communities or of society as a whole—is marked by this primordial duality."[9] The *Catechism of the Catholic Church* affirms: "Man and woman have been *created*, which is to say, *willed* by God: on the one hand, in perfect equality as human persons; on the other, in their respective beings as man and woman. 'Being man' or 'being woman' is a reality which is good and willed by God."[10]

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[6] *Catechism of the Catholic Church*, no. 365 (https://www.vatican.va/archive/ENG0015/__P1B.HTM): "The unity of soul and body is so profound that one has to consider the soul to be the 'form' of the body: i.e., it is because of its spiritual soul that the body made of matter becomes a living, human body; spirit and matter, in man, are not two natures united, but rather their union forms a single nature."

[7] International Theological Commission, *Communion and Stewardship: Human Persons Created in the Image of God* (2002), no. 26 (https://www.vatican.va/roman_curia/congregations/cfaith/cti_documents/rc_con_cfaith_doc_20040723_communion-stewardship_en.html).

[8] Persons affected by Disorders of Sexual Development do not fall outside the two categories of male and female, but they do exhibit ambiguous or abnormal indicators of sexual difference, so that the sex of their bodies is difficult to determine, though not impossible for modern medical and genetic techniques.

[9] Saint Pope John Paul II, *Letter to Families* (1994), no. 6 (https://www.vatican.va/content/john-paul-ii/en/letters/1994/documents/hf_jp-ii_let_02021994_families.html). Cf. *Catechism of the Catholic Church*, no. 2333.

[10] *Catechism of the Catholic Church*, no. 369.

45. The Doctrinal Note further explains that Catholic principles view technological interventions on the human body that do not aim to repair some defect in the body or sacrifice a part of the body for the sake of the whole—including gender-affirming procedures—as "not morally justified" and as not "respect[ing] the fundamental order of the human person as an intrinsic unit of body and soul…" *See* **Exhibit C**.

46. The USCCB specifically directs: "Catholic health care services must not perform interventions, whether surgical or chemical, that aim to transform the sexual characteristics of a human body into those of the opposite sex or take part in the development of such procedures. They must employ all appropriate resources to

mitigate the suffering of those who struggle with gender incongruence, but the means used must respect the fundamental order of the human body. Only by using morally appropriate means do healthcare providers show full respect for the dignity of each human person." *Id.*

47. To compel Petitioners to perform gender-affirming surgeries at SJRHN (and to hold Petitioners liable for failing to do so) would be to compel conduct violating a specific tenet of their faith and would jeopardize SJRHN's classification as a Catholic hospital.

48. To compel Petitioners to perform gender-affirming surgeries at SJRHN (and to hold Petitioners liable for failing to do so) would not be the least restrictive means of furthering a government interest in protecting against sex discrimination.

49. To illustrate less restrictive means, another integral tenet of the Catholic faith is the belief that human life should be respected, and that abortion is contrary to the moral law. *See* USCCB Educational Resource: "The Catholic Church is a Pro-Life Church," attached hereto as **Exhibit D**.

50. In enacting the PHRA, the Pennsylvania General Assembly explicitly included a carve-out allowing hospitals to refuse to perform or permit abortion or sterilization contrary to its stated ethical policy, and which allows providers stating objections to performing abortions or sterilizations on moral, religious, or professional grounds, to do the same without violating the PHRA; accordingly,

hospitals may not be subject to litigation for declining to perform abortions for religious reasons. *See* 43 P.S. § 955.2.

51. When the PHRC issued the PHRC regulations, it failed to include any similar carve-outs allowing hospitals and providers to refuse to perform gender-affirming surgeries without violating the PHRA; thus, Petitioners can be and have been subject to discrimination lawsuits for SJRHN's declination to provide gender-affirming care in accordance with their religious beliefs. *See* 16 Pa. Code. §§ 41.201 – 41.207.

52. Petitioners' Answer with New Matter in response to E.S.'s Complaint asserted, in relevant part, that Petitioner SJRHN's free exercise of religion is substantially burdened by the PHRC regulations' new and expansive definition of "sex" for purposes of sex discrimination under the PHRA. *See* **Exhibit B**.

53. Petitioners also asserted that the PHRC regulations must not be construed as requiring Petitioners to provide all accommodations, advantages, facilities, and privileges without discrimination because of "sex," to include "gender identity," including providing gender-affirming surgical procedures and care, in violation of SJRHN's sincerely held religious beliefs. *See* **Exhibit B**.

54. On September 30, 2025, after SJRHN initiated the present litigation, counsel for the PHRC notified Petitioners that the PHRC would be closing E.S.'s case and dismissing E.S.'s Complaint; on October 2, 2025, the PHRC filed a Motion

to Discontinue E.S.'s case. *See* Motion to Discontinue by the PHRC, attached hereto as **Exhibit E**.

55. Despite the PHRC's finding that E.S.'s claims lack merit in light of the RFPA, E.S. has approximately two (2) years to file suit against Petitioners in the appropriate Court of Common Pleas and E.S. has represented the intent to file such suit.

56. Petitioners' free exercise of religion remains substantially burdened by the PHRC regulations' new and expansive definition of "sex" for purposes of sex discrimination under the PHRA because it allows individuals to bring administrative complaints of discrimination and subsequent discrimination lawsuits in state court against Petitioners based on SJRHN's exercise of its religious freedom, *i.e.*, declining to provide gender-affirming care at SJRHN.

57. PSH offers gender-affirming care and services to adult patients in need of such care, regardless of the patients' sex or transgender status. *See* PSH Webpage: Care for Transgender and Gender-Diverse Individuals, attached hereto as **Exhibit F**[5].

58. On January 28, 2025, President Donald J. Trump issued Executive Order 14187, which made it the policy of the United States that it will not fund,

[5] The attached Webpage was last visited on February 17, 2026, at the following web address: https://www.pennstatehealth.org/services-treatments/care-transgender-gender-diverse-individuals.

sponsor, promote, assist, or support the "so-called 'transition'" of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit gender-affirming procedures. *See* Executive Order 14187, Protecting Children from Chemical and Surgical Mutilation, FR Doc. 2025-02194, attached hereto as **Exhibit G**.

59. Executive Order 14187 directed the head of each executive department or agency that provides research or education grants to medical institutions to immediately take appropriate steps to ensure that institutions receiving Federal research or education grants, like Petitioners, cease providing gender-affirming care to children under the age of nineteen (19). *See* **Exhibit G**.

60. Executive Order 14187 directed the Secretary of HHS to take certain actions to ensure healthcare providers who receive federal funding cease providing gender-affirming care to children, including changing Medicare or Medicaid conditions of participation or conditions for coverage and clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs. *See id.*

61. Executive Order 14187 also directed the Secretary of HHS to promptly withdraw HHS's March 2, 2022 guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy" and, in consultation with the Attorney General, issue new guidance protecting whistleblowers who take action related to ensuring compliance with the order; the

Secretary of HHS did so. *See id.*; *see also* February 20, 2025 HHS Guidance, attached hereto as **Exhibit H** (rescinding the March 2, 2022 guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy"); April 14, 2025 HHS Guidance, attached hereto as **Exhibit I** ("Guidance for Whistleblowers on the Chemical and Surgical Mutilation of Children").

62. Also in accordance with Executive Order 14187's directives, HHS has issued proposed rules revising the requirements that hospitals must meet for participation in the Medicare and Medicaid programs, including rules prohibiting hospitals from performing "sex-rejecting procedures" on children, and prohibiting many state and federally-funded payments, including under the Children's Health Insurance Program ("CHIP") for "sex-rejecting procedures" provided to minors. *See Medicare and Medicaid Programs; Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children*, F.R. Doc. 2025-23465 (12/18/25) (to be codified at 42 C.F.R. Part 482); *Medicaid Program; Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children*, F.R. Doc. 2025-23464 (12/18/25) (to be codified at 42 CFR Parts 441 and 457), attached hereto as **Exhibit J**.

63. Executive Order 14187 also directed the Attorney General of the United States to prioritize enforcement of protections against female genital mutilation and

prioritize investigations and take appropriate action to end gender-affirming care for children. *See* **Exhibit G**.

64. On April 22, 2025, the Office of Attorney General of the United States issued a Memorandum for Select Component Heads to Petitioners with the subject Preventing the Mutilation of American Children ("OAG Memorandum"). *See* OAG Memorandum, attached hereto as **Exhibit K**.

65. The OAG Memorandum advises healthcare providers that, in the United States, it is a felony to perform, attempt to perform, or conspire to perform female genital mutilation on any person under the age of eighteen (18); that crime carries a maximum prison sentence of ten (10) years per count; and the Attorney General has directed all U.S. Attorneys to investigate and prosecute all female genital mutilation offenses to the fullest extent possible. *See id.*

66. The OAG Memorandum also advises healthcare providers that the United States Department of Justice ("DOJ") will undertake investigations of violations of the Food, Drug, and Cosmetic Act and the False Claims Act related to the information medical providers give to the public about the long-term side effects of gender-affirming care. *See id.*

67. To date, the DOJ has sent more than twenty (20) subpoenas to doctors and clinics involved in performing gender-affirming medical procedures on children as part of its investigations into healthcare fraud, false statements, and more. *See*

Press Release: Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children, https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical, issued July 9, 2025, attached hereto as **Exhibit L**.

68. The Secretary of HHS also issued the following declaration in December 2025:

> **Sex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors, and therefore, fail to meet professional recognized standards of health care. For the purposes of this declaration, "sex-rejecting procedures" means pharmaceutical or surgical interventions, including puberty blockers, cross-sex hormones, and surgeries such as mastectomies, vaginoplasties, and other procedures, that attempt to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex.**

See Declaration of the Secretary of the Department of Health and Human Services RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents, issued December 18, 2025, attached hereto as **Exhibit M**.

69. Following this declaration, between December 26, 2025, HHS announced it was launching an investigation into Seattle Children's Hospital for "failure to meet professional recognized standards of health care" related to the hospital's gender-affirming care for minors. *See* Posts on X by HHS, @HHS.gov, and HHS General Counsel Mike Stuart, @HHSGCMikeStuart, attached hereto as **Exhibit N**.

70. Between December 30, 2025 and January 15, 2026, HHS's General Counsel announced additional referrals for investigations into Children's Hospital Colorado; Children's Minnesota; Nemours Alfred I. DuPont Hospital for Children (DE); Ann & Robert H. Lurie Children's Hospital of Chicago (IL); Boston Children's Hospital (MA); The Children's Hospital of Philadelphia (PA); New York University – Langone Health (NY); and Doernbecher Children's Hospital (OR). *See* id.

71. These referrals are intended to investigate the entities' "failure to meet recognized standards of health care" relating to their performance of gender-affirming care because they allegedly "appear to continue to operate outside recognized standards of healthcare entirely outside [Secretary Kennedy]'s declaration that sex-rejecting procedures for children and adolescents are neither safe nor effective." *See* id.

72. In order to follow federal law and protect PSH and its medical providers from criminal prosecution, governmental investigations for violations of laws, civil liability, and the loss of critical federal funding, in or around April 2025, PSH revised its practices regarding gender-affirming care.

73. In compliance with the new federal mandates, PSH now it offers gender-affirming care only to adults aged nineteen (19) and older. *See* **Exhibit F**.

74. In response to PSH following the new federal mandates established by President Trump and his administration, at least two (2) new complaints of discrimination have been filed against PSH.

75. On or about September 5, 2025, E.W. filed a Complaint with the PHRC, captioned as *E.W. obo P.T.S. v. PSH*, PHRC Case No. 202502571 ("E.W.'s Complaint"), alleging that PSH discriminated against her minor child, P.T.S., based on P.T.S.'s sex, "transgender." *See* E.W.'s Complaint, attached hereto as **Exhibit J**.

76. E.W. does not allege PSH discriminated against P.T.S. because P.T.S. is male or because P.T.S. is female. *See* id.

77. E.W. specifically alleges that, in or around May 2025, PSH ceased providing gender-affirming care to children under the age of nineteen (19), including P.T.S., which E.W. claims constitutes sex-based discrimination prohibited by the PHRA, through the PHRC regulations. *See* id.

78. The PHRC accepted E.W.'s Complaint and required PSH to timely file an Answer to the same.

79. On or about December 8, 2025, PSH filed a Motion to Dismiss E.W.'s Complaint, arguing: 1) the PHRC regulations should be invalidated; 2) the PHRA and PHRC regulations are preempted by federal law; and 3) E.W's claim of discrimination under the PHRA fails because PSH ceased providing certain gender-

affirming care because her child is a minor and not because of her child's sex. *See* PSH Motion to Dismiss, attached hereto as **Exhibit O**.

80. By Order dated January 26, 2026, the PHRC granted PSH's Motion to Dismiss and dismissed E.W.'s claim **only** on the basis that the PHRC lacked jurisdiction because E.W. alleged to have been denied services based on their age (under 19), which is not a violation of the PHRA. The case has been returned to the appropriate regional office for further action pursuant to 16 Pa. Code § 42.61. *See* January 26, 2026 Order, attached hereto as **Exhibit P**.

81. Even if E.W.'s claim is officially dismissed by the PHRC, E.W. will still have a period of two (2) years to bring a lawsuit in state court.

82. On or about October 20, 2025, K.S. filed a Complaint with the PHRC, which she amended on or about December 29, 2025, captioned as *K.S. obo her minor child v. PSH, et al.*, PHRC Case No. 202503272 ("K.S.'s Complaint"), alleging, in part, that PSH discriminated against her minor child, K.W., based on the child's "sex (nonbinary), gender identity, [and] disability (gender dysphoria)." *See* K.S.'s Complaint, attached hereto as **Exhibit Q**.

83. K.S. does not allege PSH discriminated against K.W.. because K.W. is male or because K.W. is female. *See* id.

84. K.S. specifically alleges that, in or around June 2025, K.S. and K.W. learned PSH would be ceasing providing gender-affirming care to children under the

age of nineteen (19), including K.W., which K.S. claims constitutes sex-based discrimination prohibited by the PHRA, through the PHRC regulations. *See* id.

85. The PHRC has accepted K.S.'s Complaint and requires PSH to timely file an Answer to the same.

86. Even if the PHRC were to dismiss the Complaints of E.W. and K.S. on the basis that the federal law set forth in Executive Order 14187 and subsequent documents issued by HHS and the OAG preempt the PHRA (including the PHRC regulations), or any other bases, E.W., K.S., and other individuals currently have the ability to file discrimination lawsuits in the appropriate Courts of Common Pleas pursuant to the PHRA, including through the PHRC regulations.

COUNT I
DECLARATORY JUDGMENT

87. Petitioners incorporate Paragraphs 1 through 83 above by reference as though set forth fully herein.

88. Under the Declaratory Judgments Act, 42 Pa. C.S. §§ 7531-7541, this Court has authority "to declare, rights, status and other legal relations whether or not further relief is or could be claimed....The declaration may be either affirmative or negative in form and effect, and such declarations shall have the force and effect of a final judgment or decree." 42 Pa. C.S. § 7532.

89. The Declaratory Judgments Act further provides that "[a]ny person...whose rights, status or other legal relations are affected by a statute,

municipal ordinance, contract, or franchise, may have determined any question of construction or validity arising under the instrument, statute, ordinance, contract, or franchise, and obtain a declaration of rights, status, or other legal relations thereunder." 42 Pa. C.S. § 7533.

90. Finally, the Declaratory Judgments Act provides that "[i]ts purpose is to settle and to afford relief from uncertainty and insecurity with respect to rights, status, and other legal relations, and is to be liberally construed and administered." 42 Pa. C.S. § 7541(a).

91. The RFPA explicitly authorizes declaratory relief for persons whose free exercise of religion has been burdened or likely will be burdened in violation of the RFPA. 71 P.S. § 2405(f).

92. For the reasons discussed herein, an actual, justiciable controversy exists between Petitioners and the PHRC regarding the PHRC's issuance of and reliance on the invalid, unconstitutional, and federally preempted PHRC regulations, with respect to which Petitioners are entitled to a declaration of their rights and further relief.

93. An entity created by statute, such as the PHRC, "can only exercise those powers which have been conferred upon it by the Legislature in clear and unmistakable language." *Aetna Cas. & Ins. Co. v. Insurance Dep't*, 638 A.2d 194, 200 (Pa. 1994) (quoting *Human Relations Comm'n v. Transit Cas. Ins. Co.*, 387 A.2d

58, 62 (Pa. 1978)); *see also Small v. Horn,* 722 A.2d 664, 669 (Pa. 1998) ("Administrative agencies are creatures of the legislature…and they have only those powers that are conferred by statute."); *Koken v. Legion Ins. Co.*, 831 A.2d 1196, 1227 (Pa. Cmwlth. 2003) ("A creature of statute, such as the Insurance Commissioner acting as a rehabilitator, can only exercise those powers which have been conferred by the Legislature in clear and unmistakable language." (citing *Aetna*)).

94. The PHRC exceeded its authority by issuing the PHRC regulations which included a new and expansive definition of "sex" without being granted the authority to do so. *See Insurance Federation of Pa., Inc. v. Com., Dept. of Ins.*, 889 A.2d 550, 555 (Pa. 2005) (explaining that authority may be given to a government official or administrative agency to make rules and regulations to cover "mere matters of detail for the implementation of a statute" but that "where the statute itself is lacking in essential substantive provisions the law does not permit a transfer of the power to supply them, for the legislature cannot delegate its power to make a law").

95. The PHRC's issuance of the PHRC regulations must have been, but was not, 1) adopted within its granted power; and 2) reasonable. *See Tire Jockey*, 915 A.2d at 1186.

96. The PHRC's issuance of the PHRC regulations substantially burdens SJRHN's free exercise of religion in violation of the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401 et seq. ("RFPA").

97. The PHRC's issuance of and reliance on the PHRC regulations are improper where federal law preempts the PHRA (and the PHRC regulations).

98. The PHRC's issuance of and reliance on the PHRC regulations will force PSH to either comply with federal law and face continued discrimination lawsuits under the PHRA and PHRC regulations at great cost and expense or to violate federal law and subject its entities and providers to a loss of critical federal funding, civil liability, and criminal liability; PSH respectfully requests declaratory relief because either option would require it to suffer ongoing uncertainty in its day-to-day operations while proceeding through the administrative process.

99. A declaratory judgment in a pre-enforcement regulatory challenge is appropriate where the petitioner alleges that it would suffer ongoing uncertainty in its day-to-day operations and would sustain substantial expense in complying with the challenged regulations while proceeding through the administrative process. *Arsenal Coal Co.*, 477 A.2d at 1340. In this regard, "[w]here the effect of the challenged regulations upon the industry regulated is direct and immediate, the hardship thus presented suffices to establish the justiciability of the challenge in advance of enforcement." *Id.* at 1339.

100. PSH seeks a Declaratory Judgment that the PHRA and PHRC regulations are preempted by federal law and, thus, PSH's compliance with federal law and declination to provide gender-affirming care to children under the age of 19 is not violative of the PHRA, including the PHRC regulations.

WHEREFORE, Petitioners respectfully request that this Honorable Court enter declaratory judgment in their favor and against the PHRC and award such other relief as set forth in the Statement of Relief Requested section below.

STATEMENT OF RELIEF REQUESTED

WHEREFORE, based on the foregoing averments which are incorporated herein by reference, Petitioners PSH and SJRHN respectfully request that this Honorable Court:

1. Enter judgment in favor of Petitioners and against the PHRC;

2. Declare that the PHRC regulations are and always have been void, invalid, and unenforceable as the result of actions undertaken outside the agency's granted power, as unreasonable, and as violative of the RFPA;

3. Declare that the PHRA and the PHRC regulations do not compel Petitioner SJRHN to provide technological interventions on the human body that do not aim to repair some defect in the body or sacrifice a part of the body for the sake of the whole, such as gender-affirming procedures and care, in violation of specific tenets of Roman Catholic faith;

4. Declare that the PHRA and the PHRC regulations are preempted by federal law, specifically Executive Order 14187 and its subsequently issued guidance and documents as it relates to providing gender-affirming care to children under the age of nineteen (19);

5. Declare that the PHRA and the PHRC regulations do not require Petitioners to provide gender-affirming care to children under the age of nineteen (19) in direct contravention of Executive Order 14187 and its subsequently issued guidance and documents, and that the PHRC must dismiss any Complaints claiming violations of the PHRA related to Petitioners ceasing to provide gender-affirming care to minors in compliance with federal law;

6. Award Petitioners attorney's fees and costs as permitted by law, including 42 Pa. C.S. § 1726; and

7. Enter such other and further relief as this Honorable Court deems just and proper.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

/s/Anthony (T.J.) Andrisano
Anthony (T.J.) Andrisano (Pa. I.D. No. 201231)
Alyssa K. Stouder (Pa. I.D. No. 324468)
409 N. Second St., Suite 500
Harrisburg, PA 17101
(717) 237-4856
anthony.andrisano@bipc.com
alyssa.stouder@bipc.com

Geoffrey F. Sasso, Esq. (Pa. I.D. No. 202936)
Makenzie P. Leh, Esq. (Pa. I.D. No. 333895)
50 S 16th Street, Suite 3200
Philadelphia, PA 19102
(215) 665-3918
geoffrey.sasso@bipc.com
makenzie.leh@bipc.com
Attorneys for Petitioners Penn State Health and St. Joseph Regional Health Network d/b/a Penn State Health St. Joseph

DATE: February 17, 2026

CERTIFICATE OF COMPLIANCE

I hereby certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

By: */s/ Anthony (T.J.) Andrisano*
Anthony (T.J.) Andrisano (Pa. I.D. 201231)

DATE: February 17, 2026

EXHIBIT A

COMMONWEALTH OF PENNSYLVANIA

GOVERNOR'S OFFICE

PENNSYLVANIA HUMAN RELATIONS COMMISSION

E[redacted]S[redacted],	:	
Complainant	:	
	:	
v.	:	PHRC Case No. 202401365
	:	
St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph; The Pennsylvania State University; Penn State Health,	:	
Respondents	:	
	:	

AMENDED COMPLAINT

JURISDICTION

Jurisdiction is pursuant to the Pennsylvania Human Relations Act 43 P.S. §§ 951-963.

