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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON
EUGENE DIVISION

STATE OF OREGON, STATE OF WASHINGTON, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MAINE, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, JOSH SHAPIRO, in his official capacity as Governor of the Commonwealth of Pennsylvania, STATE OF RHODE ISLAND, STATE OF VERMONT, and STATE OF WISCONSIN; Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as the Secretary of the Department of Health and Human Services; THOMAS MARCH BELL, in his official capacity as Inspector General of the Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL; and the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 6:25-cv-02409-MTK AMENDED COMPLAINT

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I. INTRODUCTION

1. On December 18, 2025, without warning, Department of Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr., posted to the HHS website a "declaration" titled "Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents" ("Kennedy Declaration" or "Declaration"). The Kennedy Declaration purports to set a new quality standard for healthcare, for the entire United States, that certain medical treatments for gender dysphoria or related disorders (hereinafter "gender-affirming care" or "medically necessary transgender healthcare") for children and adolescents are "neither safe nor effective." According to the Kennedy Declaration, HHS may bar healthcare providers and institutions from participating in Medicare, Medicaid, and other federal healthcare programs if they treat *any* children or adolescents with these medical interventions, even outside federally funded health programs. *See* 42 U.S.C. § 1320a-7(b)(6)(B).

2. The Kennedy Declaration exceeds the Secretary's authority and violates the Administrative Procedure Act and the Medicare and Medicaid statutes.

3. The Kennedy Declaration is procedurally defective. At minimum, Secretary Kennedy and HHS cannot circumvent statutorily mandated notice and comment requirements by changing substantive legal standards by executive fiat. This action violates the rulemaking requirements under the APA, 5 U.S.C. § 553(b), and the rulemaking requirements under Medicare, 42 U.S.C. § 1395hh(a)(2), which provide that "[n]o rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard" governing Medicare may take effect unless the Secretary follows notice-and-comment rulemaking procedures and provides a minimum of sixty days for public comment.

4. The Kennedy Declaration also substantively violates the APA. First, the Declaration exceeds the Secretary's authority. Congress has not given the Secretary the authority to define the professionally established standard of care. The Kennedy Declaration cites no statute authorizing the Secretary to do so by "declaration," instead stating that it is issued "pursuant to the authority vested in the HHS Secretary," and "informed by 42 C.F.R. § 1001.2." But 42 C.F.R. § 1001.2 only defines "professionally recognized standards of health care." It does

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not authorize the Secretary to "declare" what those standards are. Agencies cannot grant themselves power that Congress has not conferred.

5. The Kennedy Declaration is also contrary to law. Congress expressly prohibits "any Federal officer … to exercise any supervision or control over the practice of medicine." 42 U.S.C. § 1395. Defendants have made clear that the Kennedy Declaration does just that. In announcing the Kennedy Declaration, Secretary Kennedy characterized it as "a clear directive to providers,"[1] and HHS touted that the Declaration means medically necessary gender-affirming care for transgender youth "do[es] not meet professionally recognized standards of health care" and that "practitioners who perform [gender-affirming care] on minors would be deemed out of compliance with those standards."[2]

6. The Kennedy Declaration has immediate, significant, and harmful impacts on the Plaintiff States as administrators of state Medicaid programs and as regulators of the practice of medicine.

7. The Kennedy Declaration directly harms Plaintiff States' abilities to administer approved state Medicaid plans in accordance with state laws that protect and guarantee medically necessary gender-affirming care. The Declaration further harms the Plaintiff States' administration of state Medicaid plans by purporting to announce a rule of decision that HHS will use as a basis to exclude from Medicaid a large swath of clinicians—including pediatricians, family medicine doctors, and endocrinologists—without process or authority. The Declaration also purports to provide a basis to exclude any "entity" employing those clinicians—including hospitals, clinics, and family practices—many of which the Plaintiff States rely upon to operate their Medicaid and other health care programs.

[1] U.S. Department of Health and Human Services, *Protecting Children*, at 3:50-4:30 (YouTube, Dec. 18, 2025), https://www.youtube.com/watch?v=aY1XfN6Tt0Q.

[2] Press Release, U.S. Department of Health and Human Services, HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children (Dec. 18, 2025), available at https://www.hhs.gov/press-room/hhs-acts-bar-hospitals-performing-sex-rejecting-procedures-children.html.

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8. The Kennedy Declaration also harms the Plaintiff States in their capacity as regulators of the medical profession within their jurisdictions. Each of the Plaintiff States license and discipline medical professionals. The Kennedy Declaration seeks to "supersede[] 'Statewide … standards of care'"—and with it, undermines the Plaintiff States' traditional sovereign authority to regulate the practice of medicine.

9. The Secretary has no legal authority to substantively alter the standards of care and effectively ban, by fiat, an entire category of healthcare. Nor does the Secretary have authority to threaten providers' participation in federal programs, including reimbursement by Medicare and Medicaid, by fiat. The Kennedy Declaration directly violates the Social Security Act's provision barring federal officers or employees from exercising control over the practice of medicine, and it ignores the Congressionally required procedures established to ensure any such decisions are based on prevailing medical standards and rigorous scientific evidence, and subject to public notice and comment.

II. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and the Administrative Procedure Act, 5 U.S.C. § 702.

11. Venue is proper in this district under 28 U.S.C. § 1391(b)(2), (e)(1) and 5 U.S.C. § 703. Defendants are a United States agency and officers or employees sued in their official capacities. The principal offices of the Oregon Health Authority and the capital of Oregon are in Marion County, and a substantial part of the events or omissions giving rise to this Complaint occurred and continue to occur within Marion County and the District of Oregon.

III. PARTIES

A. Plaintiffs

12. Plaintiff State of Oregon is a sovereign state of the United States. Oregon is represented by Attorney General Dan Rayfield, who is the chief legal officer of Oregon. The Oregon Health Authority administers the Oregon Health Plan, which is Oregon's Medicaid plan and Children's Health Insurance Program (CHIP). The Oregon Health Plan provides coverage for gender-affirming care for individuals under nineteen years old. Oregon HB 2002, enacted in

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2023, guarantees coverage for all medically necessary gender-affirming care services in commercial insurance, the Oregon Health Plan, and public employee health plans. Oregon law also provides that laws of other states that authorize civil or criminal action against a person for receiving, providing, or aiding or abetting in the provision of gender-affirming care are contrary to the public policy of Oregon. Or. Rev. Stat. § 24.500(2). Oregon law also protects medical professionals from discipline, license revocation, or adverse action by malpractice insurers when that adverse action is based solely on providing gender-affirming care in other jurisdictions. Or. Rev. Stat. §§ 675.070, 675.540, 675.745, 676.313, 677.190.

13. Plaintiff State of Washington, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Nick Brown is Washington's chief law enforcement officer and is authorized under Wash. Rev. Code § 43.10.030(1) to pursue this action. Plaintiff State of Washington administers Apple Health, which includes its Medicaid program through the Washington State Health Care Authority. Apple Health includes Washington's Medicaid, CHIP, and programs funded with state-only funds. The Washington Health Care Authority is required by state law to cover gender-affirming care in its public health programs. Wash. Rev. Code § 74.09.700. And health insurance plans issued on or after January 1, 2022, are likewise required to cover gender-affirming care. Wash. Rev. Code § 48.43.0128. Washington law also protects medical professionals from discipline, license revocation, or adverse action by malpractice insurers based upon adverse action in other jurisdictions based solely on providing gender-affirming care. Wash. Rev. Code § 18.130.450.

14. Plaintiff State of New York is a sovereign state in the United States of America. New York is represented by Attorney General Letitia James, who is the chief law enforcement officer of New York. The New York State Constitution prohibits discrimination on the basis of gender identity and gender expression. N.Y. Const. art. I, § 11(a). Under New York law, health care providers cannot deny services or treat a person less well than others on the basis of their protected characteristics including sex and gender identity or expression. N.Y. Exec. Law § 296 *et. seq.* New York law also protects access to health care without discrimination on the basis of sex, gender identity, gender expression, transgender status, or diagnosis of gender dysphoria and

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requires providers to treat their patients fairly and bans discrimination on the basis of sex, gender identity, disability, age, or source of payment. N.Y. Comp. Civ. R. & Regs. tit. 10, §§ 405.7(b)(2), (c)(2); N.Y. Comp. Civ. R. & Regs. tit. 9, § 466.13; N.Y. Pub. Health Law §§ 2803(1)(g), 2803-C-2. In New York State (NYS), the state Medicaid program, overseen by the NYS Department of Health (DOH), provides comprehensive health coverage to more than 7 million New Yorkers annually. NYS DOH also administers the Child Health Plus program, which is available for individuals under the age of nineteen who reside in New York. These programs provide coverage for a wide range of services, depending on the enrollee's age, financial circumstances, family situation, or living arrangements, through a large network of health care providers. NYS provides Medicaid coverage through the state-administered Medicaid fee-for-service program and through managed care arrangements. The majority of NYS Medicaid members are covered under Medicaid Managed Care. The costs of covering Medicaid services are shared between the state and federal government with a Federal Medical Assistance Percentage (FMAP) that generally provides 50% matching federal funding for most services.

15. Plaintiff State of California is a sovereign state in the United States of America. California is represented by Rob Bonta, the Attorney General of California, who is the chief law enforcement officer of California. The California Department of Health Care Services (DHCS) administers the state's Medicaid program, known as Medi-Cal, and California's CHIP. DHCS requires Medi-Cal managed care health plans to provide gender-affirming care. Insurers and healthcare plans covered by California law are prohibited from denying an individual a plan contract, health insurance policy, or coverage for a benefit included in the contract or policy, based on a person's sex, which is defined to include gender identity. Cal. Ins. Code § 10140. California law protects healthcare professionals from denial of application for licensure or suspension, revocation, or other discipline based on the performance, recommendation, or provision of gender-affirming care by medical boards that certify health professionals. Cal. Bus. & Prof. Code, §§ 850.1, 852. And California law protects medical professionals from the reach of other states with civil, criminal, and professional consequences related to the provision of gender-affirming care. Cal. Pen. Code, § 13778.3.

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16. Plaintiff State of Colorado, represented by and through the Attorney General, is a sovereign state of the United States of America. Attorney General Philip J. Weiser acts as the chief legal representative of the State and is authorized by Colo. Rev. Stat. § 24-31-101 to pursue this action. Colorado's Medicaid program is Health First Colorado, administered by the Colorado Department of Health Care Policy and Financing (HCPF). Colorado also provides Child Health Plan Plus (CHP+), which provides comprehensive health care benefits to uninsured children up to age nineteen who do not qualify for Medicaid and meet certain income criteria. As of January 2025, over 500,000 children were covered by Health First Colorado and CHP+. Both Health First Colorado and CHP+ are jointly funded by the federal government and Colorado state government, at different rates depending on the individual and population. On average, about 60 percent of all funding for HCPF's budget, including Health First Colorado, CHP+, other programs and administration comes in the form of federal matching funds. In fiscal year 2024, Colorado's total expenditures for Health First Colorado and CHP+ were approximately $15.1 billion total funds, including $4.5 billion general State funds. The Colorado Antidiscrimination Act prohibits discrimination on the basis of gender identity and expression. Colo. Rev. Stat. § 24-34-601. Under Colorado law, patients have a legal right to seek gender-affirming care. Colo. Rev. Stat. §§ 10-16-121(1)(f), 12-30-121, 13-21-133, 16-3-102(2), 16-3-301(4); Colo. Rev. Stat. § 10-16-104(30)(b), (d); 10 Code Colo. Regs. 2505-10-8.735. Similarly, State-regulated health insurance plans are prohibited from withholding coverage from individuals based on gender identity or gender dysphoria. 3 Code Colo. Regs. §702-4, Reg. 4-2-42, §5(A)(1)(o); Colo. Rev. Stat. § 10-16-104(30)(b). Likewise, because gender-affirming health care services are considered legally protected health care activities, *see* Colo. Rev. Stat. § 12-30-121(2), the Colorado Medical Board, the Colorado State Board of Nursing, and other affected health care regulatory boards may not deny licensure or otherwise impose disciplinary action against a licensee's licenses based solely on the provision of gender-affirming care, so long as the care provided otherwise meets generally accepted standards of medical practice in Colorado. Colo. Rev. Stat. § 12-30-121(2)(a). In addition, Colorado law protects patients and licensees who provide gender-affirming care from lawsuits and criminal prosecution in other states. Colo. Rev. Stat. §§ 12-30-

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121(2); 13-21-133. Colorado also regulates the practice of medicine for providers and entities, including several major hospitals, that likewise provide gender-affirming care services. These institutions rely on Medicaid reimbursement, and up through the Kennedy Declaration, Colorado Health First and CHP+ have successfully received Medicaid reimbursement for the provision of such services.

17. Plaintiff State of Connecticut, represented by and through the Attorney General, William M. Tong, is a sovereign state of the United States of America. Attorney General Tong is the State's chief legal officer and is authorized under Connecticut General Statutes § 3-125 to act in federal court on behalf of the State on matters of public concern. The Connecticut Department of Social Services administers Connecticut's Medicaid and CHIP. Connecticut's Medicaid and CHIP plans provide coverage for gender-affirming care for individuals under nineteen years old.

18. Plaintiff District of Columbia is a municipal corporation organized under the Constitution of the United States. It is empowered to sue and be sued, and it is the local government for the territory constituting the permanent seat of the federal government. The District is represented by and through its chief legal officer, Attorney General Brian L. Schwalb. The Attorney General has general charge and conduct of all legal business of the District and all suits initiated by and against the District and is responsible for upholding the public interest. D.C. Code. § 1-301.81. In the District, neither health care providers nor health insurers may discriminate against or refuse services or treatment to a person based on their gender identity or expression. D.C. Code §§ 12-1402.31(a)(1), 31-2231.11(c).

19. Plaintiff State of Delaware is a sovereign state of the United States. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941). Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504. The Delaware Department of Health and Social Services' Division of Medicaid and Medical Assistance administers the Delaware Medical Assistance Plan (DMAP), which is Delaware's Medicaid plan and CHIP. DMAP provides coverage for gender-affirming care for individuals under nineteen years old. In 2013, Delaware

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enacted the Gender Identity Nondiscrimination Act of 2013 (GINA), which added gender identity to the already-existing list of protected classes in Delaware's nondiscrimination laws. 6 Del C. §§ 4501-4, 4601-5, 4607, 4619; 9 Del C. § 1183; 11 Del. C. § 1304, 18 Del. C. § 2304, 19 Del. C. §§ 710-11, 25 Del. C. §§ 5105, 5116, 5141, 5316, 5953, 6962. In 2016, the Delaware Department of Insurance, pursuant to GINA and the Affordable Care Act, issued Bulletin No. 86, which prohibited "the denial, cancellation, termination, limitation, refusal to issue or renew, or restriction of insurance coverage or benefits thereunder because of a person's gender identity or transgender status, or because the person is undergoing gender transition. This includes the availability of health insurance coverage and the provision of health insurance benefits."

20. Plaintiff State of Hawai'i, represented by and through its Attorney General Anne E. Lopez, is a sovereign state of the United States of America. The Attorney General is Hawaii's chief legal officer and chief law enforcement officer and is authorized by Hawaii Revised Statues § 28-1 to pursue this action.

21. Plaintiff State of Illinois is a sovereign state of the United States. Illinois is represented by Kwame Raoul, the Attorney General of Illinois, who is the chief law enforcement officer of Illinois and authorized to sue on the State's behalf. Under Illinois law, the Attorney General is authorized to represent the State's interests by the Illinois Constitution, article V, section 15. *See* 15 Ill. Comp. Stat. 205/4. The Illinois Department of Healthcare and Family Services administers the Illinois Medical Assistance Program, which includes medical services authorized for eligible individuals under Illinois's Medicaid Plan and CHIP. The Illinois Medical Assistance Program provides coverage for medical services that are used to treat gender dysphoria for individuals under the age of nineteen years old. The Lawful Health Care Activity Act, enacted in 2024, provides that "the treatment of gender dysphoria or the affirmation of an individual's gender identity or gender expression, including … care, and services of a medical, behavioral health, mental health, surgical, psychiatric, therapeutic, diagnostic, preventative, rehabilitative, or supportive nature" is "lawful health care" in Illinois. 735 Ill. Comp. Stat. 40/28-10. The Illinois Medical Practice Act also protects medical professionals who provide or assist in providing lawful gender-affirming care. 225 Ill. Comp. Stat. 60/22(C)(3). The Department of

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Financial and Professional Regulation may not "revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action" against medical professionals who provide or assist in providing gender-affirming care in Illinois. *Id*. This protection applies to nurses, pharmacists, registered surgical assistants and technologists, behavioral analysts, professional and clinical counselors, clinical psychologists, social workers, and marriage and family therapists. *See* 225 Ill. Comp. Stat. 65/65-65(a)(1); 225 Ill. Comp. Stat. 65/70-5(b-5)-(b-20); 225 Ill. Comp. Stat. 85/30.1(a); 225 Ill. Comp. Stat. 85/30(c-5)-(c-20); 225 Ill. Comp. Stat. 130/75(b-1)-(b-4); 225 Ill. Comp. Stat. 6/60(c-1)-(c-4); 225 Ill. Comp. Stat. 107/80(c-1)-(c-4); 225 Ill. Comp. Stat. 15/15(b)-(e); 225 Ill. Comp. Stat. 20/19(4.5)-(4.20); 225 Ill. Comp. Stat. 55/85(d-5)-(d-20).

22. Plaintiff State of Maine is a sovereign state of the United States of America. Maine is represented by Aaron M. Frey, the Attorney General of Maine. The Attorney General is authorized to pursue this action pursuant to 5 Me. Rev. Stat. Ann. tit. 5 § 191. The Office of MaineCare Services in the Maine Department of Health and Human Services administers MaineCare, which is Maine's Medicaid plan and includes CHIP. Maine law requires the Department to provide reimbursement for medically necessary treatment for or related to gender dysphoria or a comparable or equivalent diagnosis. Me. Rev. Stat. Ann. tit. 22 § 3174-MMM (Supp. 2025). Section 3174-MMM also prohibits the Department from discriminating in its reimbursement of medically necessary treatment on the basis of a MaineCare Member's gender identity or expression, or on the basis that the Member is a transgender individual. Further, the Legislature has declared that gender-affirming healthcare is legally-protected healthcare activity, and that any act of another state that prohibits, criminalizes, sanctions, authorizes a civil action against or otherwise interferes with a person in Maine who engages in such legally-protected healthcare activity, including aid and assistance with gender-affirming healthcare, is against the public policy of the state of Maine. Me. Rev. Stat. Ann. tit. 14 § 9001 (Supp. 2025).

23. Plaintiff State of Maryland is a sovereign state of the United States of America. Maryland is represented by Attorney General Anthony G. Brown who is the chief legal officer of Maryland. The Maryland Department of Health administers the Maryland Medical Assistance

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Program, which includes Maryland's Medicaid Plan and the Maryland Children's Health Program (MCHP). The Maryland Medical Assistance Program covers gender-affirming care for individuals under nineteen years old. Under the Trans Health Equity Act, the Program is required to cover gender-affirming care, ensuring equitable health care access for individuals who are transgender and gender diverse. 2023 Md. H.B. 283. Maryland law also defines "legally protected health care" to include gender-affirming care, Md. Code Ann., State Pers. & Pens. § 2-312(a)(3)(ii). Therefore, Maryland law protects medical professionals from out-of-state civil judgments and subpoenas related to legally protected health care, Md. Code Ann., Cts. & Jud. Proc., §§ 11-802, 9-402, as well as from changes in insurance coverage or premiums due to the provision of legally protected healthcare, Md. Code Ann., Ins., § 19-117.

24. Plaintiff Commonwealth of Massachusetts is a sovereign state of the United States and is represented by and through its Attorney General, Andrea Joy Campbell. Attorney General Campbell is authorized to pursue this action under Mass. Gen. Laws ch. 12, §§ 3, 10. Massachusetts's Executive Office of Health and Human Services operates the umbrella system known as MassHealth, which encompasses the state-federal Medicaid program, CHIP, and the 1115 Demonstration Project. Massachusetts prohibits discrimination on the basis of gender identity in the provision of healthcare services and insurance coverage, including by providers who treat patients covered by MassHealth. Mass. Gen. Laws ch. 272, §§ 92A, 98; 130 Mass. Code. Regs. § 450.202(B). Accordingly, MassHealth provides coverage for a range of gender-affirming care, including for those under 18 years of age. Access to gender-affirming care is a right secured by the constitution and laws of the Commonwealth, and acts or omissions undertaken to aid or encourage, or attempt to aid or encourage, another person in the exercise and enjoyment of the right to access healthcare services are also legally protected healthcare activities under Massachusetts law. Mass. Gen. Laws ch. 12, § 11 I ½(a)-(d).

25. Plaintiff State of Michigan is a sovereign state of the United States of America. The State of Michigan is represented by Attorney General Dana Nessel, who is the chief law enforcement officer of the State of Michigan. Michigan's Medicaid program covers medically necessary gender-affirming and gender-confirming medical treatment.

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26. Plaintiff State of Minnesota is a sovereign state of the United States of America. Minnesota's Attorney General, Keith Ellison, is the chief law enforcement officer of Minnesota and is authorized under Minnesota Statutes Chapter 8 and has common law authority to bring this action on behalf of the State and its residents, to vindicate the State's sovereign and quasi-sovereign interests, and to remediate all harm arising out of—and provide full relief for—violations of the law. Minnesota's Department of Human Services (referred to as DHS) administers Minnesota's Medicaid program (known as Medical Assistance) as well as MinnesotaCare, Minnesota's Basic Health Plan. DHS' operation of Medical Assistance also includes use of funding for some populations from CHIP. Both Medical Assistance and MinnesotaCare generally provide coverage for gender-affirming care for individuals under nineteen years old. Minnesota Statute § 256B.0625, subdiv. 3(a) and Minnesota Statute § 62Q.585 require that most health insurance plans offered, sold, issued, or renewed must provide coverage for all medically necessary gender-affirming care services. Minnesota law also prevents other states from interfering with gender-affirming care provided in Minnesota. Minn. Stat. § 260.925.

27. Plaintiff State of Nevada, represented by and through Attorney General Aaron D. Ford, is a sovereign State within the United States of America. The Attorney General is the chief law enforcement officer of the State of Nevada and is authorized to pursue this action under Nev. Rev. Stat. § 228.110 and Nev. Rev. Stat. § 228.170. The Nevada State Constitution prohibits discrimination on the basis of sex, gender identity, and gender expression. Nev. Const. art. 1, § 24. The Nevada Division of Health Care Financing and Policy administers Nevada's Medicaid program, known as Nevada Medicaid, and Nevada's CHIP. Under Nevada law, insurers and carriers cannot discriminate against any person "on the basis of actual or perceived gender identity or expression." Nev. Rev. Stat. §§ 689A.033, 689B.0675, 689C.1975, 695A.198, 695B.3167, 695C.204, 695G.415. Similarly, Nevada law guarantees coverage for all medically necessary gender-affirming care services in commercial insurance, Nevada Medicaid, and public employee health plans. Nev. Rev. Stat. §§ 422.272362, 689A.0432, 689B.0334, 689C.1652, 695A.1867, 695B.1915, 695C.16934, 695G.1718.

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28. Plaintiff State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the chief law enforcement officer for the State of New Jersey. The New Jersey Law Against Discrimination prohibits discrimination and harassment based on gender identity or expression in places of public accommodation, including clinics, hospitals, and other medical settings. *See* N.J. Stat. Ann. §§ 10:5-5(*l*), (rr), 10:5-12(f). Under New Jersey law, managed care organizations that contract with New Jersey Department of Human Services to administer New Jersey's Medicaid programs are also prohibited from categorically excluding gender-affirming care from health insurance coverage. N.J. Stat. Ann. § 30:4D-9.1.