PARTIES

The Complainant herein is:

E[redacted]S[redacted]
[redacted]

The Respondents herein are:

St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph
100 Crystal A Drive MC CA210
Hershey, PA 17033

The Pennsylvania State University
208 Old Main
University Park, PA 16802

Penn State Health
100 Crystal A Drive MC CA210
Hershey, PA 17033

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E[redacted] S[redacted],	:	
	:	PHRC Case No.
Complainant	:	
	:	
v.	:	
	:	
St. Joseph Regional Health Network, Penn State Health, and The Pennsylvania State University,	:	
	:	
Respondents	:	2025 JAN 22 AM 9:01

COMPLAINT

1. COMPLAINANT

E[redacted] S[redacted]
[redacted]

Counsel:
Richard T. Ting
ACLU of Pennsylvania
P.O. Box 23058
Pittsburgh, PA 15222
rting@aclupa.org
412-634-1151

2. RESPONDENTS

St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph, a Pennsylvania nonprofit corporation with a registered office at:
100 Crystal A Drive MC CA210
Hershey, PA 17033

Penn State Health,
a Pennsylvania nonprofit corporation with a registered office at:
100 Crystal A Drive MC CA 210
Hershey, PA 17033

The Pennsylvania State University, a state-related university as part of the Commonwealth System of Higher Education, and a Pennsylvania nonprofit corporation with a registered office at:
208 Old Main
University Park, PA 16802

3. Respondent St. Joseph Regional Health Network, under the direction and control of Penn State Health and The Pennsylvania State University, operates Penn State Health St. Joseph Medical Center, which is a public accommodation which is open to, accepts, or solicits the patronage of the general public.

4a. Penn State Health St. Joseph Medical Center is located at 2500 Bernville Road, Reading, PA 19605.

4b. I did not visit Penn State Health St. Joseph Medical Center, because I was denied services there.

5. **Protected Class:** Sex, nonbinary

6. **Dates of Discrimination:**

Beginning: 07/23/2024 **Ending:** 07/23/2024

Continuing? No.

7. **DESCRIBE THE DISCRIMINATORY CONDUCT, WITH SPECIFICITY, AND EXPLAIN HOW THE DISCRIMINATORY CONDUCT IS RELATED TO YOUR PROTECTED CLASS:**

(e.g. denial of admittance, denial of disability accommodation, retaliation, different terms and conditions of services provided)

Discriminatory Conduct

This complaint relates to refusal to provide gender-affirming procedures at Penn State Health St. Joseph Medical Center, a hospital located at 2500 Bernville Road, Reading, PA 19605 (Berks County). Penn State Health St. Joseph Medical Center is operated by St. Joseph Regional Health Network, and is part of the Penn State Health system, which is controlled by The Pennsylvania State University.

On July, 23, 2024, The Pennsylvania State University, Penn State Health, and/or St. Joseph Regional Health Network (d/b/a Penn State Health St. Joseph) discriminated against me on the basis of sex by cancelling my mastectomy surgery, which was scheduled for July 24, 2024, at Penn State Health St. Joseph Medical Center. The reason for the cancellation is that Penn State Health and St. Joseph Regional Health Network do not allow gender-affirming procedures at Penn State Health St. Joseph Medical Center.

Dr. [redacted] a Penn State Health surgeon specializing in all aspects of plastic and reconstructive surgery, including breast reconstruction and cosmetic surgery, agreed to perform my surgery. The surgery was deemed medically necessary by my

primary care provider, Dr. [redacted] to alleviate emotional duress of gender dysphoria. Dr. [redacted] in pre-surgery notes explained the surgery would benefit me "given the severity of [my] anxiety and emotional distress with the gender dysphoria."

On July 23, 2024, at 2:08 PM, Penn State Health St. Joseph Medical Center's scheduling department called me to confirm my 5:30 AM arrival time for my surgery the next day. On July 23, 2024, at 4:39 PM, [redacted] Chief Nursing Officer for Penn State Health St. Joseph Medical Center, and [redacted] Vice President of Medical Affairs for Penn State Health St. Joseph Medical Center, called me to tell me my surgery was cancelled. In that and subsequent conversations, Ms. [redacted] and Ms. [redacted] told me that I may not receive gender-affirming procedures at Penn State Health St. Joseph Medical Center because such procedures are not in alignment with the Diocese at St. Joseph and the Catholic Church.

Cancellation of my surgery less than 24 hours before the scheduled time was devastating. I planned for this procedure for almost six months and put my life on hold for it. When Ms. [redacted] and Ms. [redacted] told me my surgery was cancelled, I became distraught and had to leave the room. My mother had to continue and finish the phone call for me.

In simple terms, my world came crashing down. I was hysterical and immediately caved into my previous history of acute depressive and manic episodes due to various reasons (Generalized Anxiety Disorder, Major Depressive Disorder, PTSD and Gender Dysphoria). The immediate course of my life was completely derailed and I did not know what to do. I considered checking myself into an in-patient mental health facility.

My understanding is that Dr. [redacted] in the past had performed mastectomies for gender-affirming purposes at Penn State Health St. Joseph Medical Center, with express permission from Penn State Health and/or St. Joseph Regional Health Network. Ms. [redacted] and Ms. [redacted] have told me that Dr. [redacted] and other doctors have permission to perform breast reduction and mastectomy surgeries at Penn State Health St. Joseph Medical Center for reasons other than gender-affirming care, but Dr. [redacted] no longer has permission to perform gender-affirming procedures at Penn State Health St. Joseph Medical Center. Ms. [redacted] and Ms. [redacted] told me Dr. [redacted] should not have been given past permission to perform such procedures at Penn State Health St. Joseph Medical Center.

Penn State Health offers gender-affirming mastectomies at other Penn State Health facilities. After my surgery was cancelled, Ms. [redacted] and Ms. [redacted] gave me the options of finding a different surgeon at Penn State Health Hampden Medical Center, or trying to get permission for Dr. [redacted] to perform my surgery at a facility other than Penn State Health St. Joseph Medical Center. Penn State Health and St.

Joseph Regional Health Network do not require patients seeking mastectomies for reasons other than gender-affirming care to seek these alternatives.

Although I would have preferred to have my surgery performed by Dr. [redacted] since my primary care doctor referred me to him and I had spent months building a trusting relationship with him, Dr. [redacted] was unable to secure an alternate location to perform my surgery. I eventually was able to have a mastectomy at Penn State Health Hampden Medical Center, but this required referral to a different doctor and additional pre-surgery appointments.

Relationships Among Respondents

Penn State Health controls St. Joseph Regional Health Network. According to St. Joseph Regional Health Network's 2022 IRS Form 990, Penn State Health is St. Joseph Regional Health Network's sole member, Penn State Health controls election and removal of St. Joseph Regional Health Network's directors and officers, and Penn State Health has the authority "to adopt or modify the mission, vision, or objectives of [St. Joseph Regional Health Network]" and "to approve and authorize additions and eliminations of clinical services of [St. Joseph Regional Health Network] and to determine the distribution of clinical and support services across the [Penn State Health] system."

The Pennsylvania State University controls Penn State Health. According to Penn State Health's 2022 IRS Form 990, Penn State Health's program services "promote, support, and further The Pennsylvania State University," and "the purposes of [Penn State Health and The Pennsylvania State University's College of Medicine] are intertwined and mutually supportive." The Pennsylvania State University is one of two members of Penn State Health (the other being Highmark Health), and maintains control over many aspects of Penn State Health's governance.

Additionally, The Pennsylvania State University, by allowing Penn State Health and St. Joseph Regional Health Network to use service marks and symbols (e.g., the "Penn State" name, Nittany Lion logos and statues) associated with The Pennsylvania State University, has authorized Penn State Health and St. Joseph Regional Health Network to hold themselves out as providing health care services that originate from The Pennsylvania State University.

8. Based upon the foregoing, I allege that the Respondents violated Section 5 of the Pennsylvania Human Relations Act, 43 P.S. §§ 951-963.

9. The Pennsylvania Human Relations Commission has jurisdiction over this matter pursuant to the Pennsylvania Human Relations Act, 43 P.S. §§ 951-963.

10. I pray that the Respondents be required to provide all appropriate remedies under Section 9 of the Pennsylvania Human Relations Act.

VERIFICATION

I hereby verify that the statements contained in this Complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements herein are made subject to the penalties of 18 Pa.C.S.A. § 4904, relating to unsworn falsification to authorities.

1/21/2025
Date


Sign[redacted]

E[redacted] S[redacted]
Printed Name

WARNING: COMPLAINTS MUST BE SIGNED AND FILED WITHIN 180 DAYS OF THE ALLEGED ACT OF HARM.

EXHIBIT B

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E S,	:	
	:	
Complainant	:	PHRC Case No. 202401365
v.	:	
	:	
St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph; The Pennsylvania State University; Penn State Health,	:	
Respondents	:	
	:	

RESPONDENTS ST. JOSEPH REGIONAL HEALTH NETWORK D/B/A PENN STATE HEALTH ST. JOSEPH AND PENN STATE HEALTH'S ANSWER WITH NEW MATTER

Respondents, St. Joseph Regional Health Network d/b/a Penn State Health St. Joseph ("SJRHN") and Penn State Health ("PSH") (hereinafter, "Hospital Respondents") by and through their undersigned counsel, hereby file this Answer to the Complaint of E S ("Complainant").

The numbered paragraphs of this Answer correspond with the like-numbered paragraphs of the Complaint and, unless specifically admitted herein, each factual allegation in Complainant's Complaint is denied.

JURISDICTION

Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied.

PARTIES

Admitted in part; denied in part. It is admitted only that Complainant claims to be an individual named E[redacted] S[redacted] and that the Respondents are identified as including St. Joseph Regional Health Network d/b/a Penn State Health St. Joseph and Penn State Health. It is further admitted that Hospital Respondents have an address of 100 Crystal A Drive MC CA210, Hershey, PA 17033. Hospital Respondents are without sufficient information regarding Complainant's legal name and current address and, therefore, they deny the same and leave Complainant to their proofs. The averments of this Paragraph directed to a respondent other than Hospital Respondents do not require a response by Hospital Respondents. To the extent a response is deemed necessary by Hospital Respondents, the averments are denied. Any remaining averments of this Paragraph are also denied.

RESPONSE TO COMPLAINT

1. Admitted in part; denied in part. It is admitted only that Complainant claims to be an individual named E[redacted] S[redacted]. Hospital Respondents are without sufficient information regarding Complainant's legal name and current address and, therefore, they deny the same and leave Complainant to their proofs. Any remaining averments of this Paragraph are also denied.

2. Admitted in part; denied in part. It is admitted only that the Respondents are identified as including St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph and Penn State Health, and that Hospital Respondents have an address of 100 Crystal A Drive MC CA210, Hershey, PA 17033. The averments of this Paragraph directed to a respondent other than Hospital Respondents do not require a response by Hospital Respondents. To the extent a response is deemed necessary by Hospital Respondents, the averments are denied. Any remaining averments of this Paragraph are also denied.

3. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied.

4a. Admitted in part; denied in part. It is admitted only that Hospital Respondents have an address at 2500 Bernville Road, Reading, PA 19605. All remaining averments of this Paragraph are denied.

4b. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied.

5. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied.

6. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied. It is specifically denied that Complainant was subjected to any unlawful discrimination.

7. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied. It is specifically denied that Complainant was subjected to any unlawful discrimination.

Discriminatory Conduct[1]

Admitted in part; denied in part. It is admitted only that [redacted] and Dr. [redacted] spoke with Complainant via telephone on or about July 23, 2024, and that Complainant had a mastectomy surgery performed at Penn State Health Hampden Medical Center. All remaining averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied. It is specifically denied that Complainant was subjected to any unlawful discrimination.

Relationships Among Respondents

Denied. The IRS Forms referenced are written documents which speak for themselves and Hospital Respondents deny Complainant's characterization of the same. All remaining averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied.

8. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied. It is specifically denied that Complainant was subjected to any unlawful discrimination.

9. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied.

[1] Hospital Respondents utilize Complainant's headings for ease of reference only and such use should not be construed as admissions. It is specifically denied that Complainant was subjected to any unlawful discrimination.

10. Denied. The averments of this Paragraph are legal conclusions to which no responsive pleading is required. In the event the averments are deemed to require a responsive pleading, the averments are denied. It is specifically denied that Complainant was subjected to any unlawful discrimination.

NEW MATTER

1. The responses to the foregoing paragraphs are incorporated herein by reference as if set forth at length herein.

2. Complainant's claims are barred because Complainant lacks standing to assert the claims.

3. Complainant's claims are barred because the PHRC and Pennsylvania courts lack subject matter jurisdiction over the claims, including, without limitation, the PHRC exceeding its legal authority to issue regulations, and/or issuing regulations containing procedural defects, vagueness, and/or overbreadth.

4. Complainant's claims fail because they are legally insufficient.

5. Complainant's claims are barred because Hospital Respondents are not the proximate or legal cause of Complainant's alleged injury.

6. Complainant's claims are barred because Complainant has suffered no actual harm or damages.

7. Complainant's claims are barred in whole or in part to the extent Complainant is seeking to recover damages that are speculative in nature.

8. To the extent it is determined that Complainant is entitled to any damages, Complainant has failed to mitigate the same.

9. Complainant's claims are barred to the extent they seek to hold Hospital Respondents jointly liable for conduct attributable only to one party.

10. All actions of Hospital Respondents in this matter were taken in good faith and for legitimate, non-discriminatory reasons.

11. Hospital Respondents did not engage in any discriminatory conduct.

12. Hospital Respondents did not act with any discriminatory intent.

13. Hospital Respondents did not intentionally, deliberately, or knowingly engage in any conduct in violation of any statute, nor did Hospital Respondents exhibit reckless disregard for the requirements of any law or act with malice toward Complainant.

14. Hospital Respondents acted in good faith and had reasonable grounds for believing that their conduct and actions were lawful and in compliance with federal and state law and regulations.

15. Complainant's claims are barred by the ecclesiastical abstention doctrine.

16. Complainant's claims and/or the PHRC's regulations are barred by and/or are inapplicable due to the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401-2408.

17. Complainant's claims are barred by the First Amendment to the United States Constitution, U.S. Const. Amend. 1, and the Pennsylvania Constitution, Pa. Const. Art. 1, § 3.

18. Complainant was not subjected to unlawful discrimination in violation of the Pennsylvania Human Relations Act ("PHRA") or any similar law.

19. The Complaint fails to state a *prima facie* case for discrimination and/or any other cause of action.

20. All actions taken by Hospital Respondents relative to Complainant were based on legitimate, non-discriminatory factors.

21. Hospital Respondents maintain policies against discrimination and harassment as well as a reasonable and available procedure for handling patient complaints, and Hospital Respondents have ensured Complainant was not subjected to discrimination and/or harassment.

22. Complainant's claims may be barred in whole or in part by the doctrines of laches, fraud, waiver, estoppel and/or unclean hands.

23. Hospital Respondents have not violated any of Complainant's rights or harmed or damaged them in any way and are not liable to Complainant for any reason in any amount.

24. Complainant has failed to sufficiently identify any individual outside of Complainant's protected class that was treated more favorably than Complainant.

25. Complainant's claims are barred, in whole or in part, to the extent Complainant failed to comply with any of the procedural requirements of the PHRA or any similar law.

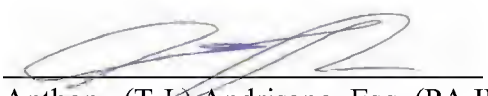
26. Complainant's claims are barred, in whole or in part, to the extent they are untimely filed.

27. Complainant has not sustained any damages, including the fact that they received the procedure at issue.

Hospital Respondents reserve the right to assert additional defenses based upon information learned during the course of this proceeding.

WHEREFORE, Respondents St. Joseph Regional Health Network d/b/a Penn State Health St. Joseph and Penn State Health respectfully request that the allegations in the above-captioned Complaint be found to lack any merit and that the Complaint be dismissed with prejudice.

Respectfully submitted,



Anthony (T.J.) Andrisano, Esq. (PA ID 201231)
Alyssa K. Stouder, Esq. (PA ID 324468)
Buchanan Ingersoll & Rooney PC
409 N. Second Street, Suite 500
Harrisburg, PA 17101
Telephone: (717) 237-4856
Facsimile: (717) 233-0852
anthony.andrisano@bipc.com
alyssa.stouder@bipc.com
Attorneys for Respondents
St. Joseph Regional Health Network d/b/a
Penn State Health St. Joseph and
Penn State Health

Dated: March 31, 2025

VERIFICATION

I, Anthony (T.J.) Andrisano, Esquire, verify that I am an attorney for Respondents, St. Joseph Regional Health Network d/b/a Penn State Health St. Joseph and Penn State Health (collectively referred to as "Hospital Respondents") and, having read the foregoing, verify that the statements made in the within Hospital Respondents' Answer with New Matter to the Complaint are true, accurate and correct to the best of my knowledge, information and belief. This pleading is based on information furnished to counsel, which information has been gathered by counsel in the course of this proceeding.

This verification is made subject to the penalties of 18 Pa. C.S.A. §4904 relating to unsworn falsification to authorities.

Date: March 31, 2025

Anthony (T.J.) Andrisano, Esq.
Attorney for Respondents
St. Joseph Regional Health Network d/b/a
Penn State Health St. Joseph and
Penn State Health

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Answer with New Matter was served upon the following parties this 31st day of March, 2025, via electronic mail and via First-Class U.S. mail, postage prepaid:

E[redacted] S[redacted]
c/o Richard T. Ting, Esq.
ACLU of Pennsylvania
PO Box 23058
Pittsburgh, PA 15222
rting@aclupa.org

Ian Fahnestock
Human Relations Representative
PA Human Relations Commission
333 Market Street, 8th Floor
Harrisburg, PA 17101
ifahnestoc@pa.gov

By: s/ Jamie C. Cabuyadao
Jamie C. Cabuyadao
Practice Assistant

EXHIBIT C

DOCTRINAL NOTE ON THE MORAL LIMITS TO TECHNOLOGICAL MANIPULATION OF THE HUMAN BODY

Committee on Doctrine
United States Conference of Catholic Bishops

1. Modern technology offers an ever-increasing range of means—chemical, surgical, genetic—for intervening in the functioning of the human body, as well as for modifying its appearance. These technological developments have provided the ability to cure many human maladies and promise to cure many more. This has been a great boon to humanity. Modern technology, however, produces possibilities not only for helpful interventions, but also for interventions that are injurious to the true flourishing of the human person. Careful moral discernment is needed to determine which possibilities should be realized and which should not, in order to promote the good of the human person. To do this discernment, it is necessary to employ criteria that respect the created order inscribed in our human nature.

THE NATURAL ORDER

2. A fundamental tenet of the Christian faith is that there is an order in the natural world that was designed by its Creator and that this created order is good (Gen 1:31; Ps 19:1ff.). The Church has always affirmed the essential goodness of the natural order and called on us to respect it. The Second Vatican Council taught: "From the fact of being created, every thing possesses its own stability, truth and goodness, and its own laws and order, which should be respected by us in recognizing the methods which are appropriate to the various sciences and arts."[1] Pope Benedict XVI explained that the natural world has an "inbuilt order," a "grammar" that "sets forth ends and

[1] Second Vatican Council, Pastoral Constitution *Gaudium et Spes*, no. 36; in *Decrees of the Ecumenical Councils*, ed. Norman P. Tanner, S.J. (Washington, D.C.: Georgetown University Press, 1990).

criteria for its wise use, not its reckless exploitation."[2] Pope Francis has warned against a "technological paradigm" that treats the natural world as "something formless, completely open to manipulation."[3] He observes that human beings have always been intervening in nature,

> but for a long time this meant being in tune with and respecting the possibilities offered by the things themselves. It was a matter of receiving what nature itself allowed, as if from its own hand. Now, by contrast, we are the ones to lay our hands on things, attempting to extract everything possible from them while frequently ignoring or forgetting the reality in front of us.[4]

3. What is true of creation as a whole is true of human nature in particular: there is an order in human nature that we are called to respect. In fact, human nature deserves utmost respect since humanity occupies a singular place in the created order, being created in the image of God (Gen. 1:27). To find fulfillment as human persons, to find true happiness, we must respect that order. We did not create human nature; it is a gift from a loving Creator. Nor do we "own" our human nature, as if it were something that we are free to make use of in any way we please. Thus, genuine respect for human dignity requires that decisions about the use of technology be guided by genuine respect for this created order.

4. A crucial aspect of the order of nature created by God is the body-soul unity of each human person. Throughout her history, the Church has opposed dualistic conceptions of the human person that do not regard the body as an intrinsic part of the human person, as if the soul were essentially complete in itself and the body were merely an instrument used by the soul.[5] In opposition to dualisms both ancient and modern, the Church has always maintained that, while

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[2] Pope Benedict XVI, Encyclical Letter *Caritas in Veritate* (2009), no. 48 (https://www.vatican.va/content/benedict-xvi/en/encyclicals/documents/hf_ben-xvi_enc_20090629_caritas-in-veritate.html).

[3] Pope Francis, Encyclical Letter *Laudato Si'* (2015), no. 106 (https://www.vatican.va/content/francesco/en/encyclicals/documents/papa-francesco_20150524_enciclica-laudato-si.html).

[4] Pope Francis, *Laudato Si'*, no. 106.