29. Plaintiff State of New Mexico is a sovereign state in the United States of America. New Mexico is represented by Attorney General Raúl Torrez, who is the chief law enforcement officer of New Mexico and is authorized to pursue this action under N.M. Stat. Ann. § 8-5-2(B). The New Mexico Health Care Authority (HCA) administers both New Mexico's Medicaid program and CHIP. Pursuant to the CHIP State Plan, CHIP enrollees receive Medicaid covered services rather than a separate set of CHIP specific benefits. HCA's policy is to provide Medicaid coverage for medically necessary gender-affirming care as a covered service for members consistent with applicable coverage criteria, including members under nineteen years old. New Mexico's Reproductive and Gender-Affirming Health Care Freedom Act prohibits public bodies from discriminating on the basis of a person's use of or refusal to use gender-affirming health care services. N.M. Stat. Ann. § 24-34-3(A) (2023). New Mexico also prohibits public bodies from denying, restricting, or interfering with "a person's ability to access or provide … gender-affirming health care within the medical standard of care." N.M. Stat. Ann. § 24-34-3(B) (2023). Additionally, New Mexico's Reproductive and Gender-Affirming Health Care Protection Act prohibits public bodies from releasing information "in furtherance of a foreign investigation or proceeding that seeks to impose civil or criminal liability or professional disciplinary action upon an individual or entity" for engaging in the provision of gender-affirming health care. See N.M. Stat. Ann. §§ 24-35-1–8 (2023).

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30. Plaintiff Josh Shapiro brings this suit in his official capacity as Governor of the Commonwealth of Pennsylvania. The Pennsylvania Constitution vests "[t]he supreme executive power" in the Governor, who "shall take care that the laws be faithfully executed." Pa. Const. art. IV, § 2. The Governor oversees all executive agencies in Pennsylvania and is authorized to bring suit on their behalf. 71 Pa. Stat. Ann. §§ 732-204(c), 732-301(6), 732-303. The Pennsylvania Department of Human Services administers the Pennsylvania Medical Assistance Program, which is Pennsylvania's Medicaid program, and administers the Pennsylvania CHIP. Pennsylvania Medical Assistance and Pennsylvania CHIP provide coverage for gender-affirming care for individuals under nineteen years old when medically necessary.

31. Plaintiff State of Rhode Island is a sovereign state of the United States. Rhode Island is represented by Attorney General Peter F. Neronha, who is the chief legal officer of Rhode Island. The Rhode Island Executive Office of Health and Human Services is the single state agency that administers the Rhode Island Medicaid program, which encompasses both Rhode Island's Medicaid program and CHIP. The Rhode Island Medicaid program provides coverage for gender-affirming care for individuals under nineteen years old. Additionally, Rhode Island law prohibits discrimination on the basis of sex, gender identity, or gender expression in the provision of health care. State-licensed health care facilities are prohibited from denying care on the basis of sex, gender identity, or gender expression. 23 R.I. Gen. Laws § 23-17-19.1; see also 28 R.I. Gen. Laws § 28-5.1-12 (requiring state-licensed or chartered health care facilities to comply with the state policy of equal opportunity and nondiscrimination in patient admissions and health care service); 220 R.I. Code R. 80-05-1 (obligating health care facilities to admit patients without discriminating on the basis of gender identity or expression). State agencies, including the Rhode Island Executive Office of Health and Human Services, are obligated to render services to Rhode Islanders "without discrimination based on … gender identity or expression," and state agencies are further prohibited from becoming "party to any agreement, arrangement, or plan that has the effect of sanctioning those patterns or practices." 28 R.I. Gen. Laws § 28-5.1-7. The Rhode Island Medicaid program has, for over a decade, provided gender-

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affirming care to its members, including those under nineteen years old.[3] All Rhode Island Medicaid managed care organizations are required to provide such care to their members. The Rhode Island Medicaid program has sought and received Federal Financial Participation for the provision of such services.

32. Plaintiff State of Vermont, represented by Vermont Attorney General Charity Clark, is a sovereign state of the United States of America. Attorney General Clark is Vermont's chief legal officer and is authorized to pursue this action on behalf of the State. Vt. Stat. Ann. tit. 3, § 159. The State of Vermont administers its Medicaid program through the Vermont Agency of Human Services. Vermont Medicaid provides coverage for gender-affirming care for all residents, including individuals under nineteen years old. Vt. Stat. Ann. tit. 8, § 4071; Vt. Agency of Human Servs., Health Care Administrative Rules § 4.238. Vermont also guarantees coverage for all medically necessary gender-affirming care services in commercial insurance and public employee health plans. Vt. Stat. Ann. tit. 8, § 4071; Vt. Dep't of Financial Reg., Ins. Bulletin 174 (June 12, 2019). Vermont law also provides that laws that authorize civil or criminal action against a person for receiving, providing, or aiding and abetting in the provision of gender-affirming care are contrary to the public policy of Vermont. Vt. Stat. Ann. tit. 12, § 7302. Finally, Vermont law protects health care providers from disciplinary action based solely on the provider performing or assisting in gender-affirming care. Vt. Stat. Ann. tit. 26, § 1354(d).

33. Plaintiff State of Wisconsin is a sovereign state of the United States of America. Wisconsin is represented by Joshua L. Kaul, the Attorney General of Wisconsin. Attorney General Kaul is authorized to sue on behalf of the State. Wisconsin's Medicaid program is administered by the Wisconsin Department of Health Services. In *Flack v. Wisconsin Department of Health Services*, Case No. 18-cv-309-wmc (W.D. Wis.), the United States District Court for the Western District of Wisconsin issued a decision finding that administrative rules that excluded coverage of gender-affirming care services violated federal law, and it issued a permanent injunction enjoining the Wisconsin Department of Health Services from enforcing

[3] EOHHS Gender Dysphoria/Gender Nonconformity Coverage Guidelines (October 28, 2015), https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf.

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this exclusion. As a result of this permanent injunction, and since October 31, 2019, Wisconsin Medicaid provides coverage for gender-affirming care for individuals, including those under nineteen years old.

B. Defendants

34. Defendant Robert F. Kennedy, Jr., is the Secretary of the Department of Health and Human Services, and that agency's highest ranking official. He is charged with the supervision and management of all decisions and actions of that agency. 42 U.S.C. §§ 3501a, 3502. He is sued in his official capacity.

35. Defendant Thomas March Bell is Inspector General of the Department of Health and Human Services. He is sued in his official capacity.

36. Defendant Office of Inspector General is a component of the Department of Health and Human Services. 5 U.S.C. §§ 401, 402.

37. Defendant the United States Department of Health and Human Services is a Department within the Executive Branch of the United States government. 42 U.S.C. §§ 3501, 3501a.

IV. FACTUAL BACKGROUND

A. Gender-Affirming Care Is Medically Necessary Health Care Protected by State Laws

38. The Kennedy Declaration targets so-called "sex-rejecting procedures," a category of medical interventions known by medical professionals as "gender-affirming care." Gender-affirming care includes puberty-blocking medications, hormone therapy, and gender-affirming surgery. Gender-affirming care is medically appropriate, necessary health care backed by overwhelming medical consensus, including the support of the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Psychological Association, the Endocrine Society, and other American medical organizations.

39. Research and clinical data support gender-affirming care as a safe and effective treatment for gender dysphoria in adolescents. Patients receiving gender-affirming care have

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high rates of satisfaction and low incidence of regret compared with other medical treatments. Conversely, untreated gender dysphoria can have devastating impacts to the mental health and wellbeing of those youth and adolescents, and can lead to increased incidence of anxiety, depression, eating disorders, substance abuse, self-harm, and suicidality. For many patients, medically necessary gender-affirming care is life-saving.

B. The Kennedy Declaration

40. On December 18, 2025, Secretary Kennedy issued a "Declaration of the Secretary of the Department of Health and Human Services," subtitled, "RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents." A copy of the Kennedy Declaration is attached as Exhibit A to the Complaint.

41. The Kennedy Declaration purports to be issued pursuant to the Secretary's "authority and responsibilities under federal law, and pursuant to 42 C.F.R. § 1001.2." The cited regulation, 42 C.F.R. § 1001.2, is a definitional provision governing decisions to exclude health care providers from participation in Medicare and Medicaid. *See* 42 C.F.R. § 1001.1(b). This regulation does not confer any authority to the Secretary. *See Biden v. Missouri*, 142 S. Ct. 647, 656 (2022) (Thomas, J., dissenting) (refusing to find vast powers hidden in definitional provisions). The provision only refers to situations in which HHS or one of its component agencies has made a determination regarding a treatment modality's safety and efficacy—it does not purport to confer authority to the Secretary to make such pronouncements. *See* Department of Health and Human Services, Office of Inspector General, Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting From Public Law 104–191, 62 Fed. Reg. 47,182, 47,185, 47.189 (Sep. 8, 1997) (agency's explanation of the language). An agency has no power to confer authority on itself. *See New York v. FERC*, 535 U.S. 1, 18 (2002) ("[A]n agency literally has no power to act … unless and until Congress confers power upon it.") (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355 (1986)).

42. The Kennedy Declaration is purportedly based on a report that HHS issued in May 2025, and subsequently revised in November 2025, titled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" (the "HHS Review"). The Kennedy

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Declaration creates a new term, "sex-rejecting procedures," which is never used in the HHS Review, and defines it to include both pharmaceutical interventions like puberty blockers and hormone therapy, as well as surgeries such as mastectomies and vaginoplasties. The Kennedy Declaration then states that these "'sex-rejecting procedures' 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." The Declaration expressly purports to supersede "Statewide or national standards of care," including those backed by medical consensus with support from national medical organizations.

43. The Kennedy Declaration then threatens that HHS 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." While the Kennedy Declaration states only that providers "may" be excluded, and that a separate determination would be made under 42 C.F.R. § 1001.701, the Declaration itself establishes an HHS policy that the provision of any gender-affirming medical care to adolescents categorically fails to meet professionally recognized standards of care, and therefore is sufficient grounds to exclude a health care provider from participation in the Medicare and Medicaid programs.

44. The Declaration thus purports to bind the HHS Office of the Inspector General (OIG), as well as "Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG." 42 C.F.R. § 1001.1. The authority to exclude individuals or entities from participation in Medicare is set out in sections 1128 (42 U.S.C. § 1320a-7) and 1156 (42 U.S.C. § 1320c-5) of the Social Security Act. OIG is statutorily authorized to exclude individual providers only upon notice and due process of law, with such decisions appealable to the HHS Departmental Appeals Board, and subject to judicial review. The Department's regulations do not give the Secretary authority to predetermine exclusion decisions. 42 C.F.R. §§ 1001.2001 *et seq*.

45. Exclusion is an exceedingly serious punishment. "The effect of an OIG exclusion is that no Federal health care program payment may be made for any items or services furnished

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(1) by an excluded person or (2) at the medical direction or on the prescription of the excluded person." Office of the Inspector General, Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs at 6 (May 8, 2013). To give an example of the consequences of exclusion, the OIG explained, "no payment may be made to a hospital for the items or services furnished by an excluded nurse to Federal health care program beneficiaries, even if the nurse's services are not separately billed and are paid for as part of a Medicare diagnosis-related group payment received by the hospital." *Id.*

46. The exclusion also prohibits "payment for items or services furnished by an excluded individual … beyond patient care." *Id.* "[P]reparation of surgical trays," "review of treatment plans," and even "transportation services" are included in the exclusion. *Id.* at 7. "[A]dministrative and management services" are also prohibited, such that "an excluded individual may not serve in an executive or leadership role … at a provider that furnishes items or services payable by Federal health care programs." *Id.*

47. Violating an exclusion by furnishing items or services for which Federal health care program payment is sought can result in penalties including civil monetary penalties, civil actions, and criminal prosecutions. *Id.* at 9. And civil monetary penalties can be imposed on providers that employ or enter into contracts with excluded persons to provide items or services payable by Federal health care programs. *Id.* at 10. The OIG makes public the List of Excluded Individuals and Entities (https://exclusions.oig.hhs.gov) that employers can use to make employment decisions. *Id.* at 11; *see also* Office of the Inspector General, Search the Exclusions Database.

48. The Kennedy Declaration was issued with apparent immediate effect without prior notification to members of the public or to the health care providers it purports to regulate, despite statutory mandates that "no rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" under the Medicare program shall take effect unless it is promulgated by

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regulation with notice of the proposed regulation in the Federal Register and at least 60 days for public comment. 42 U.S.C. §§ 1395hh(a)(2), (b)(1).

49. The Kennedy Declaration offers no attempt to justify legislative rulemaking outside statutorily mandated notice and comment procedures and cites no exception or exemption to these requirements. Only certain limited exceptions to this notice and comment requirement apply, including where "a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment," "a statute establishes a specific deadline" for the regulation's requirements that is less than 150 days after the date of the enactment of that statute, or certain other exceptions codified in the APA. None of these exceptions apply here.

50. By contrast, on the very same day that HHS issued the Kennedy Declaration, it announced two other notices of proposed rulemaking seeking to amend certain program requirements under Medicare and Medicaid to restrict the expenditure of federal funds for medically necessary healthcare for transgender youth and to exclude hospitals that deliver these services from participation in the Medicare and Medicaid programs. These notices were published in the Federal Register and provided for a 60-day period of public comment. *See* Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicaid Program, Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59,441 (Dec. 19, 2025); Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs, Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59,463 (Dec. 19, 2025).

51. The Kennedy Declaration also purports to establish a standard of care and supersede other standards of care, despite the Medicare statute's clear "prohibition against any Federal interference," that restricts Federal officers or employees from "exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided[.]" 42 U.S.C. § 1395.

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52. To Plaintiff States' knowledge, HHS has never before issued a "declaration" or other sub-regulatory guidance document purporting to apply a categorical definition of "safety and effectiveness" to any medical intervention. The Kennedy Declaration is the first, and it does so for an array of interventions recognized as valid treatment modalities by medical professionals in the Plaintiff States.

C. Plaintiff States Administer State Medicaid Programs

53. The Medicaid health insurance program was created by federal law and is funded by the federal government. Medicaid is the federally matched medical aid program created under Title XIX of the Social Security Act in which the federal government provides matching funds to States to help pay for health care for low-income and other eligible individuals. State Medicaid programs provide health insurance for individuals, including children, whose household incomes fall below certain eligibility thresholds that vary by state. Plaintiff States administer their Medicaid programs and receive federal matching funds to provide healthcare services to Medicaid-insured residents.

54. CHIP is a related state-federal cooperative healthcare program authorized by section 2103 of the Social Security Act that offers coverage for certain low-income children and pregnant women. Thousands of children rely on CHIP for comprehensive coverage, including those that fall outside Medicaid eligibility but are unable to afford private or group health coverage. States are enabled to design their CHIP plan as a program separate from their state Medicaid plan, as an expansion of their Medicaid plan, or both. In all three instances, States retain significant discretion to determine which services and care are included, and which providers may participate, in their CHIP plans. Each of the Plaintiff States has a CHIP program.

55. Medicaid affords "substantial discretion" to participating states. *Alexander v. Choate*, 469 U.S. 287, 303 (1985). That commitment to state discretion is apparent from the text and structure of the Medicaid statute itself. States can choose whether to participate in Medicaid in the first place. *See* 42 U.S.C. § 1396a. And even after states sign up, Medicaid is not a take-it-or-leave-it proposition. Instead, the statute affords each participating state "substantial discretion

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to choose the proper mix of amount, scope, and duration limitations on coverage." *Alexander*, 469 U.S. at 303.

56. Although states' participation in Medicaid is voluntary, since "1982 every State ha[s] chosen to participate …." *NFIB v. Sebelius*, 567 U.S. 519, 542 (2012). Once states choose to participate, states must comply with federal statutory and regulatory requirements, including the creation of a State Plan outlining the administration of their respective Medicaid programs. 42 C.F.R. § 431.10. Congress has delegated policy decisions about what services should be covered to participating states by allowing them to develop their own State Plans that specify, among other things, the particular covered services within the broad categories of inclusions in the Act. 42 U.S.C. § 1396a(a)(10); 42 C.F.R. § 431.10.

57. As relevant here, State Plans also describe the state-specific standards to determine provider qualifications. The Medicaid Act provides that any individual eligible for assistance under a state Medicaid program may choose, as relevant here, any provider "qualified to perform the service or services required … who undertakes to provide him such services." 42 U.S.C. § 1396a(a)(23). By leaving the term "qualified" undefined, the Act leaves substantial discretion to states—exercising their traditional role regulating health and safety—in determining providers' qualifications for inclusion in their Medicaid programs. *See Medina v. Planned Parenthood South Atlantic*, 606 U.S. 357, 364 (2025).

58. Pursuant to 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320c-5, Defendants have limited authority to determine which providers may participate in Medicaid programs as qualified providers. Neither section authorizes HHS to exclude providers from participation in Medicaid based solely on their provision of medically necessary gender-affirming care. And neither section authorizes the Secretary of HHS to set professionally recognized standards of care to be used to exclude providers.

59. Moreover, if HHS seeks to exclude a provider based on these sections, it must provide specific process to the provider as set forth in the Social Security Act and implementing regulations. *See* 42 C.F.R. §§ 1001.1 *et seq.* These processes include but are not limited to issuance of a Notice of Intent to Exclude and an opportunity to respond to and challenge any

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determinations by HHS. Any exclusion may be appealed to an Administrative Law Judge and the resulting decision may be appealed to the HHS Departmental Appeals Board. 42 C.F.R. § 1001.2007(c).

60. HHS has continuously provided payments for gender-affirming care for minors. For example, the Oregon Health Plan, ensures "[c]omprehensive coverage for children under a Medicaid Section 1115 demonstration waiver." Under Oregon's 1115 waiver, Oregon may use a "Prioritized List of Health Services" to determine the services covered under state Medicaid and CHIP plans. Oregon's Prioritized List of Health Services, in turn, includes coverage for Gender Affirming Treatment, including medical and surgical treatment/psychotherapy. The Oregon Health Plan also provides coverage for gender-affirming care for individuals under nineteen years old through the Early and Periodic Screening, Diagnosis, and Treatment Program, which provides benefits for members of Oregon Health Plan under the age of 21 (or members who are under 26 and have Young Adults with Special Health Care Needs benefits) and covers medically necessary services as defined in Section 1905(a) of the Social Security Act (42 U.S.C. § 1396d). Those covered services include gender-affirming medical treatment.

61. For further example, Washington's Apple Health program has successfully sought reimbursement from the federal government for gender-affirming care for decades, and it claims millions of dollars annually for reimbursement for gender-affirming care provided as a part of Apple Health, including to adolescents. There are almost 6,000 distinct providers that provide gender-affirming care in Washington through the Medicaid program.

62. For further example, New York's Medicaid program, including Child Health Plus, provides coverage for medically necessary gender-affirming care for both minors and adults who meet defined criteria. *See* 18 NY Code R. Regs. 505.2; NYS Dep't of Health, Office of Health Insurance Programs, *Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria*, https://www.health.ny.gov/health_care/managed_care/plans/docs/treat_gender_dysphoria.pdf; NYS Dep't of Health, Office of Health Insurance, *Physician Surgery Procedure Codes; New York State Medicaid Provider Procedure Code Manual*,

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https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf. *See also Cruz v. Zucker*, 218 F. Supp. 3d 246, 249 (S.D.N.Y. 2016) (entering judgement for plaintiffs where undisputed facts showed exclusion of treatment of gender dysphoria for people under 18 and blanket ban on coverage of medically necessary cosmetic procedures for gender dysphoria under previous regulatory regime violated Medicaid's Availability and Comparability Provisions). Participating providers across New York who provide this care bill Medicaid and Child Health Plus for covered services, including medically necessary transgender health care for people under 18, in the same manner as they do for other forms of medically necessary health care. NYS DOH then obtains reimbursement for the federal matching share for this care from CMS Consistent with other services and benefits covered under the approved state plan.

D. Plaintiff States Regulate the Medical Professions

63. The Plaintiff States license or otherwise establish qualifications and discipline for physicians and other medical professionals operating in their states. *See generally, e.g.*, Or. Rev. Stat. ch. 677; Or. Admin. R. ch. 847; Wash. Rev. Code ch. 18.71, ch. 18.79; Wash. Admin. Code tit. 246; N.Y. Educ. L. §§ 6520 *et seq.*; D.C. Code §§ 3-1201 *et seq.*; D.C. Mun. Reg. tit. 17 §4600 *et seq.*; Colo. Rev. Stat. § 12-240-101, *et seq.*; 3 Colo. Code Reg. § 713-1; 225 Ill. Comp. Stat. 60/1 *et seq.*; Mass. Gen. Laws ch. 13, §§ 9-11; Mass. Gen. Laws ch. 112, §§ 2-12DD, 61; 243 Mass. Code. Reg. 2.00 *et seq.*; Mich. Comp. Laws §§ 333.17001 *et seq.*; N.J. Stat. Ann. § 45:9-1 *et seq.*; 63 Pa. Cons. Stat. §§ 422.1–51a; *id.* §§ 271.1–19; R.I. Gen. Laws §§ 5-37-1 *et seq.*, 5-34-1 *et seq.*, 5-44-1 *et seq.*, 5-54-1 *et seq.*, 216 R.I. Code R. §§ 40-05-1, 40-05-3, 40-05-15, 20-05-24; Wis. Stat. § 15.08; Wis. Stat. ch. 448; Wis. Admin. Code Med. chs. 1–27. Medical professionals are subject to regulation, oversight, and discipline by the Plaintiff States. *See, e.g.*, Or. Rev. Stat. §§ 675.070, .540, .745, 677.190; Wash. Rev. Code § 18.130.040; N.Y. Educ. L. §§ 6524, 6530 *et seq.*; N.Y. Pub. Health L. §§ 230 *et seq.*; Colo. Rev. Stat. §§ 12-240-115, -120, -121; Conn. Gen. Stat. § 20-13c; 225 Ill. Comp. Stat. 60/7.1, 7.5, 22; Mich. Comp. Laws §§ 333.16221, 333.16226, .17011, .17033; N.J. Stat. Ann. § 45:9-6; R.I. Gen. Laws §§ 5-37-6.3, 5-34-24, 5-44-18, 5-54-13; Wis. Stat. §§ 20-13c; Wis. Stat. §§ 448.02; .05, .40, .978.

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64. Similarly, the Plaintiff States license and regulate hospitals. *See, e.g.*, Or. Admin. R. ch. 333; Wash. Rev. Code ch. 70.41; NY Pub. Health §§ 2800 *et seq.*; Colo. Rev. Stat. § 25-3-101 *et seq.*; 210 Ill. Comp. Stat. 85/1 *et seq.*; Mass. Gen. Laws c. 111, §§ 3, 51-56, 70; 105 Mass. Code. Regs. § 130.00 *et seq.*; N.J. Admin. Code § 8:43G-1.1 *et seq.*; 35 Pa. Stat. §§ 448.801a–448.822; R.I. Gen. Laws §§ 23-17-1 *et seq.*; 216 R.I. Code R. § 40-10-4; Wis. Stat. ch. 50, subch. II; Wis. Admin. Code § DHS 124.03.

V. THE KENNEDY DECLARATION HARMS THE PLAINTIFF STATES

A. The Kennedy Declaration Harms the Plaintiff States' Medicaid programs

65. The Plaintiff States administer their respective state Medicaid programs and are harmed by the Kennedy Declaration as administrators of those programs.

66. The Social Security Act does not define what makes a provider "qualified" to perform services under Medicaid pursuant to 42 U.S.C. § 1396a(a)(23), and instead leaves that determination to the States as program administrators, and in their traditional role as regulators of health and safety. *See Medina*, 606 U.S. at 364.