[5] While in ancient and medieval thought dualism was typically expressed in terms of soul and body, in modern thought it is often expressed in terms of mind and body.

there is a distinction between the soul and the body, *both* are constitutive of what it means to be human, since spirit and matter, in human beings, "are not two natures united, but rather their union forms a single nature."[6] The soul does not come into existence on its own and somehow happen to be in this body, as if it could just as well be in a different body. A soul can never be in another body, much less be in the wrong body. *This* soul only comes into existence together with *this* body. What it means to be a human person necessarily includes bodiliness. "Human beings are physical beings sharing a world with other physical beings." [7]

5. Human bodiliness is, in turn, intrinsically connected with human sexual differentiation. Just as every human person necessarily has a body, so also human bodies, like those of other mammals, are sexually differentiated as male or female: "Male and female he created them" (Gen 1:27).[8] Saint John Paul II reminded us that, in the Book of Genesis, we learn that "Man is created 'from the very beginning' as male and female: the life of all humanity—whether of small communities or of society as a whole—is marked by this primordial duality."[9] The *Catechism of the Catholic Church* affirms: "Man and woman have been *created*, which is to say, *willed* by God: on the one hand, in perfect equality as human persons; on the other, in their respective beings as man and woman. 'Being man' or 'being woman' is a reality which is good and willed by God."[10]

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[6] *Catechism of the Catholic Church*, no. 365 (https://www.vatican.va/archive/ENG0015/__P1B.HTM): "The unity of soul and body is so profound that one has to consider the soul to be the 'form' of the body: i.e., it is because of its spiritual soul that the body made of matter becomes a living, human body; spirit and matter, in man, are not two natures united, but rather their union forms a single nature."

[7] International Theological Commission, *Communion and Stewardship: Human Persons Created in the Image of God* (2002), no. 26 (https://www.vatican.va/roman_curia/congregations/cfaith/cti_documents/rc_con_cfaith_doc_20040723_communion-stewardship_en.html).

[8] Persons affected by Disorders of Sexual Development do not fall outside the two categories of male and female, but they do exhibit ambiguous or abnormal indicators of sexual difference, so that the sex of their bodies is difficult to determine, though not impossible for modern medical and genetic techniques.

[9] Saint Pope John Paul II, *Letter to Families* (1994), no. 6 (https://www.vatican.va/content/john-paul-ii/en/letters/1994/documents/hf_jp-ii_let_02021994_families.html). Cf. *Catechism of the Catholic Church*, no. 2333.

[10] *Catechism of the Catholic Church*, no. 369.

Just as bodiliness is a fundamental aspect of human existence, so is either "being a man" or "being a woman" a fundamental aspect of existence as a human being, expressing a person's unitive and procreative finality. The Congregation for the Doctrine of the Faith insists that

> the importance and the meaning of sexual difference, as a reality deeply inscribed in man and woman, needs to be noted. "Sexuality characterizes man and woman not only on the physical level, but also on the psychological and spiritual, making its mark on each of their expressions." It cannot be reduced to a pure and insignificant biological fact, but rather "is a fundamental component of personality, one of its modes of being, of manifestation, of communicating with others, of feeling, of expressing and of living human love." This capacity to love – reflection and image of God who is Love – is disclosed in the spousal character of the body, in which the masculinity or femininity of the person is expressed.[11]

6. In our contemporary society there are those who do not share this conception of the human person. Pope Francis has spoken about an ideology that promotes "a personal identity and emotional intimacy radically separated from the biological difference between male and female," in which "human identity becomes the choice of the individual, one which can also change over time."[12] In response to this, Pope Francis affirmed:

> It needs to be emphasized that "biological sex and the socio-cultural role of sex (gender) can be distinguished but not separated." … It is one thing to be understanding of human weakness and the complexities of life, and another to accept ideologies that attempt to sunder what are inseparable aspects of reality. Let us not fall into the sin of trying to replace the Creator. We are creatures, and not omnipotent. Creation is prior to us and must be received as a gift. At the same time, we are called to protect our humanity, and this means, in the first place, accepting it and respecting it as it was created.[13]

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[11] Congregation for the Doctrine of the Faith, *Letter on the Collaboration of Men and Woman in the Church and in the World* (2004), no. 8 (https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20040731_collaboration_en.html); quotations from Congregation for Catholic Education, *Educational Guidance in Human Love: Outlines for Sex Education* (1983), no. 5 and no. 4, respectively.

[12] Pope Francis, Post-Synodal Apostolic Exhortation *Amoris Laetitia* (2016), no. 56; quoting the *Relatio Finalis* of the Synod on the Family (2015), no. 8 (https://www.vatican.va/content/francesco/en/apost_exhortations/documents/papa-francesco_esortazione-ap_20160319_amoris-laetitia.html).

[13] Pope Francis, *Amoris Laetitia*, no. 56; quoting the *Relatio Finalis*, no. 58.

TECHNOLOGICAL INTERVENTIONS

7. The human person, body and soul, man or woman, has a fundamental order and finality whose integrity must be respected. Because of this order and finality, neither patients nor physicians nor researchers nor any other persons have unlimited rights over the body; they must respect the order and finality inscribed in the embodied person. Pope Pius XII taught that the patient "is not the absolute master of himself, of his body, of his mind. He cannot dispose of himself just as he pleases."[14] The Pope went on to affirm that, with regard to the faculties and powers of one's human nature, a patient "is the user and not the owner" and thus "does not have an unlimited power to effect acts of destruction or of mutilation of a kind that is anatomical or functional."[15] The body is not an object, a mere tool at the disposal of the soul, one that each person may dispose of according to his or her own will, but it is a constitutive part of the human subject, a gift to be received, respected, and cared for as something intrinsic to the person. As Pope Francis affirmed: "The acceptance of our bodies as God's gift is vital for welcoming and accepting the entire world as a gift from the Father and our common home, whereas thinking that we enjoy absolute power over our own bodies turns, often subtly, into thinking that we enjoy absolute power over creation."[16]

8. There are essentially two scenarios recognized by the Church's moral tradition in which technological interventions on the human body may be morally justified: 1) when such

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[14] Pope Pius XII, "Discours aux participants au Congrès International d'Histopathologie du Système Nerveux," 14 September 1952 (https://www.vatican.va/content/pius-xii/fr/speeches/1952/documents/hf_p-xii_spe_19520914_istopatologia.html). See also his "Discours à la VIII[e] Assemblée de l'Association Médicale Mondiale," 30 September 1954 (https://www.vatican.va/content/pius-xii/fr/speeches/1954/documents/hf_p-xii_spe_19540930_viii-assemblea-medica.html).

[15] Pope Pius XII, "Discours," 14 September 1952.

[16] Pope Francis, *Laudato Si'*, no. 155. In the same paragraph, Pope Francis quotes Pope Benedict XVI, who asserted: "Man too has a nature that he must respect and that he cannot manipulate at will" (Address to the Bundestag, 22 September 2011 (https://www.vatican.va/content/benedict-xvi/en/speeches/2011/september/documents/hf_ben-xvi_spe_20110922_reichstag-berlin.html).

interventions aim to repair a defect in the body; 2) when the sacrifice of a part of the body is necessary for the welfare of the whole body. These kinds of technological interventions respect the fundamental order and finality inherent in the human person. However, there are other technological interventions that aim neither to repair some defect in the body nor to sacrifice a part for the sake of the whole but, rather, aim to alter the fundamental order of the body. Such interventions do not respect the order and finality inscribed in the human person.

REPAIRING A DEFECT IN THE BODY

9. Much of the practice of medicine involves using the available technology to repair defects in the body, usually when it has been affected by some injury or ailment.[17] The intention to repair defects in the body shows respect for the fundamental order of the body, which is commendable. In fact, each of us has a duty to care for our bodies. The *Ethical and Religious Directives for Catholic Health Care Services* affirm that "every person is obliged to use ordinary means[18] to preserve his or her health."[19] This obligation no longer holds, however, when the benefits of the intervention are no longer proportionate to the burdens involved.[20] Thus, judging whether or not

[17] Sometimes the technology is used not to return the body to a previous state but to compensate for some lack of normal development in the body.

[18] Use of extraordinary means is never morally obligatory. Cf. Pope Pius XII, "Discours du Pape Pie XII en réponse à trois questions de morale médicale sur la réanimation," 24 November 1957 (https://www.vatican.va/content/pius-xii/fr/speeches/1957/documents/hf_p-xii_spe_19571124_rianimazione.html); Congregation for the Doctrine of the Faith, "Commentary on the Responses to Certain Questions of the United States Conference of Catholic Bishops Concerning Artificial Nutrition and Hydration," 1 August 2007 (https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20070801_nota-commento_en.html).

[19] United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services,* Sixth Edition (2018), no. 32 (https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf); cf. no. 56. See also Congregation for the Doctrine of the Faith, *Declaration on Euthanasia* (1980), Pt. IV (https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19800505_euthanasia_en.html).

[20] USCCB, *Ethical and Religious Directives*, no. 32: "…no person should be obliged to submit to a health care procedure that the person has judged, with a free and informed conscience, not to provide a reasonable hope of benefit without imposing excessive risks and burdens on the patient or excessive expense to family or community".

a reparative medical intervention is morally licit requires a consideration not only of the object of the act and of the intention in undertaking it, but also of the consequences of the action, which would include an evaluation of the likelihood of discernible benefit to the person and a comparison of expected benefits with expected burdens. Sometimes the expected benefits (such as improved health or function) will outweigh the expected burdens (such as cost or physical pain involved in the procedure), but sometimes they will not.

10. A similar analysis is involved in considering the morality of interventions undertaken to improve the body not in terms of its functioning but rather in terms of its appearance, which can involve either restoring appearance or improving it. In this regard, Pope Pius XII acknowledged that the physical beauty of a person "is in itself a good, though subordinated to others that are much higher, and consequently precious and desirable."[21] He goes on to point out that physical beauty "does not stand at the summit of the scale of values, for it is a good that is neither spiritual nor essential"; indeed, it is "a good, but a corporal one … As a good and a gift from God, it must be esteemed and cared for, without, however, requiring recourse to extraordinary means as a duty."[22] Since the moral analysis requires that the expected benefits of a procedure be proportionate to the expected burdens and risks, a higher level of burden and risk can be justified in the case of someone who seeks to repair defects in order to achieve a normal appearance than in the case of someone who already has a normal appearance and who, as Pope Pius XII put it, seeks "the perfection of

[21] Pope Pius XII, "Discorso ai partecipanti al X Congresso Nazionale della Società Italiana di chirurgia plastica," 4 Oct. 1958, III (https://www.vatican.va/content/pius-xii/it/speeches/1958/documents/hf_p-xii_spe_19581004_chirurgia-plastica.html).

[22] Pope Pius XII, "Discorso," 4 October 1958, III.

his or her features."[23] Still, both of these could be morally licit, if undertaken with the correct intention and in the correct circumstances.[24]

The Sacrifice of a Part for the Sake of the Whole

11. Pope Pius XII's predecessor, Pope Pius XI, also stressed the need to respect the fundamental order of the body, affirming that, as a rule, one is not allowed "to destroy or mutilate" members of one's body. At the same time, however, he affirmed that there can be exceptions when the welfare of the body as a whole is at stake.

> Christian doctrine establishes, and the light of human reason makes it most clear, that private individuals have no other power over the members of their bodies than that which pertains to their natural ends; and they are not free to destroy or mutilate their members, or in any other way render themselves unfit for their natural functions, *except when no other provision can be made for the good of the whole body*.[25]

This teaching was further developed by Pope Pius XII, who explained that

> each particular organ is subordinated to the body as a whole and must yield to it in case of conflict. Therefore, the one who has been given the use of the whole organism has the right to sacrifice a particular organ, if its retention or its functioning causes significant harm to the whole, harm that cannot possibly be avoided any other way.[26]

12. Pope Pius XII stipulated three conditions that must be fulfilled for a medical intervention "that involves anatomical or functional mutilation" to be morally permissible:

> First, the retention or functioning of a particular organ in the organism as a whole causes serious damage to it or constitutes a threat.

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[23] Pope Pius XII, "Discorso," 4 October 1958, III.

[24] Pope Pius XII provides some examples of incorrect intentions, such as increasing one's power of seduction or protecting a guilty party from justice. He also gives as an example of an illicit cosmetic intervention one "that causes damage to the regular functions of the physical organs" ("Discorso," 4 October 1958, III).

[25] Pope Pius XI, Encyclical Letter *Casti Connubii* (1930), no. 71 (https://www.vatican.va/content/pius-xi/en/encyclicals/documents/hf_p-xi_enc_19301231_casti-connubii.html). Emphasis added.

[26] Pope Pius XII, "Discours aux Participants au XXVIe Congrès Organisé par la Société Italienne d'Urologie," 8 October 1953, I (https://www.vatican.va/content/pius-xii/fr/speeches/1953/documents/hf_p-xii_spe_19531008_congresso-urologia.html). Cf. St. Thomas Aquinas, *Summa theologiae* II-II, q. 65, a. 1; I-II, q. 90, a. 2.

> Second, this damage cannot be avoided, or at least appreciably diminished, otherwise than by the mutilation in question and the effectiveness of the mutilation is well assured.
>
> Finally, it can reasonably be expected that the negative effect, i.e., the mutilation and its consequences, will be compensated for by the positive effect: removal of the danger for the whole organism, lessening of suffering, etc.[27]

These conditions ensure proper respect for the fundamental order of the human person in that they establish that the sacrifice of the part of the body is not itself what is sought, that this is truly a last resort that is necessary for the welfare of the body, there being no other options for securing the welfare of the body as a whole.

Attempts to Alter the Fundamental Order of the Human Body

13. While the foregoing two types of technological interventions take the basic order of the human person as a given and do not intend to alter it, there is another type of intervention that regards this order as unsatisfactory in some way and proposes a more desirable order, a redesigned order. Some proposals for genetic engineering fit into this category: not those that aim to repair some defect, but those that are non-therapeutic manipulations of human genetic material. The Congregation for the Doctrine of the Faith has explained that "procedures used on somatic cells for strictly therapeutic purposes are in principle morally licit" since these procedures "seek to restore the normal genetic configuration of the patient or to counter damage caused by genetic anomalies or those related to other pathologies."[28] By contrast, genetic engineering "for purposes other than medical treatment" is not morally permissible.[29] Here the intention is to replace the

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[27] Pope Pius XII, "Discours," 8 October 1953, I.

[28] Congregation for the Doctrine of the Faith, *Instruction on Certain Bioethical Questions* (*Dignitas Personae*) (2008), no. 26 (https://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html). The Congregation adds the qualifications that the patient must not be "exposed to risks to his health or physical integrity which are excessive or disproportionate to the gravity of the pathology for which a cure is sought" and that the patient or his legitimate representative must give informed consent.

[29] Congregation for the Doctrine of the Faith, *Instruction on Certain Bioethical Questions* (*Dignitas Personae*), no. 27.

natural order with what is imagined to be a new and better order. The Congregation warns that "in the attempt to create *a new type of human being* one can recognize *an ideological element* in which man tries to take the place of his Creator."[30] In a similar way, some proposals for "cybernetic enhancement" also aim to redesign the fundamental order of the human being and to produce a new type of human being by replacing some or all[31] bodily organs with artificial devices. These kinds of technological interventions are, in most cases, currently in the developmental stage or are under theoretical consideration.

14. What is widely in practice today, however, and what is of great concern, is the range of technological interventions advocated by many in our society as treatments for what is termed "gender dysphoria" or "gender incongruence."[32] These interventions involve the use of surgical or chemical techniques that aim to exchange the sex characteristics of a patient's body for those of the opposite sex or for simulations thereof. In the case of children, the exchange of sex characteristics is prepared by the administration of chemical puberty blockers, which arrest the natural course of puberty and prevent the development of some sex characteristics in the first place.

15. These technological interventions are not morally justified either as attempts to repair a defect in the body or as attempts to sacrifice a part of the body for the sake of the whole. First, they do not repair a defect in the body: there is no disorder in the body that needs to be addressed; the bodily organs are normal and healthy. Second, the interventions do not sacrifice one part of

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[30] Congregation for the Doctrine of the Faith, *Instruction on Certain Bioethical Questions* (*Dignitas Personae*), no. 27

[31] Some even envision transferring what they imagine to be the essence of the human person from the brain into a computer, thereby leaving bodily existence behind altogether.

[32] The term "gender dysphoria" was introduced in 2013 in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (Arlington, VA: American Psychiatric Association, 2013), 452-53. The term "gender incongruence" was introduced in 2022 in the eleventh revision of the *International Classification of Diseases* published by the World Health Organization (https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f411470068).

the body for the good of the whole. When a part of the body is legitimately sacrificed for the sake of the whole body, whether by the entire removal or substantial reconfiguration of a bodily organ, the removal or reconfiguring of the bodily organ is reluctantly tolerated as the only way to address a serious threat to the body. Here, by contrast, the removal or reconfiguring is itself the desired result.[33]

16. Instead, rather than to repair some defect in the body or to sacrifice a part for the sake of the whole, these interventions are intended to transform the body so as to make it take on as much as possible the form of the opposite sex, contrary to the natural form of the body. They are attempts to alter the fundamental order and finality of the body and to replace it with something else.

17. There is a wide range of interventions used for this purpose, corresponding to the variety of ways in which sexual differentiation affects various parts of the body. Currently, not all persons who seek this kind of treatment undergo all the interventions available, either because they are unable to do so, or they choose not to do so for some reason; instead, they typically undergo some limited selection of the available interventions. These interventions differ in the magnitude of the changes brought about in the body. They are alike, however, in that they all have the same basic purpose: that of transforming sex characteristics of the body into those of the opposite sex.

18. Such interventions, thus, do not respect the fundamental order of the human person as an intrinsic unity of body and soul, with a body that is sexually differentiated. Bodiliness is a fundamental aspect of human existence, and so is the sexual differentiation of the body. Catholic health care services must not perform interventions, whether surgical or chemical, that aim to

[33] With some procedures of this category, the removal of the organ is directly intended in order to allow for its replacement with a simulation of the corresponding organ of the opposite sex; in other procedures, the removal of the organ is directly intended because the absence of the organ is a characteristic of the opposite sex; in still others, the reconfiguring of the organ is directly intended in order to make the organ resemble as much as possible the corresponding organ of the opposite sex.

transform the sexual characteristics of a human body into those of the opposite sex or take part in the development of such procedures. They must employ all appropriate resources to mitigate the suffering of those who struggle with gender incongruence, but the means used must respect the fundamental order of the human body. Only by using morally appropriate means do healthcare providers show full respect for the dignity of each human person.

CONCLUSION: MORAL LIMITS TO THE TECHNOLOGICAL MANIPULATION OF THE HUMAN BODY

19. The use of technology in order to manipulate the natural world has a history that goes back to the earliest use of tools. What is different in our day is the greatly expanded capabilities that modern technology offers and the rapid development of ever-new possibilities. As the boundaries of what is technologically possible continue to expand, it is imperative to identify moral criteria to guide our use of technology. As the range of what we *can* do expands, we must ask what we *should* or *should not* do. An indispensable criterion in making such determinations is the fundamental order of the created world. Our use of technology must respect that order.

20. To be sure, many people are sincerely looking for ways to respond to real problems and real suffering.[34] Certain approaches that do not respect the fundamental order appear to offer solutions. To rely on such approaches for solutions, however, is a mistake. An approach that does not respect the fundamental order will never truly solve the problem in view; in the end, it will only create further problems. The Hippocratic tradition in medicine calls upon all healthcare providers first and foremost to "do no harm." Any technological intervention that does not accord with the fundamental order of the human person as a unity of body and soul, including the sexual difference inscribed in the body, ultimately does not help but, rather, harms the human person.

[34] With regard to those who identify as transgender or non-binary, there is a range of pastoral issues that need to be addressed, but that cannot be addressed in this document.

21. Particular care should be taken to protect children and adolescents, who are still maturing and who are not capable of providing informed consent. As Pope Francis has taught, young people in particular

> need to be helped to accept their own body as it was created, for "thinking that we enjoy absolute power over our own bodies turns, often subtly, into thinking that we enjoy absolute power over creation… An appreciation of our body as male or female is also necessary for our own self-awareness in an encounter with others different from ourselves. In this way we can joyfully accept the specific gifts of another man or woman, the work of God the Creator, and find mutual enrichment."[35]

22. The search for solutions to problems of human suffering must continue, but it should be directed toward solutions that truly promote the flourishing of the human person in his or her bodily integrity. As new treatments are developed, they too should be evaluated according to sound moral principles grounded in the good of the human person as a subject with his or her own integrity. Catholic health care services are called to provide a model of promoting the authentic good of the human person. To fulfill this duty, all who collaborate in Catholic health care ministry must make every effort, using all appropriate means at their disposal, to provide the best medical care, as well as Christ's compassionate accompaniment, to all patients, no matter who they may be or from what condition they may be suffering. The mission of Catholic health care services is nothing less than to carry on the healing ministry of Jesus, to provide healing at every level, physical, mental, and spiritual.[36]

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[35] Pope Francis, Encyclical Letter *Amoris Laetitia*, no. 285; quotation from his Encyclical Letter *Laudato Si'*, no. 155.

[36] See USCCB, *Ethical and Religious Directives for Catholic Health Care Services*, General Introduction.

USCCB Committee on Doctrine

Most Reverend Daniel E. Flores
Bishop of Brownsville
Chairman

Most Reverend Michael C. Barber, S.J.
Bishop of Oakland

Most Reverend Richard G. Henning
Auxiliary Bishop of Diocese of Rockville Centre

Most Reverend Steven J. Lopes
Bishop of the Personal Ordinariate of the Chair of St. Peter

Most Reverend James Massa
Auxiliary Bishop of Brooklyn

Most Reverend Robert J. McManus
Bishop of Worcester

Most Reverend Michael F. Olson
Bishop of Fort Worth

Most Reverend Kevin C. Rhoades
Bishop of Fort Wayne-South Bend

Most Reverend William E. Lori
Archbishop of Baltimore
Bishop Consultant

Doctrinal Note on the Moral Limits to Technological Manipulation of the Human Body is a statement of the Committee on Doctrine. It was authorized by the USCCB Administrative Committee at its March 2023 meeting. It has been directed for publication by the undersigned.

Rev. Michael J. K. Fuller
General Secretary, USCCB

EXHIBIT D

Why is the Catholic Church such a strong voice for life?