67. Each state must develop a process by which providers may enroll in Medicaid as covered or participating providers, and through which each state approves or rejects providers for enrollment. See 42 C.F.R. § 455.400 *et seq*. This process must follow all screening and categorization procedures outlined in the regulations.

68. HHS OIG has limited authority to determine which providers may participate in Medicaid programs as qualified providers. If HHS OIG seeks to exclude a provider based on the Social Security Act sections 1128 (42 U.S.C. § 1320a-7) or 1156 (42 U.S.C. § 1320c-5), it must follow the process set forth in the Social Security Act and its implementing regulations. This process includes, among other things, issuance of a Notice of Intent to Exclude and an opportunity to respond to and challenge any determinations by HHS. Any exclusion may be appealed to an Administrative Law Judge and the resulting decision may be appealed to the HHS Departmental Appeals Board. 42 C.F.R. § 1001.2007.

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69. Exclusion from the Medicaid program carries significant collateral consequences, such as reputational stigma; the inability to work at institutions that rely on Medicaid or Medicare; exclusion from private insurance panels; emergency suspension of the provider's license (in some States); and difficulties obtaining loans for office space or equipment.

70. The Kennedy Declaration announces a binding rule of decision that the provision of medically necessary transgender healthcare constitutes legally sufficient grounds for exclusion from the Medicaid program. As result, Plaintiff States are likely to face a loss of Medicaid-enrolled providers in critical specialties (such as pediatrics and endocrinology) and higher hurdles in persuading new and existing providers to participate in Medicaid. It is foreseeable that existing qualified providers will voluntarily depart from the Medicaid program rather than face the impossible choice of restricting care to their patients or risking career-ending consequences. This is particularly problematic where States already face significant barriers to attracting and retaining high-quality providers to their Medicaid programs at a time when reliance on State-funded health care is growing.

71. The Kennedy Declaration also directly impairs the Plaintiff States' administration of state Medicaid and CHIP programs under the very terms agreed and guaranteed by HHS. Each Plaintiff State has adopted a state Medicaid plan that provides coverage for gender-affirming care. *See* 42 C.F.R. §§ 430.10 *et seq*. Each of these Plans has been approved by the Centers for Medicare and Medicaid Services, and each Plaintiff State has sought, and received, reimbursement for medically necessary gender-affirming care that the Kennedy Declaration now seeks to prohibit by excluding providers of that care. The Kennedy Declaration thus unilaterally and retroactively discards the state plans without proper procedure, harming the Plaintiff States. *See generally* 42 C.F.R. §§ 430.10 *et seq*. (describing procedures for establishing and amending State Medicaid Plans).

72. For example, the statutory guarantees of coverage under the Oregon Health Plan for gender-affirming care directly conflict with and are undermined by the Kennedy Declaration. The Kennedy Declaration forces the administrator of Oregon Health Plan into an impossible position, regardless of whether participating providers decide to continue providing gender-

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affirming care to patients under the age of nineteen or cease such care. If providers choose to continue providing care, Oregon faces losing the largest providers of health care in the state from participation in state health care plans, including OHSU and Legacy Health. That loss would significantly harm health care networks covered by state health plans, limit the availability of health care for all residents on a state health plan, and strain Oregon's health care system. And if providers cease care, patients under a state health plan will lose access to gender-affirming care for which they are statutorily guaranteed coverage, and the State of Oregon would lose its ability to fulfill its mission as a Medicaid administrator.

73. The Kennedy Declaration similarly harms all Plaintiff States by threatening to exclude providers from participation in Medicare and Medicaid. It threatens provider networks by forcing providers to choose between cessation of gender-affirming care or subjecting themselves to exclusion from participation in federally funded health care programs, including all of the incidental and collateral consequences such an exclusion would entail.

B. The Kennedy Declaration Harms the Plaintiff States as Regulators of the Practice of Medicine

74. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cnty., Fla. v. Auto. Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) *(*citing *Rice v. Sante Fe Elevator Corp*., 331 U.S. 218 (1947)). "The licensing and regulation of physicians is a state function." *P*a. *Med. Soc. v. Marconis*, 942 F.2d 842, 847 (3d Cir. 1991); *see also Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (recognizing the state's powers to regulate medical professions from "time immemorial"). Congress did not delegate to the Secretary of HHS the authority to exercise control over the practice of medicine, *Rasulis v. Weinberger*, 502 F.2d 1006 (7th Cir. 1974), and Congress went out of its way to state that no provision of the Social Security Act should be construed as authorizing the Secretary to exercise such control, *see* 42 U.S.C. § 1395.

75. The Kennedy Declaration infringes on the Plaintiff States' role as regulators of the practice of medicine by attempting to impose coercive conditions on its providers' participation

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in federal health care programs, and retroactive and coercive conditions on the Plaintiff States' access to federal health care funding. *See Arizona v. Yellen*, 34 F.4th 841, 851–53 (9th Cir. 2022).

76. The Kennedy Declaration also infringes on the Plaintiff States' traditional role in regulating the practice of medicine within the Plaintiff States by declaring substantive standards of care that conflict with state law and undermine state civil rights protections. *E.g.*, Or. Rev. Stat. § 743A.325. The Kennedy Declaration thereby impairs Plaintiff States' authority to "exercise … sovereign power over individuals and entities within [its] jurisdiction, including the power to create and enforce a legal code." *Washington v. U.S. Food & Drug Admin.*, 108 F. 4th 1163, 1176 (9th Cir. 2024) (internal quotation marks omitted). That interest "is sufficient to convey standing to … challenge a federal statute that preempts or nullifies state law." *Id.* The Kennedy Declaration obstructs compliance with state law and effectively nullifies those state laws.

C. The Kennedy Declaration's Harm to the Plaintiff States is Immediate and Ongoing

77. The Kennedy Declaration has immediate harmful effect upon the Plaintiff States. The Kennedy Declaration threatens to exacerbate an already serious shortage of providers willing to participate in Plaintiff States' Medicaid programs, especially in critical specialties like pediatrics and endocrinology, including the provision of medically necessary gender-affirming care. It also immediately disrupts the Plaintiff States' regulation of the practice of medicine by creating a separate and legally unsupported standard of care that purports to displace state standards.

VI. CAUSES OF ACTION

COUNT 1
Violation of APA — Without Observance of Procedure Required by Law (5 U.S.C. § 706(2)(D)) — Violation of Medicare Rulemaking and Notice and Comment Requirements (42 U.S.C. §§ 1302, 1395hh)

78. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

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79. Defendants include "agenc[ies]" under the APA, 5 U.S.C. § 551(1), and the Kennedy Declaration is a final agency action subject to review under the APA. The Kennedy Declaration marks the consummation of HHS's decision-making process because it announces the agency's decision to immediately implement a policy that will dramatically change the agency policy regarding gender-affirming care. The Kennedy Declaration announces that the provision of medically necessary healthcare for transgender minors "will be deemed not to meet the professionally recognized standards of health care" and thus allows exclusion of the provider from Medicare and Medicaid.

80. When HHS seeks to change a substantive legal standard under the Medicare Act, it must first allow the public 60 days to comment on the proposed regulation. "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title subchapter shall take effect unless it is promulgated by the Secretary by regulation." 42 U.S.C. § 1395hh(a)(2). Subject to exceptions not applicable here, "before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." *Id.*

81. The Kennedy Declaration violates Medicare notice and comment requirements because it changes a substantive legal standard and was not a "previously published notice of proposed rulemaking or interim final rule." 42 U.S.C. § 1395hh(a)(4). HHS has no "lawful excuse for neglecting its statutory notice-and-comment obligations," and thus HHS's "new policy cannot stand." *Azar v. Allina Health Servs.*, 587 U.S. 566, 568 (2019).

COUNT 2
Violation of APA —
Without Observance of Procedure Required by Law (5 U.S.C. § 706(2)(D)) —
Violation of APA Rulemaking and Notice and Comment Requirements
(5 U.S.C. § 553; 42 U.S.C. § 1302)

82. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

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83. Under the APA, a court "shall … hold unlawful and set aside agency action, findings and conclusions found to be … without observance of procedure required by law[.]" 5 U.S.C. § 706(2)(D).

84. The Kennedy Declaration constitutes a rule for purposes of the APA because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4).

85. Subject to express exceptions not applicable here, federal agencies must complete the process of agency rulemaking before issuing a rule. *Id.* § 553(b). The Kennedy Declaration is subject to notice and comment because it is a substantive, legislative rule. "Legislative rules … create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp Indus. Ass'n v. Drug Enf't Admin.*, 333 F.3d 1082, 1087 (9th Cir. 2003). Thus, the Kennedy Declaration is not exempt from notice-and-comment rulemaking as an "interpretative rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A).

86. When the APA was enacted in 1947, it exempted from its notice-and-comment requirements any "matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts." 5 U.S.C. § 553(a)(2). Case law interpreted that provision to exclude Medicaid as a "benefit" program. *See, e.g.*, *Cubanski v. Heckler*, 781 F.2d 1421, 1428–29 (9th Cir. 1986), *vacated sub nom. on other grounds, Bowen v. Kizer*, 485 U.S. 386 (1988). Subsequent statutory changes, however, have removed Medicaid regulations from that general exemption. In 1987, Congress enacted legislation requiring each notice of proposed rulemaking affecting Medicaid or Medicare "that may have a significant impact on the operations of a substantial number of small rural hospitals" to include an "initial regulatory impact analysis" on these hospitals, and each final rule to include a final regulatory impact analysis. 42 U.S.C. § 1302(b) (P.L. 100-203, Dec. 22, 1987). That requirement is inconsistent with a blanket exemption of Medicaid regulations from the APA's notice-and-comment requirements.

87. In 1971, HHS waived any exemption from rulemaking requirements, which determined "[t]he public participation requirements prescribed by 5 U.S.C. § 553(b) and (c) will

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be followed by all agencies of the Department in rulemaking relating to … grants, benefits, or contracts." 36 Fed. Reg. 13,804 (1971). This commitment, known as the "Richardson Waiver," is enforceable. *Cubanski*, 781 F.2d at 1428–29; *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 356–57 (D.C. Cir. 2017).

88. In March of this year, HHS attempted to disavow the Richardson Waiver in a one-page Federal Register notice. 90 Fed. Reg. 11,029 (March 3, 2025). That revocation is ineffective, because it is arbitrary and capricious: HHS's departure from its decades' old policy lacks "a rational connection between the facts found and the choice made." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

89. Regardless of whether notice and comment are required, a substantive rule must be published in the Federal Register at least 30 days before its effective date. 5 U.S.C. § 553(d).

90. Because the Kennedy Declaration did not follow these required procedures, as required by the APA and the Richardson Waiver, it is procedurally invalid.

COUNT 3
Violation of APA — In Excess of Statutory Authority
(5 U.S.C. § 706(2)(C))

91. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

92. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be … in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

93. The Kennedy Declaration exceeds the Secretary's authority because it purports to set a national standard of care, but there is no statute that permits the Secretary of HHS to do so. No statute allows the Secretary to unilaterally declare that a treatment modality is not safe and effective and thus grounds for exclusion from the program.

94. Under the Medicare statute, Federal officers or employees are prohibited from "excercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. This provision explicitly states the intent "to

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minimize federal intrusion" into state healthcare regulation. *Mass. Med. Soc. v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (opinion of Breyer, J.).

95. "An agency literally has no power to act … unless and until Congress confers power upon it." *FERC*, 535 U.S. at 18. The Kennedy Declaration does not identify any statutory authority for "declaring" a national standard of care. And although the Kennedy Declaration states that it is "informed by" a regulation, 42 C.F.R. § 1001.2, an agency cannot grant itself authority to create substantive law by promulgating a regulation. In any event, the cited regulation is a definitional provision that does not provide any substantive grant of authority at all.

96. The Kennedy Declaration threatens to invoke 42 U.S.C. § 1320a-7(b)(6)(B), which provides that "[t]he Secretary may exclude … from participation in any Federal health care program … [a]ny individual or entity that the Secretary determines … 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 …." But that statute is a limitation on, not an expansion of, the Secretary's authority to identify a standard of care, because it empowers the Secretary to exclude providers who violate "*professionally recognized* standards of health care"—not standards of care that he declares by edict. Moreover, that provision contemplates actions based on the "quality" of "items or services," not a categorical prohibition on a disfavored category of care.

97. Because the Kennedy Declaration exceeds the Secretary's statutory authority, it is invalid.

COUNT 4
Violation of APA (5 U.S.C. § 706(2)(A)) —
Not in Accordance with Law

98. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

99. ***Regulation of the practice of medicine.*** The Kennedy Declaration violates 42 U.S.C. § 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or

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employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided ….").

100. The Secretary's actions violate multiple, substantive statutory requirements for Medicaid programs.

101. ***Altering the terms of federally approved Medicaid state plans.*** Pursuant to 42 U.S.C. § 1396b, "the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved" amounts specified by statute. Pursuant to 42 U.S.C.§ 1396a, the Secretary has approved state Medicaid and CHIP plans for each Plaintiff State under which each state provides health services to eligible individuals. "The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program." 42 C.F.R. § 430.10. The Kennedy Declaration purports to unilaterally amend a state plan by threatening to drastically reduce the number of eligible providers by deeming them presumptively excluded from participation, and by curtailing the states' traditional authority under the Medicaid Act to determine which providers are eligible. Accordingly, Defendants' action is ultra vires and contrary to law.

102. ***Free Choice of Provider.*** The Kennedy Declaration's prohibition of medical providers who provide medically necessary gender-affirming care from participating in the Medicaid program violates the requirement that Medicaid beneficiaries have a free choice of provider. The Medicaid statutes gives states the authority to set qualifications for providers who may participate in their State Plan. 42 U.S.C. § 1396a(a)(23); 42 C.F.R. § 431.51; *see also Medina*, 606 U.S. at 364 ("States have traditionally exercised primary responsibility over … regulation of the practice of medicine.").

103. ***Comparability requirement.*** The Kennedy Declaration's denial of medically necessary services to Medicaid recipients violates Medicaid's comparability requirement by effectively forcing plans to offer a service to one category of patients (individuals with "a verifiable disorder of sexual development" or other purposes unrelated to such disorders), but to deny the same service to a different category (namely those with a diagnosis of gender dysphoria

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or gender incongruence), on the basis of medical diagnosis. 42 U.S.C.§ 1396a(a)(10)(B); 42 C.F.R. § 440.240. It similarly forces plans to offer services to some patients (those above a certain threshold age), while denying the same services to a different category (those under the threshold age).

104. ***Medical necessity requirement.*** The Kennedy Declaration's effect of denying medically necessary services to Medicaid enrollees violates the Medicaid Act's requirement that medically necessary services be made available to Medicaid enrollees. 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. §§ 440.210, 440.220, 440.230.

105. Because the Kennedy Declaration is not in accordance with law, it is invalid.

COUNT 5
Violation of APA (5 U.S.C. § 706(2)(A)) —
Arbitrary and Capricious and an Abuse of Discretion

106. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

107. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

108. The Kennedy Declaration is arbitrary and capricious because it departs from CMS's past practice of allowing States to include gender-affirming care in their Medicaid state plans and never prohibiting providers from providing gender-affirming care as a condition of participation. This abrupt reversal disrupts the Plaintiff States' settled expectations, and those of patients already undergoing care, based on CMS's approval of their state plans and CMS's implementation of those state plans through ongoing payments for gender-affirming care. The agency failed to adequately address these "serious reliance interests" engendered by its prior policy while also failing to "show that there are good reasons for the new policy." *Encino Motorcars, LLC*, 579 U.S. at 221 (citation modified).

109. The Kennedy Declaration also fails to include consideration of important aspects of the problem the Declaration creates, namely, the shortage of Medicaid providers, particularly in the fields of pediatrics and endocrinology; the reliance interests of Plaintiff States in

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structuring their Medicaid Programs based on the availability of providers who meet statutory criteria for eligibility; and the harms to patients and providers within Plaintiff States that would be caused should this rule be implemented. And Defendants failed to adequately consider alternatives.

110. The Kennedy Declaration also fails to include consideration of reasonable alternatives. For example, nowhere in the Kennedy Declaration does Secretary Kennedy claim that provision of gender-affirming care to each and every child or adolescent with gender dysphoria results in harmful outcomes, nor does he cite a single study making such a claim. For example, he cites a study from Sweden recommending that "[h]ormonal interventions may serve as last-resort measures for select youth." But the Kennedy Declaration seeks the extreme outcome of eliminating gender-affirming care entirely without considering less extreme actions, like restricting such care to a "last resort" measure.

111. The Kennedy Declaration also fails to explain its rationale adequately, particularly with respect to the statutory authority upon which it is based. It cites no statute as a basis upon which the Secretary may declare a certain treatment modality or protocol to fall below professionally recognized standards of care and thus fails to explain the Secretary's authority to promulgate the declaration in the first place.

112. Accordingly, the Kennedy Declaration is arbitrary and capricious and an abuse of the Secretary's discretion, and therefore invalid. *See* 5 U.S.C. § 706(2)(A).

VII. PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray that the Court:

a. Declare and hold unlawful the Kennedy Declaration;

b. Stay, vacate, and set aside the Kennedy Declaration;

c. Preliminarily and permanently enjoin Defendants; their officers, agents, servants, employees, and attorneys; and anyone acting in concert or participation with Defendants from implementing, instituting, maintaining, enforcing, or giving effect to the Kennedy Declaration in any form;

d. Postpone the effective date of the Kennedy Declaration pending judicial review;

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e. Award Plaintiffs' costs of suit and reasonable attorneys' fees and expenses pursuant to any applicable law; and

f. Award such additional relief as the interests of justice may require.

DATED: January 6, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on January 6, 2026, I served the foregoing AMENDED COMPLAINT upon the parties hereto by the method indicated below, and addressed to the following:

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Exhibit A

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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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON
EUGENE DIVISION

STATE OF OREGON, STATE OF WASHINGTON, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MAINE, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, JOSH SHAPIRO, in his official capacity as Governor of the Commonwealth of Pennsylvania, STATE OF RHODE ISLAND, STATE OF VERMONT, and STATE OF WISCONSIN; Plaintiffs, v. ROBERT F. KENNEDY, JR., in his official capacity as the Secretary of the Department of Health and Human Services; THOMAS MARCH BELL, in his official capacity as Inspector General of the Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL; and the UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. AMENDED COMPLAINT

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I. INTRODUCTION

1. On December 18, 2025, without warning, Department of Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr., posted to the HHS website a "declaration" titled "Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents" ("Kennedy Declaration" or "Declaration"). The Kennedy Declaration purports to set a new quality standard for healthcare, for the entire United States, that certain medical treatments for gender dysphoria or related disorders (hereinafter "gender-affirming care" or "medically necessary transgender healthcare") for children and adolescents are "neither safe nor effective." According to the Kennedy Declaration, HHS may bar healthcare providers and institutions from participating in Medicare, Medicaid, and other federal healthcare programs if they treat *any* children or adolescents with these medical interventions, even outside federally funded health programs. *See* 42 U.S.C. § 1320a-7(b)(6)(B).

2. The Kennedy Declaration exceeds the Secretary's authority and violates the Administrative Procedure Act and the Medicare and Medicaid statutes.

3. The Kennedy Declaration is procedurally defective. At minimum, Secretary Kennedy and HHS cannot circumvent statutorily mandated notice and comment requirements by changing substantive legal standards by executive fiat. This action violates the rulemaking requirements under the APA, 5 U.S.C. § 553(b), and the rulemaking requirements under Medicare, 42 U.S.C. § 1395hh(a)(2), which provide that "[n]o rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard" governing Medicare may take effect unless the Secretary follows notice-and-comment rulemaking procedures and provides a minimum of sixty days for public comment.

4. The Kennedy Declaration also substantively violates the APA. First, the Declaration exceeds the Secretary's authority. Congress has not given the Secretary the authority to define the professionally established standard of care. The Kennedy Declaration cites no statute authorizing the Secretary to do so by "declaration," instead stating that it is issued "pursuant to the authority vested in the HHS Secretary," and "informed by 42 C.F.R. § 1001.2." But 42 C.F.R. § 1001.2 only defines "professionally recognized standards of health care." It does

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not authorize the Secretary to "declare" what those standards are. Agencies cannot grant themselves power that Congress has not conferred.

5. The Kennedy Declaration is also contrary to law. Congress expressly prohibits "any Federal officer … to exercise any supervision or control over the practice of medicine." 42 U.S.C. § 1395. Defendants have made clear that the Kennedy Declaration does just that. In announcing the Kennedy Declaration, Secretary Kennedy characterized it as "a clear directive to providers,"[1] and HHS touted that the Declaration means medically necessary gender-affirming care for transgender youth "do[es] not meet professionally recognized standards of health care" and that "practitioners who perform [gender-affirming care] on minors would be deemed out of compliance with those standards."[2]

6. The Kennedy Declaration has immediate, significant, and harmful impacts on the Plaintiff States as administrators of state Medicaid programs and as regulators of the practice of medicine.

7. The Kennedy Declaration directly harms Plaintiff States' abilities to administer approved state Medicaid plans in accordance with state laws that protect and guarantee medically necessary gender-affirming care. The Declaration further harms the Plaintiff States' administration of state Medicaid plans by purporting to announce a rule of decision that HHS will use as a basis to exclude from Medicaid a large swath of clinicians—including pediatricians, family medicine doctors, and endocrinologists—without process or authority. The Declaration also purports to provide a basis to exclude any "entity" employing those clinicians—including hospitals, clinics, and family practices—many of which the Plaintiff States rely upon to operate their Medicaid and other health care programs.

[1] U.S. Department of Health and Human Services, *Protecting Children*, at 3:50-4:30 (YouTube, Dec. 18, 2025), https://www.youtube.com/watch?v=aY1XfN6Tt0Q.

[2] Press Release, U.S. Department of Health and Human Services, HHS Acts to Bar Hospitals from Performing Sex-Rejecting Procedures on Children (Dec. 18, 2025), available at https://www.hhs.gov/press-room/hhs-acts-bar-hospitals-performing-sex-rejecting-procedures-children.html.

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8. The Kennedy Declaration also harms the Plaintiff States in their capacity as regulators of the medical profession within their jurisdictions. Each of the Plaintiff States license and discipline medical professionals. The Kennedy Declaration seeks to "supersede[] 'Statewide … standards of care'"—and with it, undermines the Plaintiff States' traditional sovereign authority to regulate the practice of medicine.

9. The Secretary has no legal authority to substantively alter the standards of care and effectively ban, by fiat, an entire category of healthcare. Nor does the Secretary have authority to threaten providers' participation in federal programs, including reimbursement by Medicare and Medicaid, by fiat. The Kennedy Declaration directly violates the Social Security Act's provision barring federal officers or employees from exercising control over the practice of medicine, and it ignores the Congressionally required procedures established to ensure any such decisions are based on prevailing medical standards and rigorous scientific evidence, and subject to public notice and comment.

II. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and the Administrative Procedure Act, 5 U.S.C. § 702.

11. Venue is proper in this district under 28 U.S.C. § 1391(b)(2), (e)(1) and 5 U.S.C. § 703. Defendants are a United States agency and officers or employees sued in their official capacities. The principal offices of the Oregon Health Authority and the capital of Oregon are in Marion County, and a substantial part of the events or omissions giving rise to this Complaint occurred and continue to occur within Marion County and the District of Oregon.