The *Catechism of the Catholic Church* puts it this way:

"Human life must be respected and protected absolutely from the moment of conception. From the first moment of his existence, a human being must be recognized as having the rights of a person—among which is the inviolable right of every innocent being to life..."[1]

"Since the first century the Church has affirmed the moral evil of every procured abortion. This teaching has not changed and remains unchangeable. Direct abortion, that is to say, abortion willed either as an end or a means, is gravely contrary to the moral law..."[2]

"We are the *people of life* because God, in his unconditional love, has given us the Gospel of life ... and we are called to act accordingly."

Saint John Paul II
Evangelium Vitae, 79
1995

People of Life

People of Life is the pro-life action campaign of the Catholic Church in the United States, under the direction of the USCCB Secretariat of Pro-Life Activities.

USCCB Secretariat of Pro-Life Activities
3211 Fourth Street, N.E.
Washington, DC 20017-1194
202-541-3070
www.usccb.org/prolife

1 *Catechism of the Catholic Church*, 2nd ed., 2270.
2 *Catechism of the Catholic Church*, 2nd ed., 2271.
3 *The Didache*, by Charles H. Hoole, [1894], at sacred-texts.com. <http://www.sacred-texts.com/chr/did/did03.htm>
4 Translated by S. Thelwall. From Ante-Nicene Fathers, Vol. 3. Edited by Alexander Roberts, James Donaldson, and A. Cleveland Coxe. (Buffalo, NY: Christian Literature Publishing Co., 1885.) Revised and edited for New Advent by Kevin Knight. <http://www.newadvent.org/fathers/0301.htm>.
5 Charles H. Hoole, 1885 translation <http://www.earlychristianwritings.com/text/barnabas-hoole.html>
6 Congregation for the Doctrine of the Faith, *Declaration on Procured Abortion*, (Vatican City: Libreria Editrice Vaticana, 1974), no. 11.
7 Pope John Paul II, *Evangelium vitae*, (Vatican City: Libreria Editrice Vaticana, 1995), no. 28.
8 Ibid.

1914

The Catholic Church *is a Pro-Life Church*

All persons, not just Catholics,

can know from scientific and medical evidence that what grows in a mother's womb is a new, distinct human being. All persons can understand that each human being merits respect. At the very least, respecting human life excludes the deliberate and direct destruction of life.

Throughout her rich tradition, the Catholic Church has always been pro-life. As Saint John Paul II reminded us, we believe that "all human life is sacred, for it is created in the image and likeness of God." Aborting an unborn child destroys a precious human life which God has called uniquely into existence.

Our Faith also obliges us to follow in the footsteps of Jesus Christ, who spoke and acted strongly and compassionately in favor of the most despised and vulnerable persons in society. Jesus touched lepers, spoke with prostitutes, and showed mercy and tenderness to the sick, the poor and children.

Our society has many vulnerable persons including women in difficult pregnancies as well as unborn children whose lives may legally be ended at any time during pregnancy,

The* DIDACHE *2nd Cent.
"You shall not commit murder. You shall not commit adultery. You shall not corrupt the young. You shall not commit fornication. You shall not steal. You shall not kill an unborn child or murder a newborn infant."[3]

and for any reason. In following Jesus Christ, Catholics have a responsibility to speak and act in defense of these persons. This is part of our special care for the poor and powerless.

TERTULLIAN *3rd Cent.*
"For us, killing and murder forbidden once and for all, it is not permitted to destroy what is conceived in the mother's womb. To hinder the birth of a child is a faster way to murder. It makes little difference whether one destroys a life already born or prevents it from coming to birth. It is a human being, for the whole fruit is already present."[4]

The Church's mission to defend

human life applies over the entire course of life, from conception to natural death. And so the Catholic Church has defended human rights and conducted international relief and development efforts. Catholic hospitals and other healthcare facilities form the largest network of private, not-for-profit healthcare providers in the United States. Our Catholic charitable organizations provide countless social services to all Americans, regardless of race, creed or national origin.

***The Letter of* BARNABAS**
2nd Cent.
"You shall not murder a child by abortion, nor kill it after birth."[5]

The Catholic Church strives to be a prophetic voice, speaking out to protest injustices and indignities against the human person. We will continue in this work, whether our words are popular or unpopular.

Since its beginning, the Church has maintained a firm and clear teaching on the sacredness of human life. Abortion was rejected in the earliest known Christian manual of discipline, the Didache.

Early Christian fathers likewise condemned abortion as the killing of innocent human life. A third century Father of the Church, Tertullian, called it "accelerated homicide." Early Church councils considered it one of the most serious crimes. Since that time, science has only further confirmed the humanity of the child growing in his or her mother's womb. Church teaching continues to insist, to the present day, that a just society protects and cares for life before as well as after birth.

DECLARATION ON PROCURED ABORTION, 11
Congregation for the Doctrine of the Faith,1974
"The first right of the human person is his life. He has other goods and some are more precious, but this one is fundamental - the condition of all the others. Hence it must be protected above all others."[6]

Saint John Paul II challenged us:

"We find ourselves not only faced with but necessarily in the midst of this conflict: we are all involved and we all share in it, with the inescapable responsibility of choosing to be unconditionally pro-life."[7] As a people who believe in life, how are we responding to this challenge?

EVANGELIUM VITAE, 28
1995
". . . we are facing an enormous and dramatic clash between good and evil, death and life, the 'culture of death' and the 'culture of life'. We find ourselves not only faced with but necessarily in the midst of this conflict: we are all involved and we all share in it, with the inescapable responsibility of choosing to be unconditionally pro-life."[8]

EXHIBIT E

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E S,	:	
	:	PHRC Case No. 202401365
Complainant	:	
	:	
v.	:	
	:	
St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph; The Pennsylvania State University; Penn State Health,	:	
Respondent	:	

COMMISSION'S MOTION TO DISCONTINUE

AND NOW, comes Stacy McNaney, Assistant Chief Counsel, on behalf of the Pennsylvania Human Relations Commission (hereinafter "Commission"), and files this Motion to Discontinue, and sets forth the following in support:

1. On January 22, 2025, E S ("Complainant") filed a Complaint alleging that St. Joseph Regional Health Network et. al. ("Respondents") discriminated against Complainant by denying access to services based on sex.
2. On March 31, 2025, Respondents filed an Answer to the Complainant raising the Pennsylvania Religious Freedom Protection Act, 71 P.S. §§ 2401-2408 ("RFPA"), as a defense and requesting dismissal.
3. On August 29, 2025, Respondents filed a Petition for Review against the Commission in the Commonwealth Court of Pennsylvania, docketed at 335 MD 2025. The Petition alleges that the Commission's enactment and enforcement of its August 2023 regulations burdens Respondent's free exercise of religion in violation of the RFPA.

4. On September 5, 2025, Respondent filed a Motion to Stay the instant case pending resolution of the matter filed in Commonwealth Court.

5. Respondent has established that it is entitled to relief pursuant to the RFPA. The Commission's regional office staff closed the instant case on October 1, 2025.

WHEREFORE, in accordance with the foregoing, the Commission respectfully requests that this matter be marked discontinued and dismissed.

Respectfully submitted,

October 2, 2025
Date

/s/ Stacy McNaney
Stacy McNaney, Esq.
Assistant Chief Counsel
PA Human Relations Commission
333 Market Street, 8th floor
Harrisburg, PA 17101
smcnaney@pa.gov

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E[redacted] S[redacted],	:	
	:	PHRC Case No. 202401365
Complainant	:	
	:	
v.	:	
	:	
St. Joseph Regional Health Network, d/b/a Penn State Health St. Joseph; The Pennsylvania State University; Penn State Health,	:	
Respondent	:	

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served this 2nd day of October 2025, upon the persons and in the manner indicated below:

Attorney for Complainant:
Richard T. Ting, Esq.
ACLU of Pennsylvania
PO Box 23058
Pittsburgh, PA 15222
rting@aclupa.org
Via email

Attorneys for Respondents:
Anthony (T.J.) Andrisano, Esq.
Alyssa K. Stouder, Esq.
Buchanan Ingersoll & Rooney PC
409 N. Second Street, Suite 500
Harrisburg, PA 17101
anthony.andrisano@bipc.com
alyssa.stouder@bipc.com
Via email

/s/ Stacy McNaney

EXHIBIT F

PennState Health

Care for Transgender and Gender-Diverse Individuals

Gender-Affirming Health Care - Adults

Penn State Health Internal Medicine provides care for transgender and gender-diverse adults aged 19 and older in a supportive and safe environment. Primary care clinicians and other health care providers at Penn State Health are trained in gender-affirming care, and they support the comprehensive health needs of transgender and gender-diverse adult patients throughout central Pennsylvania and the surrounding mid-Atlantic region.

Our services include:

- Primary care
- Hysterectomy and/or bilateral salpingo-oophorectomy
- Chest surgeries
- Vocal care
  - Speech-Language Pathology
- Sexual health care
  - Contraception
- Reproductive and family building care
  - Reproductive Endocrinology and Infertility
- Hormone therapy and other gender-focused consultative care

For more information or to schedule an appointment, call 800-243-1455 or visit https://www.pennstatehealth.org/doctors.

Gender Health Program - Pediatrics

The Gender Health Clinic at Penn State Health Children's Hospital provides psychosocial care for children, adolescents and young adults throughout Pennsylvania. The clinic's collaborative team of providers are specially trained to meet the needs of their patients within a supportive and safe environment.

Penn State Health does not perform gender-affirming surgery on individuals under age 19.

Your Voice, Our Action: The Sexual and Gender Minority Advisory Council

At Penn State Health, our commitment to improving health care services extends to our governance. The Sexual and Gender Minority Advisory Council works to advance health care outcomes for our patients, using feedback from our community to inform policy changes, education initiatives and service improvements.

Our People, Our Pride: The LGBTQ+ Business Employee Resource Group

We understand that the strength of our health care system lies in the diversity of our staff. Our LGBTQ+ Business Employee Resource Group fosters an inclusive workplace where every voice is heard, promoting policies and practices that make Penn State Health a welcoming environment for our LGBTQ+ employees.

We Ask About Pronouns Because We Care

Sometimes people make assumptions about a person's gender based on their appearance. These assumptions can send a potentially harmful message that people have to look a certain way to demonstrate gender. Using a person's preferred name and correct pronouns is important to ensure every person feels heard, valued and respected.

Asking for your preferred name and pronouns helps us understand who you are and ensures you are addressed in a way that makes you feel comfortable and respected.

Frequently Asked Questions

Who has access to view a patient's preferred name vs. legal name?
Anyone who accesses a patient's electronic medical record will see their legal name, with the preferred name in parentheses.

What name will Penn State Health use in mailed appointment reminders, bills, etc.?
Penn State Health will use the legal name on file in all mailed correspondence. A preferred name is meant to indicate how to address a patient when speaking to them directly.

What name will be listed in the patient portal?
A patient's preferred name can be listed in the patient portal in the "Update Account" setting.

What name will be listed on patient materials, such as stickers, armbands, etc.?
Armbands will include a patient's legal name, with their preferred name and pronouns in parentheses. However, the Centers for Medicare & Medicaid Services (CMS) requires a patient's legal name for medications and lab orders.

HAMPDEN MEDICAL CENTER

717-981-9000

HERSHEY MEDICAL CENTER

800-243-1455

HOLY SPIRIT MEDICAL CENTER

717-763-2100

LANCASTER MEDICAL CENTER

223-287-9000

PENNSYLVANIA PSYCHIATRIC INSTITUTE

717-782-6493

ST. JOSEPH MEDICAL CENTER

610-378-2000

LANGUAGE ASSISTANCE

Spanish (español) | Nepali (नेपाली) | Arabic (عربي) | American Sign Language | Vietnamese (Tiếng Việt) | Russian (Русский) | French (Français) | Chinese (中文) | Hindi (हिंदी) | Korean (한국어) | Urdu (اردو) | German (Deutsch) | Greek (Ελληνικά) | Romanian (Română) | Serbo-Croatian (srpskohrvatski) | Haitian Creole (Kreyòl Ayisyen)

EXHIBIT G

Presidential Documents

Executive Order 14187 of January 28, 2025

Protecting Children From Chemical and Surgical Mutilation

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Policy and Purpose.* Across the country today, medical professionals are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions. This dangerous trend will be a stain on our Nation's history, and it must end.

Countless children soon regret that they have been mutilated and begin to grasp the horrifying tragedy that they will never be able to conceive children of their own or nurture their children through breastfeeding. Moreover, these vulnerable youths' medical bills may rise throughout their lifetimes, as they are often trapped with lifelong medical complications, a losing war with their own bodies, and, tragically, sterilization.

Accordingly, it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called ''transition'' of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures.

Sec. 2. *Definitions.* For the purposes of this order:

(a) The term ''child'' or ''children'' means an individual or individuals under 19 years of age.

(b) The term ''pediatric'' means relating to the medical care of a child.

(c) The phrase ''chemical and surgical mutilation'' means the use of puberty blockers, including GnRH agonists and other interventions, to delay the onset or progression of normally timed puberty in an individual who does not identify as his or her sex; the use of sex hormones, such as androgen blockers, estrogen, progesterone, or testosterone, to align an individual's physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex or that attempt to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions. This phrase sometimes is referred to as ''gender affirming care.''

Sec. 3. *Ending Reliance on Junk Science.* (a) The blatant harm done to children by chemical and surgical mutilation cloaks itself in medical necessity, spurred by guidance from the World Professional Association for Transgender Health (WPATH), which lacks scientific integrity. In light of the scientific concerns with the WPATH guidance:

(i) agencies shall rescind or amend all policies that rely on WPATH guidance, including WPATH's ''Standards of Care Version 8''; and

(ii) within 90 days of the date of this order, the Secretary of Health and Human Services (HHS) shall publish a review of the existing literature on best practices for promoting the health of children who assert gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion.

(b) The Secretary of HHS, as appropriate and consistent with applicable law, shall use all available methods to increase the quality of data to guide practices for improving the health of minors with gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion, or who otherwise seek chemical or surgical mutilation.

Sec. 4. *Defunding Chemical and Surgical Mutilation.* The head of each executive department or agency (agency) that provides research or education grants to medical institutions, including medical schools and hospitals, shall, consistent with applicable law and in coordination with the Director of the Office of Management and Budget, immediately take appropriate steps to ensure that institutions receiving Federal research or education grants end the chemical and surgical mutilation of children.

Sec. 5. *Additional Directives to the Secretary of HHS.* (a) The Secretary of HHS shall, consistent with applicable law, take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions, which may involve the following laws, programs, issues, or documents:

(i) Medicare or Medicaid conditions of participation or conditions for coverage;

(ii) clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs;

(iii) mandatory drug use reviews;

(iv) section 1557 of the Patient Protection and Affordable Care Act;

(v) quality, safety, and oversight memoranda;

(vi) essential health benefits requirements; and

(vii) the Eleventh Revision of the International Classification of Diseases and other federally funded manuals, including the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

(b) The Secretary of HHS shall promptly withdraw HHS's March 2, 2022, guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy" and, in consultation with the Attorney General, issue new guidance protecting whistleblowers who take action related to ensuring compliance with this order.

Sec. 6. *TRICARE.* The Department of Defense provides health insurance, through TRICARE, to nearly 2 million individuals under the age of 18. As appropriate and consistent with applicable law, the Secretary of Defense shall commence a rulemaking or sub-regulatory action to exclude chemical and surgical mutilation of children from TRICARE coverage and amend the TRICARE provider handbook to exclude chemical and surgical mutilation of children.

Sec. 7. *Requirements for Insurance Carriers.* The Director of the Office of Personnel Management, as appropriate and consistent with applicable law, shall:

(a) include provisions in the Federal Employee Health Benefits (FEHB) and Postal Service Health Benefits (PSHB) programs call letter for the 2026 Plan Year specifying that eligible carriers, including the Foreign Service Benefit Plan, will exclude coverage for pediatric transgender surgeries or hormone treatments; and

(b) negotiate to obtain appropriate corresponding reductions in FEHB and PSHB premiums.

Sec. 8. *Directives to the Department of Justice.* The Attorney General shall:

(a) review Department of Justice enforcement of section 116 of title 18, United States Code, and prioritize enforcement of protections against female genital mutilation;

(b) convene States' Attorneys General and other law enforcement officers to coordinate the enforcement of laws against female genital mutilation across all American States and Territories;

(c) prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the Food, Drug, and Cosmetic Act by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation;

(d) in consultation with the Congress, work to draft, propose, and promote legislation to enact a private right of action for children and the parents of children whose healthy body parts have been damaged by medical professionals practicing chemical and surgical mutilation, which should include a lengthy statute of limitations; and

(e) prioritize investigations and take appropriate action to end child-abusive practices by so-called sanctuary States that facilitate stripping custody from parents who support the healthy development of their own children, including by considering the application of the Parental Kidnaping Prevention Act and recognized constitutional rights.

Sec. 9. *Enforcing Adequate Progress.* Within 60 days of the date of this order, the heads of agencies with responsibilities under this order shall submit a single, combined report to the Assistant to the President for Domestic Policy, detailing progress in implementing this order and a timeline for future action. The Assistant to the President for Domestic Policy shall regularly convene the heads of agencies with responsibilities under this order (or their designees) to coordinate and prepare for this submission.

Sec. 10. *Severability.* If any provision of this order, or the application of any provision to any person or circumstances, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

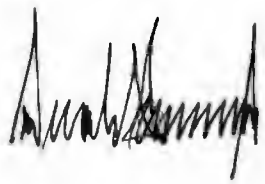
Sec. 11. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 28, 2025.

[FR Doc. 2025–02194
Filed 1–31–25; 8:45 am]
Billing code 3395–F4–P

EXHIBIT H

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Director
Office for Civil Rights
Washington, D.C. 20201

February 20, 2025

Re: Recission of "HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy" (issued March 2, 2022)

Pursuant to Section 5(b) of Executive Order ("E.O.") 14187, "Protecting Children from Chemical and Surgical Mutilation," the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) hereby rescinds, "HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy," originally issued on March 2, 2022 ("2022 OCR Notice and Guidance"). This recission is effective immediately.

Background

On March 2, 2022, HHS OCR issued the 2022 OCR Notice and Guidance, stating that transgender medical interventions may improve both physical and mental health outcomes for minors. The 2022 OCR Notice and Guidance outlined the application of federal civil rights and patient privacy laws to such medical treatments for minors in three ways.

First, the 2022 OCR Notice and Guidance stated that Section 1557 of the Affordable Care Act ("ACA")[1] prohibits discrimination based on gender identity in federally-funded healthcare settings. Specifically, it provides in relevant part:

> Categorically refusing to provide treatment to an individual based on their gender identity is prohibited discrimination. Similarly, federally-funded covered entities restricting an individual's ability to receive medically necessary care, including gender-affirming care, from their health care provider solely on the basis of their sex assigned at birth or gender identity likely violates Section 1557. For example, if a parent and their child visit a doctor for a consultation regarding or to receive gender affirming care, and the doctor or other staff at the facility reports the parent to state authorities for seeking such care, that reporting may constitute violation of Section 1557 if the doctor or facility receives federal financial assistance.

[1] 42 U.S.C. § 18116.

> Restricting a health care provider's ability to provide or prescribe such care may also violate Section 1557.

Second, the 2022 OCR Notice and Guidance noted that gender dysphoria might qualify as a disability under Section 504 of the Rehabilitation Act and the Americans with Disabilities Act, and that "[r]estrictions that prevent otherwise qualified individuals from receiving medically necessary care on the basis of their gender dysphoria, gender dysphoria diagnosis, or perception of gender dysphoria may, therefore, also violate Section 504 and Title II of the ADA."

Finally, regarding patient privacy, the 2022 OCR Notice and Guidance emphasized that healthcare providers and other covered entities cannot disclose protected health information about gender-affirming care without patient authorization, except in limited circumstances where explicitly required by law, i.e., "limited to 'a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law.'"

Basis for Rescission

HHS OCR rescinds the 2022 OCR Notice and Guidance under E.O. 14187, "Protecting Children from Chemical and Surgical Mutilation." Specifically, Section 5(b) of the E.O. provides: "The Secretary of HHS shall promptly withdraw HHS's March 2, 2022, guidance document titled 'HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy' and, in consultation with the Attorney General, issue new guidance protecting whistleblowers who take action related to ensuring compliance with this order."[2]

First, the legal basis for the 2022 OCR Notice and Guidance under Section 1557 of the ACA has been called into question by several court decisions. To start, on October 1, 2022, the District Court for the Northern District of Texas vacated this guidance, *Texas v. EEOC et al.*, No. 2:21-cv-00194-Z, ECF No. 74 (N.D. Tex. 2022), noting that Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of "sex" discrimination that the Supreme Court of the United States adopted in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), is inapplicable to the prohibitions on "sex" discrimination in Section 1557 of the ACA.

The district court's rationale was followed by several other federal courts addressing the same issue—whether the prohibition on sex discrimination found in Section 1557 of the ACA included discrimination on the basis of gender identity. *See Tennessee, et al. v. Kennedy, et al.*, No. 1:24-cv-00161-LG-BWR (S.D. Miss. July 3, 2024) ("It is further ordered and adjudged that the July 5, 2024, effective date of the final rule entitled Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024) is stayed nationwide pursuant to 5 U.S.C. § 705, in so far as this final rule is intended to extend discrimination on the basis of sex to include discrimination on the basis of gender identity in the following regulations: 42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, 460.112; 45 C.F.R. §§ 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206-211, 92.301,

[2] On February 14, 2025, the District Court for the Western District of Washington issued a Temporary Restraining Order with regard to enforcement or implementation of Sections 4 and 8(a) of E.O. 14187. *See State of Washington et al., v. Trump, et. al.,* No. 2:25-cv-00244-LK, ECF No. 158 (W.D. Was. Feb. 14, 2025). The order does not bear on this Recission, which is issued under Section 5 of the E.O.

92.303, 92.304."); *Florida v. HHS*, No. 8:24-cv-01080-WFJ-TGW (M.D. Fl. July 3, 2024), No. 24-12826 (11th Cir.) (granting Plaintiffs' motion for a preliminary injunction within the State of Florida, staying the effective date of the sex discrimination provisions in the Section 1557 final rule); *Texas, et al., v. Kennedy*, No. 6:24-cv-211-JDK (E.D. Tex. August 30, 2024), No. 24-40568 (5th Cir.) (issuing a nationwide injunction on the sex discrimination provisions challenged by Plaintiffs, specifically "42 C.F.R. §§438.3(d)(4), 438.206(c)(2), 440.262, 460.98(b)(3), 460.112(a); 45 C.F.R. §§ 92.101(a)(2) (and all references to this subsection), 92.206(b), 92.207(b)(3)–(5).").

Second, gender dysphoria likely does not meet the definition of a disability under Section 504 of the Rehabilitation Act.[3] The relevant statute specifically excludes from the definition of disability "transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, *gender identity disorders not resulting from physical impairments*, or other sexual behavior disorders."[4] In its decision vacating the 2022 OCR Notice and Guidance, the Northern District of Texas pointed to this statutory language and held that the March 2022 Notice and Guidance's conclusion concerning Section 504 was arbitrary and capricious, reasoning that Defendants "appear to misstate the law and do not detail what went into their decisionmaking." *Texas*, 2:21-cv-00194, ECF No. 74. It is likely that the Section 504 drafters intended "gender identity disorders not resulting from physical impairments" to apply to gender dysphoria.

Finally, the 2022 OCR Notice and Guidance lacks adequate legal basis under federal privacy laws, including the HIPAA Privacy, Security and Breach Notification Rules.[5] By its own terms, the HIPAA Privacy Rule permits covered entities and business associates to disclose PHI about an individual, without the individual's authorization,[6] when such disclosure is required by another law and the disclosure complies with the requirements of the other law.[7]

Accordingly, effective immediately, the 2022 OCR Notice and Guidance no longer represents the views or policies of HHS OCR. Covered entities should no longer rely on the rescinded 2022 OCR Notice and Guidance. Pursuant to E.O. 14187 HHS shall, in consultation with the Attorney General, expeditiously issue new guidance protecting whistleblowers who take action related to ensuring compliance with this order.

/s/
Anthony F. Archeval
Acting Director
HHS Office for Civil Rights

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[3] 45 C.F.R. 84.4.
[4] 29 U.S.C. § 705(20)(F)(i).
[5] 45 C.F.R. Parts 160 and 164, Subparts A, C, D, and E.
[6] *See* 45 C.F.R. 164.508(c) (HIPAA authorization required elements).
[7] 45 C.F.R. 164.512(a)(1).

EXHIBIT I

Guidance for Whistleblowers on the Chemical and Surgical Mutilation of Children

In Executive Order 14187, "Protecting Children from Chemical and Surgical Mutilation," President Trump demonstrated his Administration's commitment to ending the mutilation of children carried out by medical professionals in the name of radical gender ideology. Pursuant to Section 5(b) of that Order, the United States Department of Health and Human Services (HHS), including its Office for Civil Rights (OCR), in consultation with the Attorney General, issues this guidance for prospective whistleblowers.

The Executive Order recognizes that individuals may fear legal and/or professional repercussions if they wish to blow the whistle on "medical professionals [who] are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions."[1] Indeed, there are two significant impediments

that one might face. First, one may be worried that one cannot report the performance of chemical and surgical mutilation of children without violating patient privacy laws and regulations, namely, the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[2]. Second, one may be worried that there is nothing to stop retaliation by his or her employer, *i.e.*, one may be worried about being fired or demoted in his or her job.

We hope this guidance will allay such fears. It explains existing protections for "whistleblowers who take action related to ensuring compliance with" the Executive Order[3]. First, as explained further below, HIPAA does not prohibit the disclosure of information related to the chemical and surgical mutilation of children, provided certain conditions are met. Second, as explained further below, the law provides robust anti-retaliation protections for individuals who make a report in order to ensure compliance with the Executive Order.

I. The Health Insurance Portability and Accountability Act of 1996

OCR administers and enforces the HIPAA Privacy Rule[4], which establishes requirements with respect to the use, disclosure, and protection of protected health information (PHI) by covered entities (health plans, health care clearinghouses, and most health care providers) and, to some extent, by their business associates[5]. The Privacy Rule protects PHI by limiting the circumstances under which covered entities and their business associates are permitted or required to use or disclose PHI and by requiring covered entities to have safeguards in place to protect the privacy of PHI. Since its inception, the Privacy Rule has also afforded covered entities protection from liability under HIPAA for disclosures of PHI in connection with whistleblowing actions of their workforce members or business associates.[6]

In many instances, information that has been de-identified[7] in accordance with the Privacy Rule can be used to accomplish whistleblower objectives. But there are instances, especially involving patient care and billing, where this may not be feasible. Therefore, the whistleblower provision of the Privacy Rule provides that a

covered entity is not considered to have violated the requirements of the Privacy Rule when a workforce member or business associate discloses PHI in the following circumstances:

1. The workforce member or business associate has a good faith belief that the conduct being reported is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public[8], and

2. The workforce member or business associate of the covered entity discloses PHI to any of the following:

    a. A health oversight agency[9] or public health authority[10] authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity.

    b. An appropriate health care accreditation organization[11], such as a state medical board, for the purpose of reporting the allegation of failure to meet professional standards[12] or misconduct by the covered entity.

    c. An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining his or her legal options with respect to whistleblowing.

Thus, the Privacy Rule protects a covered entity from liability for the good-faith whistleblower action of a member of its workforce or a business associate in some situations. For example, where the workforce member or business associate of a covered entity:

- Discloses PHI to a county public health department to report unsanitary conditions during a procedure based on a good faith belief that the conditions endangered a patient.

- Discloses PHI to a state medical board to report conduct by a health care provider that the person making the report believes, in good faith, constituted professional misconduct.

- In a state that prohibits prescribing to minors puberty blockers and cross-sex hormones, provides PHI to the state medical board based on a good faith belief that a clinician has unlawfully prescribed such medications to a minor patient.

- Provides PHI to the state attorney general where the state attorney general is authorized by law to investigate or otherwise oversee the payment of claims by the state Medicaid program, and the workforce member or business associate disclosing the PHI has a good faith belief that the covered entity is fraudulently billing the state Medicaid program for health care that is not being provided.

In contrast, the Privacy Rule's whistleblower provision would not protect a covered entity from liability under HIPAA where, for example, a member of its workforce or its business associate:

- Discloses PHI to the media to publicly expose unsafe conditions in a health care facility that potentially endanger patients. Because the whistleblower protection does not cover disclosures of PHI to the media, a covered entity's workforce member or business associate would not be permitted to disclose PHI to the media absent an applicable permission under the Privacy Rule. Generally, a disclosure of PHI to the media requires a written HIPAA authorization from the individual who is the subject of the information.[13]

- Discloses PHI to law enforcement to report unlawful conduct, unless the law enforcement agency meets the definition of a health oversight agency or public health authority.[14] If the agency does not meet either of those definitions, the whistleblower provision does not apply, so a disclosure to law enforcement would require an applicable Privacy Rule permission such as the provisions permitting limited uses and disclosures to a law enforcement official for law enforcement purposes.[15]

- Discloses PHI to expose malfeasant conduct by another person, such as knowledge gained during the course of treatment about an individual's illicit drug use. Such disclosure would not be a protected activity under the whistleblower provision, because the provision only relates to whistleblower actions in relation to the conduct and conditions of the covered entity.

- Discloses PHI in response to a request from a health care accreditation organization, because the whistleblower provision applies only to a disclosure initiated by a member of a covered entity's workforce or a business associate.[16]

Note that the protection from liability for covered entities under 45 C.F.R. 164.502(j)(1) applies even where a disclosure that falls within the Privacy Rule's whistleblower provisions might otherwise violate another provision of the Privacy Rule, including the modifications made to the Privacy Rule by the "HIPAA Privacy Rule to Support Reproductive Healthcare Privacy," 89 Fed. Reg. 32976 (Apr. 26, 2024).

II. Applicable Legal Protections

Whistleblowing activities are a critical tool to help identify health care fraud and protect the public's health and safety. Congress and many states have recognized their importance by protecting whistleblowers from retaliation. This guidance highlights some of the most pertinent federal laws for "protecting whistleblowers who take action related to ensuring compliance with" the Executive Order. EO 14187 § 2(b).

a. *The National Defense Authorization Act of 2013*

The National Defense Authorization Act of 2013 (NDAA) contains a broad whistleblower protection for employees of federal contractors and grantees. It provides that "[a]n employee of a contractor, subcontractor, grantee, subgrantee, or personal services contractor may not be discharged, demoted, or otherwise discriminated against as a reprisal for disclosing to" certain statutorily defined officials and entities[17] "information that the employee reasonably believes is evidence of gross mismanagement of a Federal contract or grant, a gross waste of Federal funds, an abuse of authority relating to a Federal contract or grant, a substantial and specific danger to public health or safety, or a violation of law, rule, or regulation related to a Federal contract (including the competition for or negotiation of a contract) or grant." 41 U.S.C. § 4712.

An employee may reasonably believe that the chemical or surgical mutilation of children presents a danger to public health and safety.[18] As the Executive Order states: "Across the country today, medical professionals are maiming and sterilizing a growing number of impressionable children . . . ." EO 14187 § 1. "Countless children soon regret that they have been mutilated and begin to grasp the horrifying tragedy that they will never be able to conceive children of their own or nurture their children through breastfeeding. Moreover, these vulnerable youths' medical bills may rise throughout their lifetimes, as they are often trapped with lifelong medical complications, a losing war with their own bodies, and, tragically, sterilization." *Id.*

Moreover, the performance of child-mutilation may violate current and/or future terms of federal financial assistance, including where the use of federal funds is not authorized for this purpose under applicable law, rule, or regulation. Indeed, HHS notes the potential applicability of federal criminal law to certain acts of chemical or surgical mutilation of children, including the ban on coercive sterilization relating to beneficiaries of federal programs under 42 U.S.C. § 300a-8.

b. *The False Claims Act*

The False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, is a statute that empowers individuals to help combat fraud against the United States. Fraudulent claims for payment under federal healthcare programs like Medicare and Medicaid can fall within the FCA's scope. Thus, where an individual has knowledge of a potential FCA violation, that individual can be a whistleblower. This means that if an individual has knowledge that a healthcare provider submitted a claim (or caused the submission of a claim) for payment to a federal health care program in connection with chemical or surgical mutilation in violation of the terms of any existing law, regulation, or contract provision material to federal payment, then such individual could be a whistleblower.

The anti-retaliation provisions of the FCA protect "employee[s], contractor[s], [and] agent[s]" from discharge, demotion, suspension, or any other manner of discrimination "in the terms and conditions of employment" because of lawful acts taken by the individual in furtherance of a claim under the FCA or "other efforts to stop one or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1). To be protected under § 3730(h), an individual must generally show that: (1) he or she is a covered "employee, contractor, or agent"; (2) he or she was engaged in activity protected by the statute; (3) he or she was retaliated against; and (4) the retaliation was "because of" protected activity.

Courts have held that § 3730(h) protects not only actions taken in furtherance of a potential or actual action under the FCA but also steps taken to remedy fraud through other means, including internal reporting to a supervisor or compliance department, or refusals to participate in unlawful activity. In judging whether an individual was engaged in protected activity, most courts have adopted an "objectively reasonable" test, requiring the individual to have an objectively reasonable belief that the potential FCA defendant is violating or will soon violate the FCA. *See, e.g., U.S. ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 201 (4th Cir. 2018) ("an act constitutes protected activity where it is motivated by an objectively reasonable belief that the employer is violating, or soon will violate, the FCA.").

c. *The Church Amendments*

The Church Amendments, 42 U.S.C. § 300a-7, comprise conscience protections for healthcare personnel. As relevant here, 42 U.S.C. § 300a-7(c) prohibits entities that receive certain federal financial assistance from discriminating "in the employment, promotion, or termination of employment of any physician or other health care personnel" or discriminating "in the extension of staff or other privileges to any physician or other health care personnel" because that individual "refused to perform or assist in the performance" of a "lawful sterilization procedure" "on the grounds that his performance or assistance in the performance of the procedure . . . would be contrary to his religious beliefs or moral convictions," or "because of his religious beliefs or moral convictions respecting sterilization procedures[.]"

In addition, 42 U.S.C. § 300a-7(d) provides: "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."

The Executive Order aims to end child-mutilation procedures, which procedures could include adverse healthcare consequences like sterilization. *See* EO 14187 §§ 1, 2(c). The Church Amendments protect employees from discrimination if, based on religious beliefs or moral convictions, they refuse to participate in child-mutilation procedures—including the use of puberty-blockers or cross-sex hormones—and/or raise an objection to a supervisor about participating in such procedures.[19]

d. *HIPAA Privacy Rule Prohibition on Retaliation*

In addition to protecting covered entities from liability under HIPAA for whistleblowing by their workforce members and business associates, the Privacy Rule prevents such covered entities from using the rule as a justification to retaliate against workforce members who whistleblow. Generally, the Privacy Rule requires covered entities to have and apply appropriate sanctions against members of its workforce who failed to comply with their privacy policies or procedures or with the requirements of the rule. However, the requirement explicitly excludes the application of sanctions to a member of the covered entity's workforce for whistleblowing activity.[20] The purpose of this exclusion is to make clear that covered entities may not use the Privacy Rule as a mechanism for sanctioning workforce members or business associates who disclose PHI to the appropriate authority in accordance with the whistleblower provision.[21]

Further guidance about the HIPAA Privacy Rule </hipaa/for-professionals/privacy/guidance/index.html>, Security Rule </hipaa/for-professionals/security/index.html>, and Breach Notification Rules </hipaa/for-professionals/breach-notification/guidance/index.html> can also be found on OCR's website.

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To report a tip or file a complaint. Please go to www.hhs.gov/protect-kids <https://www.hhs.gov/protect-kids/index.html>.

For federal crimes. Please contact the United States Department of Justice here <https://www.justice.gov/action-center/report-crime-or-submit-complaint>.

View PDF [PDF, 247 KB] </sites/default/files/eo-14187-whistleblower-guidance.pdf>

Footnotes

1 As used in this guidance, the term "chemical and surgical mutilation" has the same meaning as given in Executive Order 14187, § 2(c): "the use of puberty blockers, including GnRH agonists and other interventions, to delay the onset or progression of normally timed puberty" for purposes of treating gender dysphoria; "the use of sex hormones, such as androgen blockers, estrogen, progesterone, or testosterone, to align an individual's physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex or that attempt" for purposes of treating gender dysphoria "to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions. This phrase sometimes is referred to as 'gender affirming care.'"

2 Pub. L. 104-191, 110 Stat. 1936 (August 21, 1996).

3 This guidance explains protections that exist under current statutes and regulations. The guidance does not give rise to any new rights, obligations, or legal consequences.

4 45 CFR part 160 and subparts A and E of part 164.

5 *See* 45 CFR 160.103 (definition of "Covered entity" and "Business associate"). *See also* OCR's Fact Sheet on Direct Liability of Business Associates <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html>.

6 45 CFR 164.502(j)(1). Because HIPAA applies only to covered entities and business associates, it is beyond the scope of the Privacy Rule to directly regulate the whistleblower actions of members of a covered entity's workforce. Thus, the whistleblower provision applies only to protect a covered entity from HIPAA liability based on the whistleblower action of a member of its workforce or business associates. *See* "Standards for Privacy of Individually Identifiable Health Information," 65 Fed. Reg. 82462, 82501-82502 (December 28, 2000).

7 *See* 45 CFR 164.514(a).

8 45 CFR 164.502(j)(1)(i).

9 45 CFR 164.501 (definition of "Health oversight agency"). An example of a health oversight agency authorized by law to investigate or oversee the conditions of a covered entity is the Long-Term Care Ombudsmen appointed in accordance with the Older Americans Act. Among the Ombudsmen's mandated responsibilities is a duty to identify, investigate, and resolve complaints that are made by, or on behalf of, residents related to their health, safety, welfare, or rights. 65 Fed. Reg. at 82637. Additional examples of health oversight agencies that conduct oversight of the health care system include state insurance commissions, state health professional licensure agencies, Offices of Inspectors General of federal agencies, state Medicaid fraud control units, HHS OCR, and the Food and Drug Administration (FDA). Examples of health oversight agencies that conduct oversight of government benefit programs for which health information is relevant to beneficiary eligibility include the U.S. Social Security Administration and the U.S. Department of Education. *See* 65 Fed. Reg. at 82492.

10 45 CFR 164.501 (definition of "Public health authority"). Examples of public health authorities include: the FDA, the Occupational Safety and Health Administration, the Centers for Disease Control and Prevention, and state and local public health departments. 65 Fed. Reg. at 82526.

11 Accreditation organizations are performing health care operations functions on behalf of health plans and covered health care providers. *See* 65 Fed. Reg. at 82492.

12 Professional standards are determined by state or other law. *See* 65 Fed. Reg. at 82727.

13 45 CFR 164.508(a). *See also* HHS, HIPAA FAQ #2023 <https://www.hhs.gov/hipaa/for-professionals/faq/2023/film-and-media/index.html> (Jan. 9, 2023).

14 45 CFR 164.512(b)(1)(ii).

15 45 CFR 164.512(f).

16 "Standards for Privacy of Individually Identifiable Health Information," 64 Fed. Reg. 59918, 59990 (November 3, 1999).

17 For example, the statute protects whistleblowing to members of Congress, the Department of Justice, a "Federal employee responsible for contract or grant oversight or management at the relevant agency," or a "management official or other employee of the contractor, subcontractor, grantee, subgrantee, or personal services contractor who has the responsibility to investigate, discover, or address misconduct." 41 U.S.C. § 4712(a)(2).

18 *See* Quality and Safety Special Alert Memo, Center for Medicare & Medicaid Services, "Protecting Children from Chemical and Surgical Mutilation" (March 5, 2025). The memo notes the "lack of medical evidence in support of these harmful treatments," for chemical and surgical interventions on children with gender dysphoria, and warns that such interventions are "now known to cause long-term and irreparable harm to some children." The memo also notes that the "United Kingdom, Sweden, and Finland have recently issued restrictions on the medical interventions for children, including the use of puberty blockers and hormone treatments, and now recommend exploratory psychotherapy as a first line of treatment…"

19 Subsection (c) of the Church Amendments is tied to, among other things, a "lawful sterilization procedure." Subsection (d) is broader in that respect: it pertains to procedures to which an individual has religious or moral objections, even if sterilization is not implicated. In the context of the Executive Order, that could include, for example, "surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex[.]" EO 14187 § 2(c).

20 45 CFR 164.530(e)(1).

21 *Id.*; *See also* 65 Fed. Reg. at 82636.

Content created by Assistant Secretary for Public Affairs (ASPA)
Content last reviewed April 14, 2025

EXHIBIT J

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." *Internationol Journol of Transgender Health,* vol. 23, suppl. 1, 2022 pp. S1–S259. *Taylor & Froncis Online, https://www.tondfonline.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://opo.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://opo.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 Donish 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/queenslond-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://policyseorch.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-dyspharia-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-dyspharia-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://opo.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*,

Continued

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://opo.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-califarnia-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

[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 Interoctive 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:

Table of Contents

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

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

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

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

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

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

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

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

Dated: December 16, 2025.

M.E. Platt,

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

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

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 441 and 457

[CMS–2451–P]

RIN 0938–AV73

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

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

ACTION: Proposed rule.

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

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

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

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

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

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

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

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

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

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

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

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

I. Background [1]

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

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

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

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

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

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

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

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

[3] Section 1902(a)(30)(A) of the Act states that a State plan for medical assistance must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) of the Act) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."

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

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

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

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

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

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

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

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

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

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

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

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

[7] Henriette A. Delemarre-van de Waal and Peggy T. Cohen-Kettenis, "Clinical management of gender identity disorder in adolescents: A protocol on psychological and pediatric endocrinology aspects," *European Journal of Endocrinology* 155, Supp 1 (2006): S131–**S137**, *https://doi.org/10.1530/eje.1.02231*.

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

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

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

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

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

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

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

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

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

[17] HHS Review, 9.

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

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

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

B. Medical Evidence Regarding Sex-Rejecting Procedures for Minors

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

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

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

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

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

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

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

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

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

[23] HHS Review, 134.

[24] HHS Review, 10.

[25] HHS Review, 63–65.

[26] HHS Review, 10.

[27] HHS Review, 230.

[28] HHS Review, 15.

[29] HHS Review, 15.

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

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

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

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

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

1. European Approaches for the Treatment of Pediatric Gender Dysphoria

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

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

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

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

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

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[34] HHS Review, 181.

[35] HHS Review, 182.

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

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

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

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

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

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

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

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

[44] Council for Choices in Healthcare in Finland, "Summary of a recommendation by COHERE Finland," June 16, 2020, *https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en+(1).pdf/fa2054c5-8c35-8492-59d6-b3de1c00de49/Summary_minors_en+(1).pdf?t=1631773838474*.

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

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

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

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

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

2. Medical Professional Societies Supporting Sex-Rejecting Procedures

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

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

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

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

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

The HHS Review states:

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

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

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

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

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

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

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

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

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

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

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

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

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

[58] HHS Review, 141.

[59] HHS Review, 15.

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

[61] HHS Review, 124.

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

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

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

Regarding the WPATH guidelines, the HHS review states:

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

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

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

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

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

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

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

[62] HHS Review, 147.
[63] HHS Review, 157.
[64] HHS Review, 157.
[65] E. Coleman et al., "Standards of Care."
[66] HHS Review, 14.
[67] HHS Review, 165.
[68] HHS Review, 194–195.
[69] HHS Review, 196.
[70] Jason Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, "Ensuring Comprehensive Care and Support for Transgender and Gender Diverse Children and Adolescents," *Pediatrics* 142, no. 4 (2018), *doi.org/10.1542/peds.2018-2162*.
[71] Alyson Sulaski Wyckoff, "AAP reaffirms gender-affirming care policy, authorizes systematic review of evidence to guide update," *AAP News*, August 4, 2023, *https://publications.aap.org/aapnews/news/25340/AAP-reaffirms-gender-affirming-care-policy*.
[72] HHS Review, 148–149.
[73] See "Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions," KFF,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[78] HHS Review, 257.