III. PARTIES

A. Plaintiffs

12. Plaintiff State of Oregon is a sovereign state of the United States. Oregon is represented by Attorney General Dan Rayfield, who is the chief legal officer of Oregon. The Oregon Health Authority administers the Oregon Health Plan, which is Oregon's Medicaid plan and Children's Health Insurance Program (CHIP). The Oregon Health Plan provides coverage for gender-affirming care for individuals under nineteen years old. Oregon HB 2002, enacted in

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2023, guarantees coverage for all medically necessary gender-affirming care services in commercial insurance, the Oregon Health Plan, and public employee health plans. Oregon law also provides that laws of other states that authorize civil or criminal action against a person for receiving, providing, or aiding or abetting in the provision of gender-affirming care are contrary to the public policy of Oregon. Or. Rev. Stat. § 24.500(2). Oregon law also protects medical professionals from discipline, license revocation, or adverse action by malpractice insurers when that adverse action is based solely on providing gender-affirming care in other jurisdictions. Or. Rev. Stat. §§ 675.070, 675.540, 675.745, 676.313, 677.190.

13. Plaintiff State of Washington, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Nick Brown is Washington's chief law enforcement officer and is authorized under Wash. Rev. Code § 43.10.030(1) to pursue this action. Plaintiff State of Washington administers Apple Health, which includes its Medicaid program through the Washington State Health Care Authority. Apple Health includes Washington's Medicaid, CHIP, and programs funded with state-only funds. The Washington Health Care Authority is required by state law to cover gender-affirming care in its public health programs. Wash. Rev. Code § 74.09.700. And health insurance plans issued on or after January 1, 2022, are likewise required to cover gender-affirming care. Wash. Rev. Code § 48.43.0128. Washington law also protects medical professionals from discipline, license revocation, or adverse action by malpractice insurers based upon adverse action in other jurisdictions based solely on providing gender-affirming care. Wash. Rev. Code § 18.130.450.

14. Plaintiff State of New York is a sovereign state in the United States of America. New York is represented by Attorney General Letitia James, who is the chief law enforcement officer of New York. The New York State Constitution prohibits discrimination on the basis of gender identity and gender expression. N.Y. Const. art. I, § 11(a). Under New York law, health care providers cannot deny services or treat a person less well than others on the basis of their protected characteristics including sex and gender identity or expression. N.Y. Exec. Law § 296 *et. seq.* New York law also protects access to health care without discrimination on the basis of sex, gender identity, gender expression, transgender status, or diagnosis of gender dysphoria and

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requires providers to treat their patients fairly and bans discrimination on the basis of sex, gender identity, disability, age, or source of payment. N.Y. Comp. Civ. R. & Regs. tit. 10, §§ 405.7(b)(2), (c)(2); N.Y. Comp. Civ. R. & Regs. tit. 9, § 466.13; N.Y. Pub. Health Law §§ 2803(1)(g), 2803-C-2. In New York State (NYS), the state Medicaid program, overseen by the NYS Department of Health (DOH), provides comprehensive health coverage to more than 7 million New Yorkers annually. NYS DOH also administers the Child Health Plus program, which is available for individuals under the age of nineteen who reside in New York. These programs provide coverage for a wide range of services, depending on the enrollee's age, financial circumstances, family situation, or living arrangements, through a large network of health care providers. NYS provides Medicaid coverage through the state-administered Medicaid fee-for-service program and through managed care arrangements. The majority of NYS Medicaid members are covered under Medicaid Managed Care. The costs of covering Medicaid services are shared between the state and federal government with a Federal Medical Assistance Percentage (FMAP) that generally provides 50% matching federal funding for most services.

15. Plaintiff State of California is a sovereign state in the United States of America. California is represented by Rob Bonta, the Attorney General of California, who is the chief law enforcement officer of California. The California Department of Health Care Services (DHCS) administers the state's Medicaid program, known as Medi-Cal, and California's CHIP. DHCS requires Medi-Cal managed care health plans to provide gender-affirming care. Insurers and healthcare plans covered by California law are prohibited from denying an individual a plan contract, health insurance policy, or coverage for a benefit included in the contract or policy, based on a person's sex, which is defined to include gender identity. Cal. Ins. Code § 10140. California law protects healthcare professionals from denial of application for licensure or suspension, revocation, or other discipline based on the performance, recommendation, or provision of gender-affirming care by medical boards that certify health professionals. Cal. Bus. & Prof. Code, §§ 850.1, 852. And California law protects medical professionals from the reach of other states with civil, criminal, and professional consequences related to the provision of gender-affirming care. Cal. Pen. Code, § 13778.3.

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16. Plaintiff State of Colorado, represented by and through the Attorney General, is a sovereign state of the United States of America. Attorney General Philip J. Weiser acts as the chief legal representative of the State and is authorized by Colo. Rev. Stat. § 24-31-101 to pursue this action. Colorado's Medicaid program is Health First Colorado, administered by the Colorado Department of Health Care Policy and Financing (HCPF). Colorado also provides Child Health Plan Plus (CHP+), which provides comprehensive health care benefits to uninsured children up to age nineteen who do not qualify for Medicaid and meet certain income criteria. As of January 2025, over 500,000 children were covered by Health First Colorado and CHP+. Both Health First Colorado and CHP+ are jointly funded by the federal government and Colorado state government, at different rates depending on the individual and population. On average, about 60 percent of all funding for HCPF's budget, including Health First Colorado, CHP+, other programs and administration comes in the form of federal matching funds. In fiscal year 2024, Colorado's total expenditures for Health First Colorado and CHP+ were approximately $15.1 billion total funds, including $4.5 billion general State funds. The Colorado Antidiscrimination Act prohibits discrimination on the basis of gender identity and expression. Colo. Rev. Stat. § 24-34-601. Under Colorado law, patients have a legal right to seek gender-affirming care. Colo. Rev. Stat. §§ 10-16-121(1)(f), 12-30-121, 13-21-133, 16-3-102(2), 16-3-301(4); Colo. Rev. Stat. § 10-16-104(30)(b), (d); 10 Code Colo. Regs. 2505-10-8.735. Similarly, State-regulated health insurance plans are prohibited from withholding coverage from individuals based on gender identity or gender dysphoria. 3 Code Colo. Regs. §702-4, Reg. 4-2-42, §5(A)(1)(o); Colo. Rev. Stat. § 10-16-104(30)(b). Likewise, because gender-affirming health care services are considered legally protected health care activities, *see* Colo. Rev. Stat. § 12-30-121(2), the Colorado Medical Board, the Colorado State Board of Nursing, and other affected health care regulatory boards may not deny licensure or otherwise impose disciplinary action against a licensee's licenses based solely on the provision of gender-affirming care, so long as the care provided otherwise meets generally accepted standards of medical practice in Colorado. Colo. Rev. Stat. § 12-30-121(2)(a). In addition, Colorado law protects patients and licensees who provide gender-affirming care from lawsuits and criminal prosecution in other states. Colo. Rev. Stat. §§ 12-30-

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121(2); 13-21-133. Colorado also regulates the practice of medicine for providers and entities, including several major hospitals, that likewise provide gender-affirming care services. These institutions rely on Medicaid reimbursement, and up through the Kennedy Declaration, Colorado Health First and CHP+ have successfully received Medicaid reimbursement for the provision of such services.

17. Plaintiff State of Connecticut, represented by and through the Attorney General, William M. Tong, is a sovereign state of the United States of America. Attorney General Tong is the State's chief legal officer and is authorized under Connecticut General Statutes § 3-125 to act in federal court on behalf of the State on matters of public concern. The Connecticut Department of Social Services administers Connecticut's Medicaid and CHIP. Connecticut's Medicaid and CHIP plans provide coverage for gender-affirming care for individuals under nineteen years old.

18. Plaintiff District of Columbia is a municipal corporation organized under the Constitution of the United States. It is empowered to sue and be sued, and it is the local government for the territory constituting the permanent seat of the federal government. The District is represented by and through its chief legal officer, Attorney General Brian L. Schwalb. The Attorney General has general charge and conduct of all legal business of the District and all suits initiated by and against the District and is responsible for upholding the public interest. D.C. Code. § 1-301.81. In the District, neither health care providers nor health insurers may discriminate against or refuse services or treatment to a person based on their gender identity or expression. D.C. Code §§ 12-1402.31(a)(1), 31-2231.11(c).

19. Plaintiff State of Delaware is a sovereign state of the United States. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941). Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504. The Delaware Department of Health and Social Services' Division of Medicaid and Medical Assistance administers the Delaware Medical Assistance Plan (DMAP), which is Delaware's Medicaid plan and CHIP. DMAP provides coverage for gender-affirming care for individuals under nineteen years old. In 2013, Delaware

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enacted the Gender Identity Nondiscrimination Act of 2013 (GINA), which added gender identity to the already-existing list of protected classes in Delaware's nondiscrimination laws. 6 Del C. §§ 4501-4, 4601-5, 4607, 4619; 9 Del C. § 1183; 11 Del. C. § 1304, 18 Del. C. § 2304, 19 Del. C. §§ 710-11, 25 Del. C. §§ 5105, 5116, 5141, 5316, 5953, 6962. In 2016, the Delaware Department of Insurance, pursuant to GINA and the Affordable Care Act, issued Bulletin No. 86, which prohibited "the denial, cancellation, termination, limitation, refusal to issue or renew, or restriction of insurance coverage or benefits thereunder because of a person's gender identity or transgender status, or because the person is undergoing gender transition. This includes the availability of health insurance coverage and the provision of health insurance benefits."

20. Plaintiff State of Hawai'i, represented by and through its Attorney General Anne E. Lopez, is a sovereign state of the United States of America. The Attorney General is Hawaii's chief legal officer and chief law enforcement officer and is authorized by Hawaii Revised Statues § 28-1 to pursue this action.

~~20.~~21. Plaintiff State of Illinois is a sovereign state of the United States. Illinois is represented by Kwame Raoul, the Attorney General of Illinois, who is the chief law enforcement officer of Illinois and authorized to sue on the State's behalf. Under Illinois law, the Attorney General is authorized to represent the State's interests by the Illinois Constitution, article V, section 15. *See* 15 Ill. Comp. Stat. 205/4. The Illinois Department of Healthcare and Family Services administers the Illinois Medical Assistance Program, which includes medical services authorized for eligible individuals under Illinois's Medicaid Plan and CHIP. The Illinois Medical Assistance Program provides coverage for medical services that are used to treat gender dysphoria for individuals under the age of nineteen years old. The Lawful Health Care Activity Act, enacted in 2024, provides that "the treatment of gender dysphoria or the affirmation of an individual's gender identity or gender expression, including … care, and services of a medical, behavioral health, mental health, surgical, psychiatric, therapeutic, diagnostic, preventative, rehabilitative, or supportive nature" is "lawful health care" in Illinois. 735 Ill. Comp. Stat. 40/28-10. The Illinois Medical Practice Act also protects medical professionals who provide or assist in providing lawful gender-affirming care. 225 Ill. Comp. Stat. 60/22(C)(3). The Department of

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Financial and Professional Regulation may not "revoke, suspend, place on probation, reprimand, refuse to issue or renew, or take any other disciplinary or non-disciplinary action" against medical professionals who provide or assist in providing gender-affirming care in Illinois. *Id*. This protection applies to nurses, pharmacists, registered surgical assistants and technologists, behavioral analysts, professional and clinical counselors, clinical psychologists, social workers, and marriage and family therapists. *See* 225 Ill. Comp. Stat. 65/65-65(a)(1); 225 Ill. Comp. Stat. 65/70-5(b-5)-(b-20); 225 Ill. Comp. Stat. 85/30.1(a); 225 Ill. Comp. Stat. 85/30(c-5)-(c-20); 225 Ill. Comp. Stat. 130/75(b-1)-(b-4); 225 Ill. Comp. Stat. 6/60(c-1)-(c-4); 225 Ill. Comp. Stat. 107/80(c-1)-(c-4); 225 Ill. Comp. Stat. 15/15(b)-(e); 225 Ill. Comp. Stat. 20/19(4.5)-(4.20); 225 Ill. Comp. Stat. 55/85(d-5)-(d-20).