[79] HHS Review, 68.

[80] Cass, "Cass Review."

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

[82] HHS Review, 256.

[83] HHS Review, 257–260.

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

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

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

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

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

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

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

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

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

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

[86] CMS, "Puberty Blockers."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[94] Section 1905(a)(6) of the Act states "medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law" and section 2110(a)(24) of the Act defines "child health assistance" as "payment for part or all of the cost of health benefits coverage for targeted low-income children that includes any of the following . . . (24) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services . . . if recognized by State law . . ."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. Provisions of the Proposed Regulations

A. General Discussion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We believe that the proposed definition of sex-rejecting procedures provides an appropriate degree of clarity and certainty regarding which sex-rejecting procedures would and would not be subject to the prohibitions at proposed § 441.802. We believe the proposed definition is narrowly tailored and appropriate to exclude only treatments CMS has determined to lack sufficient evidence of safety for their intended purposes. Examples such as procedures to treat precocious puberty, therapy subsequent to a traumatic injury, or the use of hormone replacement therapy to treat a growth hormone deficiency would not fall under the proposed definition of sex-rejecting procedures, and Federal Medicaid payment for such procedures would therefore not be prohibited for individuals under the age of 18, when medically necessary. As the HHS Review explains, central precocious puberty and gender dysphoria are distinct clinical entities. In addition, because the proposed definition is narrowly tailored in this way, we believe that States will be able to administer Medicaid coverage for drugs in a manner that is consistent with both the proposed rule and the requirements in section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, if manufacturers enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act, payment is available for the CODs covered under that NDRA for medically accepted indications.[102] As defined in section 1927(k)(6) of the Act, "medically accepted indications" mean use for a COD approved under the Federal Food, Drug, and Cosmetic Act or approved for inclusion in any of the compendia described in subsection 1927(g)(1)(B)(i) of the Act. There is no pharmaceutical that is solely indicated for these sex-rejecting procedures; the pharmaceuticals that are used for these procedures are approved for other indications. Thus, these pharmaceuticals will continue to be coverable by Medicaid programs for other indications in accordance with section 1927 of the Act. In addition, we note that this proposed rule only applies to pharmaceuticals that are used in the proposed definition and would not apply to other pharmaceuticals that are prescribed to a child.

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

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

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

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

C. Prohibition on CHIP Payment for Sex-Rejecting Procedures

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

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

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

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

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

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

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

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

III. Collection of Information Requirements

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

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

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

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

A. Wage Estimates

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

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

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

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

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Definitions (§ 441.801)

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

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

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

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

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

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

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

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

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

C. Summary of Proposed Requirements and Burden Estimates

TABLE 2—PROPOSED REQUIREMENTS/BURDEN ESTIMATES

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

D. Submission of PRA-Related Comments

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

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

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

IV. Response to Comments

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

V. Regulatory Impact Statement

A. Statement of Need

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

B. Overall Impact

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

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

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

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

C. Detailed Economic Analysis

1. Impacts on Federal Expenditures and Other Transfers

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

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

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

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

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

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

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

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

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

[In millions of real 2027 dollars]

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

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

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

2. Costs

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

3. Alternatives

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

D. Regulatory Flexibility Act (RFA)

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

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

TABLE 5--HEALTH CARE INDUSTRY SIZE STANDARDS

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

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

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

TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES

[$37.5 Million size standard]

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

TABLE 6—NAICS 446110 PHARMACIES AND DRUG STORES—Continued

[$37.5 Million size standard]

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

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

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

[$16.0 Million size standard]

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

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

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

[$13.5 Million size standard]

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

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

TABLE 9—NAICS 621493 FREESTANDING AMBULATORY SURGICAL AND EMERGENCY CENTERS

[$19.0 Million size standard]

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

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

TABLE 10—NAICS 621498 ALL OTHER OUTPATIENT CARE CENTERS

[$25.5 Million size standard]

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

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

TABLE 11—NAICS 622110 GENERAL MEDICAL AND SURGICAL HOSPITALS

[$47.0 Million size standard]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

E. Accounting Statement and Table

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

TABLE 13—ACCOUNTING STATEMENT

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

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

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid

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

Services, approved this document on December 15, 2025.

List of Subjects

42 CFR Part 441

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

42 CFR Part 457

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

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

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

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

Authority: 42 U.S.C. 1302.

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

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

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

§ 441.800 Basis and purpose.

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

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

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

§ 441.801 Definitions.

As used in this subpart—

FFP means Federal financial participation.

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

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

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

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

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

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

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

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

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

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

§ 441.802 General rules.

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

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

PART 457—ALLOTMENTS AND GRANTS TO STATES

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

Authority: 42 U.S.C. 1302.

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

§ 457.476 Limitations on coverage: Sex-rejecting procedures.

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

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

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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

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.

EXHIBIT K

Office of the Attorney General
Washington, D. C. 20530

April 22, 2025

MEMORANDUM FOR SELECT COMPONENT HEADS

FROM: THE ATTORNEY GENERAL

SUBJECT: PREVENTING THE MUTILATION OF AMERICAN CHILDREN

There is a radical ideological agenda being pushed throughout every aspect of American life—from TV programming and Hollywood film production to children's books and elementary school classrooms—that teaches children to deny biological reality. Gender ideology, masked as science, teaches that children should process adolescent stress and confusion as a case of mistaken identity and that the solution is not to root out and eliminate the underlying condition but to acquiesce in it permanently through life-altering chemical and surgical intervention. That ideology, pushed by far-left politicians, celebrities, politically captured academics, and legacy media, has infected an entire generation of children, who have in turn pushed transgenderism on their peers through social media and other means. Dissenting voices are bullied into silence, and "allies" are praised and rewarded. Tragic and absurd as it is that 1.4% of 13- to 17-year-olds now identify as transgender,[1] that is the predictable result of a coordinated, unchecked ideological attack on America's children.

The medical community, with its roots in hard science, is well-positioned to serve as a bulwark against this sociological disease. And indeed, parents who are desperate to help their confused, frustrated children have understandably turned to medical professionals for help. Unfortunately, those parents have been betrayed by politically captured profiteers at every step. These "professionals" have deployed junk science and false claims about the effects of so-called "gender-affirming care" to justify the barbaric practice of surgically and chemically maiming and sterilizing children. Between 2019 and 2023, an estimated 14,000 children received "treatment" for gender dysphoria, with more than 5,700 subjected to life-altering surgeries.[2] The practitioners who provided this so-called "care" profited while their patients were left permanently disfigured, scarred, and sterilized. Those children will struggle for the rest of their lives to overcome regret, and their parents will struggle equally to overcome the guilt of ruining their children's lives on the

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[1] Azeen Ghorayshi, *Report Reveals Sharp Rise in Transgender Young People in the U.S.*, N.Y. Times (June 10, 2022), https://www.nytimes.com/2022/06/10/science/transgender-teenagers-national-survey.html.

[2] Rikki Schlott, *Over 5,700 American children had trans surgery between 2019 and 2023, medical group claims: 'Treated like guinea pigs*,' N.Y. Post (Oct. 8, 2024), https://nypost.com/2024/10/08/us-news/over-5700-americans-under-18-had-trans-surgery-from-2019-23/.

false and misleading advice of medical providers who told them that surgery or hormone replacement was the best solution to their problems.[3]

Consider the case of Chloe Cole, whose story, sadly, is not unique.[4] At just 11 years old, Chloe joined Instagram and was bombarded with "LGBT content and activism."[5] She "saw how trans people online got an overwhelming amount of support," and that "really spoke to [her] because, at the time," she was just a child and "didn't really have a lot of friends of [her] own."[6] She was especially vulnerable at that age because, like many young girls, Chloe felt that her "body didn't match beauty ideals," so she "started to wonder if there was something wrong with" her, even wondering whether she would "be better off as a boy."[7] By the age of 12, Chloe identified as transgender, and she "was fast-tracked through her entire transition—from blockers to a mastectomy—in just two years."[8] "The only pushback she . . . encountered came from the first endocrinologist she saw," but she bypassed that easily by going "to another doctor who gave her the prescription with no trouble."[9] Despite the "vitriol from the transgender activist community," Chloe has bravely shared her regret with the world at just 17 years old because she simply "can't let this happen to other kids."[10] Neither can I, and neither can President Trump.

The Biden administration bears enormous responsibility for the medical community's fraud and exploitation of parents and children who have fallen prey to radical gender ideology. President Biden personally advanced the agenda by hosting transgender activist influencers like Dylan Mulvaney at the White House,[11] opposing state-level bans on gender-affirming care for minors,[12] threatening legal action against Medicaid and Obamacare providers who fail to offer

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[3] *See, e.g.*, Dr. Marc Siegel et al., *Detransitioning becomes growing choice among young people after gender-affirming surgery*, Fox News (Dec. 19, 2022), https://www.foxnews.com/health/detransitioning-becomes-growing-choice-young-people-gender-affirming-surgery.

[4] Chloe Cole, *Hearing on Gender Affirming Care before the Subcommittee on the Constitution and Limited Government of the H. Judiciary Comm.*, 118th Cong. (2023).

[5] *Rikki Schlott, 'I literally lost organs:' Why detransitioned teens regret changing genders*, N.Y. Post (June 19, 2022), https://nypost.com/2022/06/18/detransitioned-teens-explain-why-they-regret-changing-genders/.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] Emma Colton, *Biden legacy includes relentless push for transgender agenda*, Fox News (Dec. 8, 2024), https://www.foxnews.com/politics/biden-legacy-includes-relentless-push-transgender-agenda.

[12] Edie Heipel, *In interview with trans activist, Biden condemns states banning sex changes on kids*, (Oct. 24, 2022), Catholic News Agency, https://www.catholicnewsagency.com/news/252633/in-interview-with-trans-activist-biden-condemns-states-banning-sex-changes-on-kids.

such care,[13] and appointing Rachel Levine—a leading transgender activist who personally identifies as transgender—to serve as Assistant Secretary for Health. Under Levine, the Department of Health and Human Services promoted gender-reassignment surgeries and hormone replacement for the treatment of gender dysphoria in minors[14] and pressured the World Professional Association for Transgender Health ("WPATH") to eliminate age minimums for reassignment surgeries in its 2022 guidelines.[15] All the while, NIH-funded studies admitted that "little to no empirical data" supported the long-term safety of puberty blockers and hormones, let alone sex-reassignment surgery.[16] To address the lack of scientific support for his agenda, President Biden allocated more than $8 million of taxpayer funds for transgender hormone studies on mice.[17]

President Trump has put a stop to this by issuing his executive order "Protecting Children from Chemical and Surgical Mutilation," signed to halt the exploitation enabled by misguided Biden-era policies. Pursuant to the President's directive, I am issuing the following guidance to all Department of Justice employees to enforce rigorous protections and hold accountable those who prey on vulnerable children and their parents.

I. Enforcement of Laws Outlawing Female Genital Mutilation

The Department of Justice will not sit idly by while doctors, motivated by ideology, profits, or both, exploit and mutilate our children. Under my watch, the Department will act decisively to protect our children and hold accountable those who mutilate them under the guise of care. I am putting medical practitioners, hospitals, and clinics on notice: In the United States, it is a felony to perform, attempt to perform, or conspire to perform female genital mutilation ("FGM") on any person under the age of 18.[18] That crime carries a maximum prison sentence of 10 years per count.[19] I am directing all U.S. Attorneys to investigate all suspected cases of FGM—under the

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[13] Executive Order 14075, *Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals*, 87 Fed. Reg. 37189 (June 15, 2022).

[14] Timothy Nerozzi, *Biden administration endorses transgender youth sex-change operations, 'top surgery,' hormone therapy*, Fox News, March 31, 2022, https://www.foxnews.com/politics/biden-administration-transgender-agenda-youth-sex-change-hormone-therapy.

[15] Azeen Ghorayshi, *Biden Officials Pushed to Remove Age Limits for Trans Surgery, Documents Show*, N.Y. Times (June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html.

[16] Patrick Hauf, *Biden administration funds studies on danger of transgender hormonal treatments even as it pushes them on kids*, Fox News, (Oct. 20, 2022), https://www.foxnews.com/politics/biden-funds-studies-dangers-transgender-hormone-treatments.

[17] The White House, March 5, 2025, https://www.whitehouse.gov/articles/2025/03/yes-biden-spent-millions-on-transgender-animal-experiments/.

[18] *See* 18 U.S.C. § 116(a)(1).

[19] *Id.* § 116(a).

banner of so-called "gender-affirming care" or otherwise—and to prosecute all FGM offenses to the fullest extent possible.

The Department will also ensure that victims and their families are able to report violations to federal law enforcement to expose violators and receive support. The Federal Bureau of Investigation, alongside federal, state, and local partners, will pursue every legitimate lead on possible FGM cases.

II. Investigation of Violations of the Food, Drug and Cosmetic Act and False Claims Act

The Department of Justice will investigate and hold accountable medical providers and pharmaceutical companies that mislead the public about the long-term side effects of chemical and surgical mutilations. To that end:

- I am directing the Civil Division's Consumer Protection Branch to undertake appropriate investigations of any violations of the Food, Drug, and Cosmetic Act by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called "gender transition." Even if otherwise truthful, the promotion of off-label uses of hormones—including through informal campaigns like those conducted by sales reps or under the guise of sponsored continuing medical education courses—run afoul of the FDA's prohibitions on misbranding and mislabeling.[20]

- I am also directing the Civil Division's Fraud Section to pursue investigations under the False Claims Act of false claims submitted to federal health care programs for any non-covered services related to radical gender experimentation. Examples include but are not limited to physicians prescribing puberty blockers to a child for an illegitimate reason (*e.g.*, gender dysphoria) but reporting a legitimate purpose (*i.e.*, early onset puberty) to the Centers for Medicare & Medicaid Services, and hospitals performing surgical procedures to remove or modify a child's sex organs while billing Medicaid for an entirely different procedure. Falsely billing the government for the chemical or surgical mutilation of a child is a violation of the False Claims Act and is subject to treble damages and severe penalties.

- I am also notifying the public that the Department is eager to work with *qui tam* whistleblowers with knowledge of any such violations. The False Claims Act allows private citizens to file these actions on behalf of the government against those who have defrauded the government. In meritorious cases, the Department of Justice can intervene, and even if the Department takes over the case, the relator may receive a portion of the government's financial recovery. In 2024 alone, *qui tam* relators received a $344 million share of victories won by the Department. For more information about initiating a *qui tam* action, please visit the Department's website at

[20] *See* 21 U.S.C. §§ 321(m)-(n), 331, 352(a), (f); 21 C.F.R. §§ 201.100, 201.128, 202.1(l)(2).

https://www.justice.gov/archives/jm/criminal-resource-manual-932-provisions-handling-qui-tam-suits-filed-under-false-claims-act.

III. Ending Reliance on Junk Science by the Department

Consistent with Section 3 of the President's Order, the Civil Division has already directed that Department employees shall not rely on the ideologically driven WPATH guidelines, and that they should withdraw all court filings that rely on WPATH's guidelines in any case in which the Department of Justice is actively involved, whether as a party, an amicus, or through the submission of a statement of interest. For the avoidance of doubt, I now expressly extend that direction to all Department employees. I further direct the Civil Rights Division to work with the Civil Division to identify and purge all Department policies, memoranda, and publications and court filings based on WPATH guidelines. WPATH has flouted basic standards for clinical guidelines, silenced its own evidence review team to bury doubts about the science WPATH promotes, muzzled dissenting members, and worked with the prior administration to push reckless policies—like doing away with age minimums for child surgeries.[21] That is not science; it is radical ideology that endangers children with untested theories, and it has no place in the Department's work. WPATH's guidelines are fundamentally flawed and unreliable, and the Department will not use them in any way that suggests otherwise.

IV. Establish Federal and State Coalition Against Child Mutilation

Federal law enforcement must stand ready to assist states that prioritize children's health over ideology. Accordingly, the Department is launching the Attorney General's Coalition Against Child Mutilation. Through this Coalition, I will partner with state attorneys general to identify leads, share intelligence, and build cases against hospitals and practitioners violating federal or state laws banning female genital mutilation and other, related practices. The Department will support the state-level prosecution of medical professionals who violate state laws that protect children, such as Alabama's Vulnerable Child Compassion and Protection Act,[22] which makes it a felony for doctors to treat children with puberty blockers or hormones to affirm a gender identity inconsistent with biological sex.

V. Promoting New Legislation Protecting Children

I have instructed the Office of Legislative Affairs ("OLA") to draft legislation creating a private right of action for children and the parents of children whose healthy body parts have been damaged by medical professionals through chemical and surgical mutilation. The proposed legislation will establish a long statute of limitations and retroactive liability, so that no one providing such "treatment" will escape liability. The Department of Justice will work with members of the House and Senate Judiciary Committees to bring this bill to President Trump as soon as possible. Further, I have instructed OLA to draft legislation amending 18 U.S.C. § 116 to enhance protections for children whose healthy body parts have been damaged by medical

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[21] *See, e.g.*, Defs.' Mot., *Boe v. United States*, No. 2:22-cv-00184 (M.D. Ala. Jun. 26, 2024).

[22] Ala. Code § 26-26-1 (2022).

professionals practicing chemical and surgical mutilation. I will also work with state legislatures to encourage the passage of similar legislation at the state level.

* * *

Protecting America's children must be our top priority, whether from drug cartels, terrorists, or even our own medical community. Every day, we hear more harrowing stories about children who will suffer for the rest of their lives because of the unconscionable ideology behind "gender-affirming care." Under my leadership, the Department of Justice will bring these practices to an end.

EXHIBIT L

PRESS RELEASE

Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children

Wednesday, July 9, 2025

For Immediate Release

Office of Public Affairs

WASHINGTON — Today, the Department of Justice announced that it has sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children.

The Department's investigations include healthcare fraud, false statements, and more.

"Medical professionals and organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice." — Attorney General Pamela Bondi

Updated July 9, 2025

Topic

HEALTH CARE FRAUD

Component

Office of the Attorney General

Press Release Number: 25-717

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EXHIBIT M

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DECLARATION OF THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents

Date: December 18, 2025

Declarant: Robert F. Kennedy Jr., Secretary of U.S. Department of Health and Human Services

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I, Robert F. Kennedy, Secretary of the U.S. Department of Health and Human Services (HHS), pursuant to my authority and responsibilities under federal law, and pursuant to 42 CFR § 1001.2, hereby declare as follows

I. BACKGROUND AND AUTHORITY

A. Rising Prevalence of Gender Dysphoria Diagnoses in Youth

In recent years, medical professionals have documented a substantial increase in gender dysphoria diagnoses among young people in the United States, with similar trends throughout Europe.[1] In response to this phenomenon and following the publication of the "Dutch Protocol," and subsequent endorsements by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (ES), the number of children and adolescents receiving medical interventions for gender dysphoria increased substantially.[2] These interventions, referred to in this Declaration as sex-rejecting procedures, include puberty-suppressing hormones, cross-sex hormones, and surgical procedures.

Research indicates that thousands of American children have undergone these sex-rejecting procedures.[3] Yet current medical evidence does not support a favorable risk/benefit profile for using these interventions to treat pediatric gender dysphoria. Moreover, existing clinical guidelines endorsing these procedures demonstrate significant variation in methodological rigor and quality.

To address these methodological concerns and evaluate the evidence for sex-rejecting procedures for children and adolescents, on May 1, 2025, HHS released a review of the evidence to identify best practices for treating pediatric gender dysphoria.[4] On November 19, 2025, HHS released the final, peer-reviewed report, *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* ("the HHS Report").[5] The HHS Report is a comprehensive review of the evidence and literature related to sex-rejecting procedures.

B. Expansion of Medical Interventions for Gender Dysphoria

Following the 2006 publication of what became known as the "Dutch Protocol" in *The European Journal of Endocrinology*, pediatric medical interventions for gender dysphoria increased substantially.[6] During the subsequent decade, growing numbers of children and adolescents diagnosed with gender dysphoria began receiving medical procedures advocated by organizations such as the WPATH and the ES.[7]

WPATH's Standards of Care Version 8 (SOC-8) specifically acknowledged this trend, attributing the development of a dedicated adolescent chapter partly to what it characterized as exponential increases in youth referrals.[8] While earlier health system studies documented referral rates below 0.1 percent, more recent surveys identifying "transgender" youth report prevalence ranging from 1.2 to 2.7 percent, with "gender diverse" identification reaching as high as 9 percent.[9] WPATH documentation also indicates that adolescent females seek these interventions at rates between two and seven times higher than adolescent males.[10]

WPATH guidelines recommend that providers conduct thorough biopsychosocial evaluations of adolescents seeking medical transition, incorporating input from mental health specialists, medical professionals, parents or guardians, except in circumstances where parental involvement might cause harm.[11]

C. Scale of Pediatric Interventions in the United States

The number of pediatric patients seeking sex-rejecting procedures can only be roughly estimated. The decentralized and largely privatized nature of the American healthcare system has facilitated the proliferation of specialized gender clinics alongside numerous independent practitioners offering these services.[12] Conservative estimates from March 2023 identified 271 gender clinics operating across the United States, with approximately 70 rendered inactive due to state legislative restrictions.[13]

The treatment approach referenced in this declaration as sex-rejecting procedures—terminology that some refer to as “gender-affirming care”—encompasses several intervention types, when provided to minors: puberty-suppressing drugs that prevent the onset of puberty, cross-sex hormones that induce secondary sex characteristics of the opposite-sex, and surgical procedures, including breast removal and, less commonly, genital reconstruction. Thousands of American minors have undergone these interventions.[14]

Research published in 2023 estimated that from 2016 through 2020, approximately 3,700 adolescents in the U.S., aged 12 to 18 with gender dysphoria diagnoses underwent surgical interventions. This figure includes more than 3,200 youth who underwent breast or chest surgery and over 400 who had genital surgeries resulting in permanent reproductive organ alterations and compromised sexual function.[15] Separate research examining the period from 2017 to 2021 identified more than 120,000 children ages 6 through 17 diagnosed with gender dysphoria, with over 17,000 of these minors initiating either puberty blockers or hormonal therapy.[16] However, as discussed in the HHS Review, current medical evidence does not support a favorable risk/benefit profile for the use of chemical or surgical procedures in children to treat gender dysphoria.

D. Legal Authority for This Declaration

This declaration is issued pursuant to the authority vested in the HHS Secretary, and is informed by 42 CFR § 1001.2, which provides that "when the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care." As such, this declaration supersedes

"Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State." For reasons explained in this Declaration, standards of care recommended by certain medical organizations are unsupported by the weight of evidence and threaten the health and safety of children with gender dysphoria.

II. COMPREHENSIVE REVIEW OF EVIDENCE

HHS issued a comprehensive evidence review and best practices assessment regarding pediatric gender dysphoria care on May 1, 2025.[17] After the publication of this preliminary report, HHS also invited peer reviews from major medical associations, including the American Academy of Pediatrics (AAP), the American Psychiatric Association (APA), and the ES, as well as clinical experts and evidence-based medicine methodologists. While both the AAP and the ES declined to participate, HHS received reviews from the APA and seven invited peer reviewers for consideration. The report also engaged with two unsolicited reviews that were previously published in journals. In keeping with its commitment to radical transparency, HHS published all nine peer reviews alongside its detailed responses to each one,[18] as well as a final, revised report incorporating the feedback in November 2025.[19]

Employing an evidence-based medicine approach, the HHS Review identified substantial concerns regarding outcomes from specific medical interventions—namely puberty blockers, cross-sex hormones, and surgical procedures—intended to facilitate children's and adolescents' transition away from their sex. The Review documents significant risks from these procedures, including permanent harms such as infertility, while finding markedly insufficient evidence of therapeutic benefit. Crucially, the Review determined that existing evidence cannot support effectiveness claims for medical and surgical interventions in ameliorating mental health conditions or reducing gender dysphoria symptoms. As the Review states: "Analysis of the biological plausibility of harms is necessary and suggests that some short- and long-term harms are likely (in some cases expected) sequelae of treatment."[20] The evidence examined in the HHS Review demonstrates an unfavorable risk/benefit profile for medical and surgical interventions in children and adolescents with gender dysphoria diagnoses. While the HHS Review refrains from making specific clinical, policy, or legislative recommendations, it furnishes essential insights for policymakers charged with promoting health and safety, particularly for vulnerable populations such as children and adolescents.[21]

A. HHS Review Methodology

The HHS Review conducted an "umbrella review" of existing systematic reviews, including those that informed European health authorities' policy decisions, to assess their methodological quality and the evidence regarding the benefits and harms of hormonal and surgical interventions for treating pediatric gender dysphoria. The review found that the overall quality of evidence concerning the effects of sex-rejecting procedures on psychological outcomes, quality of life, regret, or long-term health, is very low.

B. Evidence Quality Regarding Therapeutic Benefits

The HHS Review also concluded that available evidence cannot support determinations regarding the effectiveness of medical and surgical interventions for mental health or alleviating gender dysphoria symptoms.

The Review states that pediatric medical transition evidence for benefit remains highly uncertain, while harm evidence demonstrates less uncertainty.[22] The evidence compilation indicates that medical and surgical interventions for children and adolescents diagnosed with gender dysphoria present an unfavorable risk-benefit profile.

C. Evidence and Analysis of Treatment Harms

While acknowledging that systematic reviews provide limited direct evidence of harms from sex-rejecting procedures in minors, the HHS Review offers plausible rationales for why such evidence may have been inadequately sought, detected, or reported. Contributing factors include the relatively recent implementation of hormonal and surgical treatment, deficiencies in monitoring and reporting adverse effects within existing studies, and publication bias.

Despite the absence of robust evidence from large-scale population studies, the HHS Review identifies known and plausible harm risks from puberty blockers, cross-sex hormones, and surgeries based on human physiology and pharmacological agents used. The Review notes that short- and long-term adverse effects are likely, and include infertility and sterility, sexual dysfunction, impaired bone density development, adverse cognitive effects, cardiovascular and metabolic disease, psychiatric conditions, surgical complications, and regret.[23]

D. International Shift Away from Pediatric Medical Transition

The HHS Review chronicles both the weak evidentiary basis and the growing international movement away from using puberty blockers, cross-sex hormones, and surgeries for treating gender dysphoria in minors, highlighting significant harm risks.[24] The Review provides methodologically rigorous assessment of evidence underlying surgical and endocrine interventions, including puberty suppression and cross-sex hormone use, while incorporating international practice evaluations such as the United Kingdom's Cass Review.

The Review documents mounting concerns regarding both the scarcity of reliable benefit evidence and the presence of significant harm risks associated with this care model, identifying psychotherapy as a non-invasive alternative approach.

E. Ethical Analysis and Conclusions

The HHS Review invokes widely recognized medical ethics principles to conclude that "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."[25]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."[26] 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. Sex-rejecting procedures introduce a unique set of iatrogenic harms for minors, which may include "surgeries to remove healthy and functioning organs."[27] 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."[28] As related previously in this Declaration, the risk-benefit profile of these procedures for children is extremely poor. "The best available evidence," it finds, is that pediatric sex-rejecting procedures "have not been shown to improve mental health outcomes." "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."[29]

Though the HHS Review deliberately avoids making clinical, policy, or legislative recommendations, it supplies critical information that should guide policymakers in decisions promoting health and safety, especially for vulnerable populations such as minors.[30]

III. INADEQUACY OF CLINICAL GUIDELINE FROM MEDICAL ORGANIZATIONS

I acknowledge that guidance from prominent U.S. medical professional organizations, including the American Medical Association (AMA), AAP, and APA, has characterized sex-rejecting procedures—termed by these organizations as "gender-affirming care"—as safe and effective.[31,32,33,34] These endorsements from medical societies have encouraged widespread clinician adoption of sex-rejecting procedures throughout the United States. The most influential sources of clinical guidance for treating pediatric gender dysphoria in the United States are the WPATH and the ES clinical practice guidelines and the AAP guidance document. However, a recent systematic review of international guideline quality by researchers at the University of York found that all three documents as very low quality and should not be implemented.[35]

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.[36]

A. Endocrine Society

The ES issued clinical practice guidelines in 2017 entitled "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons." 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.[37]

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.

B. WPATH

As explained in Chapter 9 of HHS Review, the guidelines issued by the WPATH "have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines."[38] 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." In 2022, WPATH issued guidelines entitled "Standards of Care for the Health of Transgender and Gender Diverse People, Version 8" (SOC-8). 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, during recommendation development, WPATH suppressed systematic evidence reviews, failed to appropriately manage conflicts of interest, and prioritized legal and political rather than clinical considerations.[39] 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."[40] 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.""[41]

On the surface, WPATH SOC-8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a "comprehensive biopsychosocial assessment" prior to initiating medical interventions in order "to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care." At the same time, however, WPATH recommends that clinicians use the International Classification of Diseases 11th Revision diagnosis of "Gender Incongruence of Adolescence and Adulthood," which, unlike the DSM-5 diagnosis of "Gender Dysphoria," requires only "marked and persistent incongruence between an individual's experienced gender and the assigned sex." Because SOC-8 defines transgender in a similar way ("people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth") and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC-8 effectively recognizes transgender identification as a medical condition justifying medical interventions.[42]

The HHS Review also argues: "Although WPATH's guidelines do not necessarily discourage mental healthcare, they likewise do not require it as a precondition for PMT [pediatric medical transition]. Some guideline authors opposed even minimal requirements for mental health support, arguing that such provisions were analogous to "conversion therapy."35 SOC-8's only formal recommendation is for a "comprehensive biopsychosocial assessment," although WPATH emphasizes that its guideline is "flexible," thereby leaving room for considerable variation in clinical practice."[43]
A recent systematic review evaluating international guideline quality concluded that healthcare professionals should account for the inadequate quality and independence of available guidance when utilizing WPATH and Endocrine Society international guidelines in practice.[44]

C. AMA and AAP

While the 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.[45] In support of sex-rejecting surgeries, AAP stated that while "current protocols [(ES, WPATH)] typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by-case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family." The AAP reaffirmed its policy statement in 2023, but also stated that it was conducting its own review of the evidence and guideline development---which still have not been released.[46]

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]. 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's policy statement's use of "gender diverse" casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations. Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD, the organization chose to reaffirm their policy statement in 2023.[47]

The Review comprehensively documents how SOC-8 development represented a significant departure from unbiased, evidence-driven clinical guideline development principles.[48]

The failure of professional organizations in the United States to protect children, and follow the principles of evidence-based medicine, highlights the need for this Declaration.

Global guidelines supporting care for children and adolescents experiencing gender dysphoria demonstrate variable methodological rigor and quality. The HHS Review's assessment reveals fundamental deficiencies in both the development processes and evidentiary foundations of the most frequently cited guidelines endorsing sex-rejecting procedures for minors.

IV. INTERNATIONAL EVIDENCE REVIEWS AND CONSENSUS

The HHS Review's findings align with conclusions from multiple European nations that conducted independent, rigorous systematic evidence reviews. Sweden, Finland, and the United Kingdom each commissioned independent systematic evidence reviews through their public health authorities. All three nations concluded that medicalization[49] risks may exceed benefits for children and adolescents with gender dysphoria, subsequently implementing sharp restrictions on gender transition interventions for minors.[50,51,52,53,54,55] These three countries now recommend exploratory psychotherapy as initial treatment. Sweden and Finland reserve hormonal interventions exclusively for exceptional cases, recognizing their experimental nature.[56,57,58,59]

A. United Kingdom's Cass Review

The United Kingdom's Cass Review represents the most influential evaluation to date—a four-year independent assessment of pediatric gender medicine published in April 2024. The Cass Review findings precipitated closure of the United Kingdom's Gender Identity Development Service (GIDS), which the Care Quality Commission had rated "inadequate" in 2021.

The Cass Review recommended restructuring the care delivery model away from centralized "gender clinic" approaches toward more holistic frameworks emphasizing psychosocial support delivered through regional hubs. The Review's findings also led the United Kingdom to prohibit puberty blocker use outside clinical trial settings and substantially restrict cross-sex hormone access.[60]

Though cross-sex hormones remain officially available, the National Health Service (NHS) recently disclosed that since the Cass Review's publication, no minor has satisfied eligibility criteria for receiving cross-sex hormones under updated policies.[61] Note that the United Kingdom has never provided gender dysphoria-related surgery to minors through the NHS.[62]

B. Sweden

Sweden's National Board of Health and Welfare (NBHW) reviewed and revised its guidelines for minors under age 18 in 2022. The NBHW determined that risks from puberty-suppressing treatment using GnRH-analogues (injectable medications preventing ovarian and testicular hormone production) and hormonal treatment promoting opposite-sex characteristics likely exceed potential benefits.[63,64]

The NBHW specified that mental health support and exploratory psychological care should constitute first-line treatment. Hormonal interventions may serve as last-resort measures for select youth. Sweden has elected to restrict gender transition procedures for minors to research settings exclusively, limiting eligibility to early childhood-onset gender dysphoria cases.

C. Finland

Finland's Council for Choices in Health Care, the monitoring agency for national public health services, issued guidelines in 2020 calling for psychosocial support as primary treatment, hormone therapy only after careful case-by-case consideration, and no surgical treatment for minors.[65, 66] Finland has restricted gender transition procedure eligibility to minors with early childhood-onset gender dysphoria and without mental health comorbidities.

D. Denmark

Denmark experienced increased sex-rejecting procedure referrals from 97 individuals in 2016 to 352 in 2022, with biological females aged 11-18 constituting 70 percent.[67] Concerned about rising referrals and reports of treatment regret or attempts to reverse hormone-induced bodily changes, Denmark adopted an approach emphasizing assessment and psychosocial support for minors while postponing hormone therapy decisions, including puberty blockers and cross-sex hormones, particularly when gender incongruence has been brief or when questions exist regarding gender identity stability.[68]

E. Norway

Norway's Norwegian Commission for the Investigation of Health Care Services (UKOM), an independent state agency, issued 2023 recommendations regarding treatment for children and young people with gender incongruence.[69] Recommendations included classifying puberty blockers and surgical treatment for children as experimental, revising national guidelines based on systematic

knowledge synthesis, and establishing a national registry to enhance quality and reduce treatment variation. Norway's public health authority has indicated intentions to adjust current treatment guidelines in response to UKOM concerns.[70]

F. Additional Countries

Italy,[71] Brazil,[72] and Australia[73] represent additional countries that have restricted or contemplated restricting various sex-rejecting procedures for minors.

G. International Developments Summary

Growing international concern exists regarding hormonal and surgical interventions for pediatric gender dysphoria among countries conducting rigorous, independent, evidence-based evaluations. While certain medical associations have endorsed sex-rejecting procedures, the HHS Review emphasizes that these endorsements lack grounding in evidence-based medicine and often reflect suppression of opposing ideas.

V. DECLARATION

Based on the comprehensive evidence review published by the Department of Health and Human Services, documented risks of significant harm, markedly weak evidence of benefit, unfavorable risk-benefit profiles, inadequate existing clinical guidelines, growing international consensus among countries conducting rigorous evidence reviews, and applicable medical ethics principles, I hereby declare:

Sex-rejecting procedures for children and adolescents are neither safe nor effective as a treatment modality for gender dysphoria, gender incongruence, or other related disorders in minors, and therefore, fail to meet professional recognized standards of health care. For the purposes of this declaration, "sex-rejecting procedures" means pharmaceutical or surgical interventions, including puberty blockers, cross-sex hormones, and surgeries such as mastectomies, vaginoplasties, and other procedures, that attempt to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex.

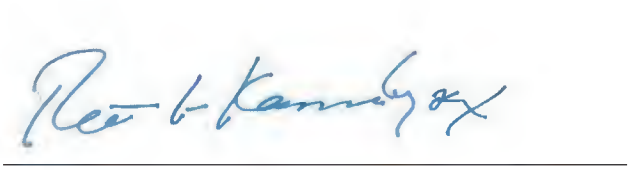
This Declaration does not apply (1) To treatment of an individual with a medically verifiable disorder of sexual development; (2) For purposes other than attempting to align an individual's physical appearance or body with an asserted identity that differs from the individual's sex; or (3) To treat complications, including any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of a sex-rejecting procedure. 42 CFR § 1001.2 allows the Secretary to declare a "treatment modality *not* to be safe and effective," (emphasis added), and accordingly nothing in this declaration recommends a particular treatment for gender dysphoria or any other condition. However, the HHS Review points to psychotherapy (talk therapy) as a noninvasive alternative to sex-rejecting procedures. As Sweden's national health authority has recommended, "[p]sychosocial support that helps adolescents deal with natal puberty without medication needs to be the first option when choosing care measures."[74]

Under 42 U.S.C. § 1320a-7(b)(6)(B), the Secretary "may" exclude individuals or entities from participation in any Federal health care program if the Secretary determines the individual or entity has furnished or caused to be furnished items or services to patients of a quality which fails to meet professionally recognized standards of health care. This declaration does not constitute a determination that any individual or entity should be excluded from participation in any Federal health care program. Any such determination could only be made after a separate determination under 42 C.F.R. § 1001.701, which is subject to further administrative and judicial review under 42 C.F.R. §§ 1001.2007,

1005.21. Before making any such determination, HHS will ensure compliance with applicable laws, regulations, court orders, and any required procedures.

This declaration rests upon the best available scientific evidence and aims to promote the health, safety, and well-being of children and adolescents, who constitute an especially vulnerable population deserving the highest standards of care.

DECLARED this 18th day of December, 2025.



Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human Services

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EXHIBIT N

HHS General Counsel Mike Stuart
@HHSGCMikeStuart

SIX hospitals located in SIX different states...

It is truly unfortunate that today I referred to @OIGATHHS for full investigation SIX more hospitals from SIX different states for allegedly failing to protect our children from sex-rejecting procedures- procedures that cause permanent terrible harm.

These hospitals appear to continue to operate outside recognized standards of healthcare and entirely outside @SecKennedy's declaration that sex-rejecting procedures for children and adolescents are neither safe nor effective.

The SIX hospitals referred for investigation are:

Nemours Alfred I. DuPont Hospital for Children (DE)

Ann & Robert H. Lurie Children's Hospital of Chicago (IL)

Boston Children's Hospital (MA)

The Children's Hospital of Philadelphia (PA)

New York University – Langone Health (NY)

Doernbecher Children's Hospital (OR)

There is no greater priority than protecting our children. It is our solemn responsibility. @HHSGov and this General Counsel will never stop doing all in our ability to protect our children from "sea to shining sea." We must be a nation that values our children. Life-altering procedures that do harm must end.

God Bless our children! God Bless them all!

6:40 PM · Jan 15, 2026 · **32.6K** Views

59 480 1.4K 41

Read 59 replies

2:48

Post

HHS General Counsel Mike Stuart
@HHSGCMikeStuart

Another day, another sad referral. When I say we will protect children, well, that's exactly what I mean.

Today, I referred for investigation to @OIGatHHS another hospital- Children's Minnesota including its Gender Health program- for failure to meet recognized standards of health care. According to claims data, the hospital has billed extensively for hormone therapy.

The HHS @SecKennedy declaration made clear that sex-rejecting procedures for children and
adolescents are neither safe nor effective. @HHSOGC and @HHSGov will continue to take all necessary action to protect children all across the nation.

6:35 PM · 05 Jan 26 · **51.1K** Views

73 Reposts **4** Quotes **507** Likes

16 Bookmarks

Post your reply

Post

HHS General Counsel Mike Stuart
@HHSGCMikeStuart

Today I referred Seattle Children's Hospital to @OIGatHHS for failure to meet recognized standards of health care as according to Sec Kennedy's declaration that sex-rejecting procedures for children and
adolescents are neither safe nor effective. Our kids safety is critical!

6:29 PM · 26 Dec 25 · **484** Views

2 Reposts **10** Likes

Most relevant replies

Post your reply

Post

HHS General Counsel Mike Stuart
@HHSGCMikeStuart

Today I again referred for investigation to @OIGatHHS another hospital for failure to meet recognized standards of health care per the @HHSGov @SecKennedy declaration that sex-rejecting procedures for children and adolescents are neither safe nor effective - Children's Hospital Colorado. Sadly, it may not be the last referral.

@HHSOGC will always take every possible action to ensure children all across the nation are safe and protected.

4:08 PM · 30 Dec 25 · **27.6K** Views

17 Reposts **5** Quotes **72** Likes **4** Bookmarks

Most relevant replies

Boris Spider @BorisSpider... · 6d
Replying to @HHSGCMikeStuart @OIGatHHS and 2 others
This is great. How about referring some hospitals to the CMS' Fraud Defense

Post your reply

EXHIBIT O

COMMONWEALTH OF PENNSYLVANIA
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E[redacted] W[redacted] o/b/o [redacted]	:	
Complainant	:	PHRC Case No. 202502571
v.	:	
PENN STATE HEALTH,	:	
Respondent.	:	

ORDER

AND NOW, this _____day of _____, 202__, upon consideration of Respondent's Motion to Dismiss, and any briefs submitted in support and opposition thereto, it is hereby ORDERED that Respondent's Motion is GRANTED, and Complainant's Complaint is hereby DISMISSED with prejudice.

_____

COMMONWEALTH OF PENNSYLVANIA
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E W o/b/o ,	:	
Complainant	:	PHRC Case No. 202502571
v.	:	
PENN STATE HEALTH,	:	
Respondent.	:	

RESPONDENT PENN STATE HEALTH'S MOTION TO DISMISS

Respondent Penn State Health ("PSH" or "Respondent"), by and through its attorneys, Buchanan Ingersoll & Rooney PC, hereby files this Motion to Dismiss the Complaint filed by E W o/b/o before the Pennsylvania Human Relations Commission (the "PHRC"), and respectfully moves the PHRC to dismiss the Complaint in its entirety, with prejudice. In support thereof, Respondent avers as follows:

1. On or about September 5, 2025, Complainant E W ("Complainant") filed a Complaint of Discrimination with the PHRC on behalf of her minor child, ("claiming only that was subjected to discrimination in violation of the Pennsylvania Human Relations Act ("PHRA") based on his[1] sex, transgender.

2. Complainant specifically alleges PSH ceased providing certain gender-affirming care to minors (individuals under the age of nineteen (19)), including in or around May 2025,

[1] PSH utilizes the pronouns "he/him/his" when referring to as Complainant indicated is a transgender male. *See* Complaint at ¶A.1.

in response to an Executive Order which prohibits medical facilities and physicians from providing this care at the risk of losing federal funding. *See* Complaint at pg. 2.

3. Executive Order 14187 ("E.O. 14187") directed the Secretary of the United States Department of Health and Human Services ("HHS") to take certain actions to ensure healthcare providers who receive federal funding cease providing gender-affirming care to children, including changing Medicare or Medicaid conditions of participation or conditions for coverage and clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs. *See* Executive Order 14187, Protecting Children from Chemical and Surgical Mutilation, FR Doc. 2025-02194, attached to the accompanying brief as **Exhibit A**[2].

4. E.O. 14187 directed the head of each executive department or agency that provides research or education grants to medical institutions to immediately take appropriate steps to ensure that institutions receiving Federal research or education grants, like Petitioners, cease providing gender-affirming care to children under the age of nineteen (19). *See id.*

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[2] The PHRC may properly take judicial notice of E.O. 14187, the HHS guidance, and the OAG Memorandum (Exhibits A through D), and may consider them as part of this Motion to Dismiss, without converting the present Motion to a Motion for Summary Judgment, because Complainant explicitly relies upon E.O. 14187, because the documents are undisputed and public documents that are integral to the Complaint. *See* Pa.R.E. 201 ("The court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned …The court: (1) may take judicial notice on its own; or (2) must take judicial notice if a party requests it and the court is supplied with the necessary information."); *see also In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1426 (3d Cir.1997) (In deciding motions to dismiss for failure to state a claim, courts may consider "document[s] *integral to or explicitly relied* upon in the complaint"); *PBGC v. White Consol. Indus.,* 998 F.2d 1192, 1196 (3d Cir.1993) ("We now hold that a court may consider an undisputably authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document."); *Clark v. Governor of New Jersey*, 53 F.4th 769, 773 n. 5 (3d Cir. 2022) ("Although not every executive order discussed herein was entered into the record below, we may take judicial notice of their content."); *Union Cnty. Jail Inmates v. Di Buono*, 713 F.2d 984, 988 n.4 (3d Cir. 1983) (taking judicial notice of state executive orders).

5. In accordance with E.O. 14187's directives, the Secretary of HHS withdrew former guidance related to gender-affirming care and issued new guidance protecting whistleblowers who take action related to ensuring compliance with E.O. 14187. *See id.*; see also February 20, 2025, HHS Guidance, attached to the accompanying brief as **Exhibit B** (rescinding the March 2, 2022, guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy"); April 14, 2025, HHS Guidance, attached to the accompanying brief as **Exhibit C** ("Guidance for Whistleblowers on the Chemical and Surgical Mutilation of Children").

6. Also in accordance with E.O. 14187's directives, on April 22, 2025, the Office of Attorney General of the United States ("OAG") issued a Memorandum for Select Component Heads to Petitioners with the subject "Preventing the Mutilation of American Children ("OAG Memorandum"), which advised healthcare providers that the United States Department of Justice would undertake investigations of certain federal statutes related to the information medical providers give to the public about the long-term side effects of gender-affirming care and would investigate an prosecute all female genital mutilation offenses to the fullest extent possible, which would encompass female genital mutilation on persons under the age of eighteen (18) and which would carry a maximum prison sentence of ten (10) years per count. See OAG Memorandum, attached to the accompanying brief as **Exhibit D**.

7. In relevant part, the PHRA guarantees individuals the right to obtain all accommodations, advantages, facilities, and privileges of any public accommodation without discrimination because of sex. 43 P.S. § 953.

8. A "public accommodation, resort or amusement" includes clinics and hospitals. 43 P.S. § 954.

9. The PHRA does not define "sex." *See* 43 P.S. § 954.

10. On or about August 16, 2023, the PHRC issued regulations, 16 Pa. Code §§ 41.201 – 41.207 (the "PHRC regulations"), which define "sex" as used in the PHRA and the Pennsylvania Fair Educational Opportunities Act ("PFEOA") as inclusive of "gender, including a person's gender identity or gender expression." 16 Pa. Code § 41.206.

11. However, even after the issuance of the PHRC regulations, and even after the United States Supreme Court held that discrimination based on homosexuality or transgender constitutes sex discrimination under Title VII in *Bostock v. Clayton Cnty. Georgia*, 140 S. Ct. 1731 (2020), the Pennsylvania Supreme Court clearly defined "sex" as "either the male or female division of a species …" for purposes of the Equal Rights Amendment to the Pennsylvania Constitution, Pa. Const. art. I, § 28. *Allegheny Reprod. Health Ctr. v. Pa. Dep't of Hum. Servs.*, 309 A.3d 808, 868-869 (Pa. 2024).

12. The Pennsylvania Supreme Court further explained: "There is no reason to conclude, based on the text of Section 28, that there was an intention to give a different meaning to sex than the meaning given to it in the PHRA that preceded it." *Allegheny*, 309 A.3d at 876.

13. The PHRC regulations should be invalidated and/or should otherwise not be considered, as they were issued in violation of the non-delegation doctrine of the Pennsylvania Constitution. *See* Pa. Const., art. II, § 1; *see also City of Lancaster v. Pa. Pub. Util. Comm'n*, 313 A.3d 1020, 1027-1028 (Pa. 2024) (the non-delegation doctrine, derived from Article II, Section non-delegation doctrine, derived from Article II, Section 1 of the Pennsylvania Constitution, "requires that the basic policy choices involved in 'legislative power' actually be made by the [l]egislature as constitutionally mandated").

14. Under Pennsylvania Supreme Court precedent, "sex" only includes "male" and "female;" thus, Complainant's claim must be dismissed because she does not allege [redacted] was discriminated against because he is male or because he is female. *See* Complaint at pg. 1 (alleging the only reason he was discriminated against was based on "Sex: Transgender").

15. To the extent the PHRA is construed as requiring Respondent to provide certain gender-affirming care to individuals under the age of nineteen (19), Complainant's claim also fails because the PHRA (and PHRC regulations) are preempted by federal law—specifically, by E.O. 14187 and the corresponding federal mandates, guidance, and directives. *See Lindsey v. Caterpillar, Inc.*, 480 F.3d 202, 205-206 (3d Cir. 2007) (explaining that state law is preempted to the extent it actually conflicts with federal law, and that actual conflict arises when it is impossible to comply with both the federal and state laws or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress).

16. Finally, even if the PHRC regulations are considered applicable, and even if the PHRA was not preempted by federal law, Complainant's claim of discrimination under the PHRA still fails because she admits that PSH ceased providing certain gender-affirming care to [redacted] ***because*** [redacted] ***is a minor under the age of nineteen (19)***, and ***not because of his sex***. *See* Complaint at ¶¶A.5-6.

WHEREFORE, Respondent respectfully requests the PHRC to grant its Motion to Dismiss the Complaint filed by E[redacted] W[redacted] o/b/o [redacted] and issue an Order dismissing the Complaint in its entirety with prejudice.

[SIGNATURE PAGE FOLLOWS]

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

By: _____

Anthony (T.J.) Andrisano (Atty. ID #201231)
Alyssa K. Stouder (Atty. ID # 324468)
409 North Second Street, Suite 500
Harrisburg, PA 17101
Phone: (717) 237-4800
Email: anthony.andrisano@bipc.com
Email: alyssa.stouder@bipc.com
Attorneys for Respondent

December 8, 2025

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Motion to Dismiss was served upon the following parties this 8th day of December, 2025, via First-Class U.S. mail, postage prepaid:

E W

I hereby certify that a true and complete copy of the foregoing Motion to Dismiss was served upon the following parties this 8th day of December, 2025, via electronic mail:

I'Janaya Young
PA Human Relations Commission
Harrisburg Regional Office
333 Market Street, 8th Floor
Harrisburg, PA 17101-2210
ijyoung@pa.gov

By: Krista M. Kiger
Krista M. Kiger
Practice Assistant

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
PENNSYLVANIA HUMAN RELATIONS COMMISSION

E[redacted] W[redacted],	:	
o/b/o [redacted],	:	
Complainant	:	
	:	
v.	:	**PHRC Case No. 202502571**
	:	
	:	
Penn State Health,	:	
Respondent	:	

ORDER

AND NOW on the 26th day of January 2026, upon consideration of Respondent's Motion to Dismiss and the Commission's response thereto, it is hereby **ORDERED** pursuant to 16 Pa. Code §42.131 (c)(1) that:

1. Pursuant to 16 Pa. Code §42.61, if during or after investigation the staff determines that the Commission lacks jurisdiction, the staff will make a finding reflecting that determination and proceed with case closure or other action as may be deemed necessary or appropriate by the Executive Director or another authorized staff person.
2. In its January 21, 2026 Reply to Respondent's Motion to Dismiss, the Commission agreed with Respondent that the PHRC did not have jurisdiction over Complainant's Complaint, because Complainant alleges they were denied services based on their age (under 19), which is not in and of itself a violation of the PHRA. Therefore, the case shall be returned to the appropriate regional office for further action pursuant to 16 Pa. Code §42.61.

PENNSYLVANIA HUMAN RELATIONS COMMISSION

By: _____

Tamara Shehadeh-Cope, Hearing Examiner

Complainant:	E W o/b/o [redacted] *Via first class mail and e-mail*
For the Commission:	Stacey McNaney, Esq. Assistant Chief Counsel PA Human Relations Commission 555 Walnut St., Ste. 808 smcnaney@pa.gov *Via email*
For Respondent:	Anthony Andrisano Jr. Alyssa Stouder anthony.andrisano@bipc.com alyssa.stouder@bipc.com *Via e-mail*

EXHIBIT Q

COMMONWEALTH OF PENNSYLVANIA

GOVERNOR'S OFFICE

PENNSYLVANIA HUMAN RELATIONS COMMISSION

K[redacted] S[redacted] o/b/o her minor child, Complainant	:	
v.	:	PHRC Case No. 202503272
Penn State Health; Penn State Health Medical Group Briarcrest, Respondents	:	

AMENDED COMPLAINT

JURISDICTION

Jurisdiction is pursuant to the Pennsylvania Human Relations Act 43 P.S. §§ 951-963.

PARTIES

The Complainant herein is:

K[redacted] S[redacted] o/b/o her minor child
[redacted]

The Respondents herein are:

Penn State Health
100 Crystal A Drive, MC CA210
Hershey, PA 17033

Penn State Health Medical Group Briarcrest
905 W Governor Rd
Suite 200
Hershey, PA 17033

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE
PENNSYLVANIA HUMAN RELATIONS COMMISSION

K.S., on behalf of her minor child,

Complainant, PHRC Case No. 202503272

v.

PENN STATE HEALTH, PENN STATE HEALTH MEDICAL GROUP BRIARCREST, and PENN STATE HEALTH MILTON S. HERSHEY MEDICAL CENTER,

Respondents.

AMENDED COMPLAINT

1. COMPLAINANT

K[redacted] S[redacted], on behalf of her minor child [redacted]

Counsel:
Anne Puluka
Dan Vitek
Community Justice Project
100 Fifth Avenue, Suite 900
Pittsburgh, PA 15222
apuluka@cjplaw.org
dvitek@cjplaw.org

2. RESPONDENTS

Penn State Health
100 Crystal A Drive, MC CA210
Hershey, PA 17033

Penn State Health Medical Group Briarcrest
905 W. Governor Road, Suite 200
Hershey, PA 17033

Penn State Health Milton S. Hershey Medical Center
500 University Drive, MC H162
Hershey, PA 17033

3. Respondents Penn State Health Medical Group Briarcrest and Penn State Health Milton S. Hershey Medical Center, under the direction and control of Respondent Penn State Health, operate a medical center and hospital which are open to, accept, or solicit the patronage of the general public.

4. Penn State Health Medical Group Briarcrest is located at 905 W. Governor Road, Suite 200, Hershey, PA 17033.

   Complainant visited Penn State Health Medical Group Briarcrest between November 2024 and July 2025.

5. **Protected Class**: Sex (nonbinary), gender identity, disability (gender dysphoria)

6. **Dates of discrimination**: July 5, 2025
   Continuing? No

7. **Describe the discriminatory conduct, with specificity, and explain how the discriminatory conduct is related to your protected class:**
   (e.g. denial of admittance, denial or disability accommodation, retaliation, different terms and conditions of services provided)

Penn State Health Medical Group Briarcrest--Adolescent Medicine ("Briarcrest") and Penn State Health Milton S. Hershey Medical Center ("MSHMC") are entities controlled by Penn State Health (collectively, "Respondents"). Briarcrest and MSHMC implemented the policy at issue here at the direction of Penn State Health.[1] According to its articles of incorporation, Penn State Health was formed "to promote, support and further the charitable, educational, and scientific purposes of The Pennsylvania State University, a Pennsylvania nonprofit corporation and instrumentality of the Commonwealth of Pennsylvania." The Pennsylvania State University is one of two members of Penn State Health and maintains control over many aspects of Penn State Health's governance. By allowing Penn State Health and its related entities and medical providers to use service marks and symbols associated with The Pennsylvania State University, the university has authorized Penn State Health, Briarcrest, and MSHMC to hold themselves out as providing health care services that originate from the Pennsylvania State University.

K.S., on behalf of her minor child, [redacted].,[2] brings this complaint against Respondents because they discontinued medically necessary gender-affirming care for [redacted] based on their sex, nonbinary gender identity, and disability in violation of the Pennsylvania Human Relations Act.

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[1] MSHMC's form 990, Schedule O, for tax year 2023 lists Penn State Health as its parent, and The Pennsylvania State University as the parent of Penn State Health. The form goes on to state that as sole member, Penn State Health has the authority to approve and authorize additions and eliminations of clinical services at MSHMC.

[2] [redacted] birth name, [redacted]., appears in the original complaint in this matter. [redacted] is in the process of pursuing a legal name change, and their chosen name is used throughout this amended complaint.

Before seeking gender-affirming care from Respondents, [redacted], who was assigned female at birth, had been experiencing symptoms of gender dysphoria for approximately one year and had begun the process of socially transitioning to a nonbinary identity. This social transition included using a gender-neutral name at school and in social situations; investigating the process for a legal name change; changing their clothing and style of dress; and adopting gender neutral or male pronouns. After discussing these changes, and the impact [redacted]'s gender discordance had on their mental health, their primary care physician diagnosed [redacted]. with gender dysphoria of adolescence in May of 2024.[3] K.S. then sought treatment for [redacted] at Briarcrest, a medical provider that specialized in treating adolescents with gender dysphoria.

[redacted] began treatment at Briarcrest in or about November of 2024 with a social worker and therapist, [redacted], an employee of MSHMC. [redacted] diagnosed [redacted]. with adjustment disorder with mixed anxiety and depression due to gender dysphoria in December of 2024. Gender dysphoria affected [redacted]'s ability to use the bathroom and their mental health, as they showed clinically significant levels of depression and anxiety. [redacted] determined that [redacted]. was eligible and ready for gender-affirming care and emotionally and cognitively mature enough to provide informed consent to the treatment after fully discussing the risks and benefits.

[redacted]. then began treatment with [redacted] at the Briarcrest. [redacted] prescribed danazol for menstrual suppression and testosterone for gender affirmation.[4] [redacted]. began taking testosterone weekly by injection in December of 2024.[5] [redacted]. continued the testosterone treatment while also regularly seeing [redacted] for counseling and [redacted] for medication monitoring. The monitoring was essential to [redacted]'s treatment because regular blood work is required to ensure they are receiving the correct dose and that the medication does not have adverse side effects.

[redacted] has thrived since beginning this treatment. Their anxiety and depression decreased markedly, as measured by assessments by [redacted] in November of 2024 and June of 2025. They feel more comfortable in their own skin and in social situations and have not experienced

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[3] Gender dysphoria, identified in American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, is a serious medical condition defined by an incongruence between an individual's expressed or experienced gender (their gender identity) and their sex assigned at birth that lasts at least six months. This condition causes impairment in social, occupational, or other important areas of functioning, and the diagnosis "requires attendant disabling physical symptoms, in addition to manifestations of clinically significant emotional distress." *Doe v. Pa. Dep't of Corrs.*, 2021 WL 1583556, at *10 (W.D. Pa. Feb. 19, 2021) (quoting *Doe v. Ma. Dep't of Corrs.*, 2018 WL 2994403 at *6 (D. Mass. 2018)). When gender dysphoria is severe, it can result in a person's inability to function in everyday life and can affect several major life activities, including the ability to breathe, sleep, use the bathroom, focus at school, eat, learn, care for oneself, and interact with others. Left untreated, gender dysphoria can result in debilitating depression, distress, impairment of function, self-harm, and suicidal ideation. Fortunately, appropriate treatment of gender dysphoria can cure all of these symptoms.

[4] Danazol is a synthetic steroid originally developed to treat pelvic pain and for menstrual suppression for patients with endometriosis. *See* Scatoni A, Roberts Z, Boskey ER, *et al.* Danazol's use for menstrual suppression in transgender individuals: A retrospective multi-site cohort study. WOMEN'S HEALTH. 2024;20. doi:10.1177/17455057241265081. Because they were able to achieve menstrual suppression with the testosterone alone, K.W. did not use the danazol.

[5] Testosterone is commonly prescribed to adolescents experiencing gender dysphoria later in puberty. Hormone therapy is also prescribed to cisgender adolescents for a variety of other conditions, including delayed puberty, or to suppress menstruation in cisgender adolescents with developmental delays to improve their quality of life.

detrimental side effects. The medication has stopped their menstrual cycle and masculinized their voice, which [redacted]. finds affirming and has significantly decreased their gender dysphoria. Because of the success of the treatment, [redacted]. planned to continue the testosterone, through [redacted] at Briarcrest, indefinitely.

In April of 2025, K.S. saw an article in the news about Penn State Health discontinuing gender-affirming care for minors and reached out to [redacted], via patient portal, with concern about [redacted]'s treatment. At that time, an employee of Briarcrest and Penn State Health assured K.S. that treatment was not being discontinued for existing patients. Nevertheless, in May of 2025, K.S. learned from a friend that Respondents intended to discontinue all gender-affirming care for patients under the age of 19.

On June 11, at a regularly scheduled appointment with [redacted], K.S. and [redacted]. learned that Respondents would be discontinuing gender-affirming medical and pharmacological treatment for patients under the age of 19 as of August 1, 2025. [redacted] provided them with a letter on Penn State Health letterhead that described the change as "an institutional policy update at Penn State Health" that was implemented "following federal guidance." The letter explained that Penn State Health would assist patients in transferring or concluding treatment and provided contact information for suicide and crisis support services. K.S. and [redacted] were also given a second letter, also printed on Penn State Health letterhead, that included a list of potential alternative medical treatment providers and a list of mental health and community support resources.

[redacted] had their final appointment with [redacted] at the end of June and with [redacted] at the end of August. In closing [redacted]'s case, [redacted] wrote in her final summary that discontinuing [redacted].'s treatment was "not based in medical practice recommendations" but rather was the result of "institutional policy change" "based on federal executive orders from January 2025." Other than providing the list of suggested alternative providers and mental health and community support resources, [redacted] did not present a structured plan for discontinuing [redacted]'s testosterone.

After learning that Respondents were discontinuing [redacted]'s care, K.S. began searching for a new medical provider that would accept [redacted]'s Medicaid insurance. None of the five recommended providers listed in the letter from Respondents were able to treat [redacted], as they either did not offer treatment for minors or did not accept Medicaid insurance. K.S. expanded her search, contacting over 20 providers in total, including some located several hours from their home, but has been unable to find a provider to continue [redacted]'s medical care.

[redacted] now continues counseling with a new provider, but does not have access to medication management or monitoring. Once [redacted] has exhausted the supply of testosterone they already have, they will be forced to stop the treatment without medical advice or monitoring. Terminating the testosterone treatment will result in [redacted] losing the masculinized features they have gained through treatment, or, in other words, "de-transitioning." They are concerned that their depression and anxiety, which decreased significantly with hormone therapy, will return if they are forced to live in a body that does not reflect their gender identity.[6] Additionally, [redacted] is

[6] According to a 2024 report from the Trevor Project, 46% of transgender and nonbinary young people seriously considered attempting suicide in the prior year. R. Nath, et al., *2024 U.S. National Survey on the Mental Health of*

at immediate risk due to lack of continued medication monitoring to ensure that they are responding to the treatment appropriately.

On information and belief, Respondents have not stopped treating cisgender adolescents and adults under the age of 19 who have been prescribed puberty-blocking medication or hormone therapy, nor have Respondents stopped taking on new cisgender patients for this treatment. Respondents have denied [redacted]. this care on the basis of [redacted]'s sex and gender identity, in violation of the PHRA. *See* 43 P.S. § 955(i)(1); 16 Pa. Code § 41.206(3).

Moreover, on information and belief, Respondents have not stopped treating adolescents and adults under the age of 19 with puberty-blocking medication or hormone therapy when such treatment is medically necessary for diagnoses other than gender dysphoria. Respondents have denied [redacted] this care on the basis of [redacted]'s disability, gender dysphoria, in violation of the PHRA. *See* 43 P.S. § 955; 43 P.S. § 954.

Having exhausted their options for alternative medical providers, K.S., on behalf of [redacted], requests that the PHRC seek immediate injunctive relief against Respondents pursuant to 43 P.S. § 959.2. Specifically, she requests the PHRC seek an injunction requiring Respondents to resume providing gender-affirming care to all patients under 19 years of age consistent with its practices prior to August 1, 2025. In addition, K.S. seeks all other appropriate remedies under the PHRA, including medical expenses associated with the termination of care, emotional distress, punitive damages, and attorneys' fees and costs. 43 P.S. §§ 959 *et seq*.

LGBTQ+ Young People, The Trevor Project (2024), https://www.thetrevorproject.org/survey-2024/assets/static/TTP_2024_National_Survey.pdf. Transgender youth receiving gender-affirming interventions, specifically puberty-blocking treatments and gender-affirming hormones, show significantly improved mental health outcomes, including lower tendencies toward depression, self-harm, and suicidal ideation. Diana M. Tordoff, et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, JAMA Network Open, 2022 Feb 1; 5(2), (available at https://pubmed.ncbi.nlm.nih.gov/35212746/).

8. Based upon the foregoing, I/we allege that the Respondent(s) violated Section 5 of the Pennsylvania Human Relations Act, 43 P.S. §§ 951-963, and the implementing regulations, 16 Pa. Code §§ 41.1-47.74..

9. The Pennsylvania Human Relations Commission has jurisdiction over this matter pursuant to the Pennsylvania Human Relations Act, 43 P.S. §§ 951-963.

10. I/we pray that the Respondent(s) be required to provide all appropriate remedies under Section 9 of the Pennsylvania Human Relations Act.

VERIFICATION

I hereby verify that the statements contained in this Complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements herein are made subject to the penalties of 18 Pa.C.S.A. § 4904, relating to unsworn falsification to authorities.

12/29/2025
Date

Signed by:
[redacted]
Signature

K[redacted] S[redacted]
Printed Name

Date

Signature

Printed Name

WARNING: COMPLAINTS MUST BE SIGNED AND FILED WITHIN 180 DAYS OF THE ALLEGED ACT OF HARM.

WARNING: IF YOU FAIL TO COMPLETE ANY PORTION OF THIS COMPLAINT, THE PHRC MAY NOT ACCEPT YOUR COMPLAINT FOR FILING.