~~21.~~22. Plaintiff State of Maine is a sovereign state of the United States of America. Maine is represented by Aaron M. Frey, the Attorney General of Maine. The Attorney General is authorized to pursue this action pursuant to 5 Me. Rev. Stat. Ann. tit. 5 § 191. The Office of MaineCare Services in the Maine Department of Health and Human Services administers MaineCare, which is Maine's Medicaid plan and includes CHIP. Maine law requires the Department to provide reimbursement for medically necessary treatment for or related to gender dysphoria or a comparable or equivalent diagnosis. Me. Rev. Stat. Ann. tit. 22 § 3174-MMM (Supp. 2025). Section 3174-MMM also prohibits the Department from discriminating in its reimbursement of medically necessary treatment on the basis of a MaineCare Member's gender identity or expression, or on the basis that the Member is a transgender individual. Further, the Legislature has declared that gender-affirming healthcare is legally-protected healthcare activity, and that any act of another state that prohibits, criminalizes, sanctions, authorizes a civil action against or otherwise interferes with a person in Maine who engages in such legally-protected healthcare activity, including aid and assistance with gender-affirming healthcare, is against the public policy of the state of Maine. Me. Rev. Stat. Ann. tit. 14 § 9001 (Supp. 2025).

~~22.~~23. Plaintiff State of Maryland is a sovereign state of the United States of America. Maryland is represented by Attorney General Anthony G. Brown who is the chief legal officer of Maryland. The Maryland Department of Health administers the Maryland Medical Assistance

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Program, which includes Maryland's Medicaid Plan and the Maryland Children's Health Program (MCHP). The Maryland Medical Assistance Program covers gender-affirming care for individuals under nineteen years old. Under the Trans Health Equity Act, the Program is required to cover gender-affirming care, ensuring equitable health care access for individuals who are transgender and gender diverse. 2023 Md. H.B. 283. Maryland law also defines "legally protected health care" to include gender-affirming care, Md. Code Ann., State Pers. & Pens. § 2-312(a)(3)(ii). Therefore, Maryland law protects medical professionals from out-of-state civil judgments and subpoenas related to legally protected health care, Md. Code Ann., Cts. & Jud. Proc., §§ 11-802, 9-402, as well as from changes in insurance coverage or premiums due to the provision of legally protected healthcare, Md. Code Ann., Ins., § 19-117.

~~23.~~24. Plaintiff Commonwealth of Massachusetts is a sovereign state of the United States and is represented by and through its Attorney General, Andrea Joy Campbell. Attorney General Campbell is authorized to pursue this action under Mass. Gen. Laws ch. 12, §§ 3, 10. Massachusetts's Executive Office of Health and Human Services operates the umbrella system known as MassHealth, which encompasses the state-federal Medicaid program, CHIP, and the 1115 Demonstration Project. Massachusetts prohibits discrimination on the basis of gender identity in the provision of healthcare services and insurance coverage, including by providers who treat patients covered by MassHealth. Mass. Gen. Laws ch. 272, §§ 92A, 98; 130 Mass. Code. Regs. § 450.202(B). Accordingly, MassHealth provides coverage for a range of gender-affirming care, including for those under 18 years of age. Access to gender-affirming care is a right secured by the constitution and laws of the Commonwealth, and acts or omissions undertaken to aid or encourage, or attempt to aid or encourage, another person in the exercise and enjoyment of the right to access healthcare services are also legally protected healthcare activities under Massachusetts law. Mass. Gen. Laws ch. 12, § 11 I ½(a)-(d).

~~24.~~25. Plaintiff State of Michigan is a sovereign state of the United States of America. The State of Michigan is represented by Attorney General Dana Nessel, who is the chief law enforcement officer of the State of Michigan. Michigan's Medicaid program covers medically necessary gender-affirming and gender-confirming medical treatment.

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~~25.~~26. Plaintiff State of Minnesota is a sovereign state of the United States of America. Minnesota's Attorney General, Keith Ellison, is the chief law enforcement officer of Minnesota and is authorized under Minnesota Statutes Chapter 8 and has common law authority to bring this action on behalf of the State and its residents, to vindicate the State's sovereign and quasi-sovereign interests, and to remediate all harm arising out of—and provide full relief for—violations of the law. Minnesota's Department of Human Services (referred to as DHS) administers Minnesota's Medicaid program (known as Medical Assistance) as well as MinnesotaCare, Minnesota's Basic Health Plan. DHS' operation of Medical Assistance also includes use of funding for some populations from CHIP. Both Medical Assistance and MinnesotaCare generally provide coverage for gender-affirming care for individuals under nineteen years old. Minnesota Statute § 256B.0625, subdiv. 3(a) and Minnesota Statute § 62Q.585 require that most health insurance plans offered, sold, issued, or renewed must provide coverage for all medically necessary gender-affirming care services. Minnesota law also prevents other states from interfering with gender-affirming care provided in Minnesota. Minn. Stat. § 260.925.

27. Plaintiff State of Nevada, represented by and through Attorney General Aaron D. Ford, is a sovereign State within the United States of America. The Attorney General is the chief law enforcement officer of the State of Nevada and is authorized to pursue this action under Nev. Rev. Stat. § 228.110 and Nev. Rev. Stat. § 228.170. The Nevada State Constitution prohibits discrimination on the basis of sex, gender identity, and gender expression. Nev. Const. art. 1, § 24. The Nevada Division of Health Care Financing and Policy administers Nevada's Medicaid program, known as Nevada Medicaid, and Nevada's CHIP. Under Nevada law, insurers and carriers cannot discriminate against any person "on the basis of actual or perceived gender identity or expression." Nev. Rev. Stat. §§ 689A.033, 689B.0675, 689C.1975, 695A.198, 695B.3167, 695C.204, 695G.415. Similarly, Nevada law guarantees coverage for all medically necessary gender-affirming care services in commercial insurance, Nevada Medicaid, and public employee health plans. Nev. Rev. Stat. §§ 422.272362, 689A.0432, 689B.0334, 689C.1652, 695A.1867, 695B.1915, 695C.16934, 695G.1718.

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~~26.~~28. Plaintiff State of New Jersey is a sovereign state in the United States of America. New Jersey is represented by Attorney General Matthew Platkin, who is the chief law enforcement officer for the State of New Jersey. The New Jersey Law Against Discrimination prohibits discrimination and harassment based on gender identity or expression in places of public accommodation, including clinics, hospitals, and other medical settings. *See* N.J. Stat. Ann. §§ 10:5-5(*l*), (rr), 10:5-12(f). Under New Jersey law, managed care organizations that contract with New Jersey Department of Human Services to administer New Jersey's Medicaid programs are also prohibited from categorically excluding gender-affirming care from health insurance coverage. N.J. Stat. Ann. § 30:4D-9.1.

~~27.~~29. Plaintiff State of New Mexico is a sovereign state in the United States of America. New Mexico is represented by Attorney General Raúl Torrez, who is the chief law enforcement officer of New Mexico and is authorized to pursue this action under N.M. Stat. Ann. § 8-5-2(B). The New Mexico Health Care Authority (HCA) administers both New Mexico's Medicaid program and CHIP. Pursuant to the CHIP State Plan, CHIP enrollees receive Medicaid covered services rather than a separate set of CHIP specific benefits. HCA's policy is to provide Medicaid coverage for medically necessary gender-affirming care as a covered service for members consistent with applicable coverage criteria, including members under nineteen years old. New Mexico's Reproductive and Gender-Affirming Health Care Freedom Act prohibits public bodies from discriminating on the basis of a person's use of or refusal to use gender-affirming health care services. N.M. Stat. Ann. § 24-34-3(A) (2023). New Mexico also prohibits public bodies from denying, restricting, or interfering with "a person's ability to access or provide … gender-affirming health care within the medical standard of care." N.M. Stat. Ann. § 24-34-3(B) (2023). Additionally, New Mexico's Reproductive and Gender-Affirming Health Care Protection Act prohibits public bodies from releasing information "in furtherance of a foreign investigation or proceeding that seeks to impose civil or criminal liability or professional disciplinary action upon an individual or entity" for engaging in the provision of gender-affirming health care. See N.M. Stat. Ann. §§ 24-35-1–8 (2023).

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~~28.~~30. Plaintiff Josh Shapiro brings this suit in his official capacity as Governor of the Commonwealth of Pennsylvania. The Pennsylvania Constitution vests "[t]he supreme executive power" in the Governor, who "shall take care that the laws be faithfully executed." Pa. Const. art. IV, § 2. The Governor oversees all executive agencies in Pennsylvania and is authorized to bring suit on their behalf. 71 Pa. Stat. Ann. §§ 732-204(c), 732-301(6), 732-303. The Pennsylvania Department of Human Services administers the Pennsylvania Medical Assistance Program, which is Pennsylvania's Medicaid program, and administers the Pennsylvania CHIP. Pennsylvania Medical Assistance and Pennsylvania CHIP provide coverage for gender-affirming care for individuals under nineteen years old when medically necessary.

~~29.~~31. Plaintiff State of Rhode Island is a sovereign state of the United States. Rhode Island is represented by Attorney General Peter F. Neronha, who is the chief legal officer of Rhode Island. The Rhode Island Executive Office of Health and Human Services is the single state agency that administers the Rhode Island Medicaid program, which encompasses both Rhode Island's Medicaid program and CHIP. The Rhode Island Medicaid program provides coverage for gender-affirming care for individuals under nineteen years old. Additionally, Rhode Island law prohibits discrimination on the basis of sex, gender identity, or gender expression in the provision of health care. State-licensed health care facilities are prohibited from denying care on the basis of sex, gender identity, or gender expression. 23 R.I. Gen. Laws § 23-17-19.1; see also 28 R.I. Gen. Laws § 28-5.1-12 (requiring state-licensed or chartered health care facilities to comply with the state policy of equal opportunity and nondiscrimination in patient admissions and health care service); 220 R.I. Code R. 80-05-1 (obligating health care facilities to admit patients without discriminating on the basis of gender identity or expression). State agencies, including the Rhode Island Executive Office of Health and Human Services, are obligated to render services to Rhode Islanders "without discrimination based on … gender identity or expression," and state agencies are further prohibited from becoming "party to any agreement, arrangement, or plan that has the effect of sanctioning those patterns or practices." 28 R.I. Gen. Laws § 28-5.1-7. The Rhode Island Medicaid program has, for over a decade, provided gender-

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affirming care to its members, including those under nineteen years old.[3] All Rhode Island Medicaid managed care organizations are required to provide such care to their members. The Rhode Island Medicaid program has sought and received Federal Financial Participation for the provision of such services.

~~30.~~32. Plaintiff State of Vermont, represented by Vermont Attorney General Charity Clark, is a sovereign state of the United States of America. Attorney General Clark is Vermont's chief legal officer and is authorized to pursue this action on behalf of the State. Vt. Stat. Ann. tit. 3, § 159. The State of Vermont administers its Medicaid program through the Vermont Agency of Human Services. Vermont Medicaid provides coverage for gender-affirming care for all residents, including individuals under nineteen years old. Vt. Stat. Ann. tit. 8, § 4071; Vt. Agency of Human Servs., Health Care Administrative Rules § 4.238. Vermont also guarantees coverage for all medically necessary gender-affirming care services in commercial insurance and public employee health plans. Vt. Stat. Ann. tit. 8, § 4071; Vt. Dep't of Financial Reg., Ins. Bulletin 174 (June 12, 2019). Vermont law also provides that laws that authorize civil or criminal action against a person for receiving, providing, or aiding and abetting in the provision of gender-affirming care are contrary to the public policy of Vermont. Vt. Stat. Ann. tit. 12, § 7302. Finally, Vermont law protects health care providers from disciplinary action based solely on the provider performing or assisting in gender-affirming care. Vt. Stat. Ann. tit. 26, § 1354(d).

~~31.~~33. Plaintiff State of Wisconsin is a sovereign state of the United States of America. Wisconsin is represented by Joshua L. Kaul, the Attorney General of Wisconsin. Attorney General Kaul is authorized to sue on behalf of the State. Wisconsin's Medicaid program is administered by the Wisconsin Department of Health Services. In *Flack v. Wisconsin Department of Health Services*, Case No. 18-cv-309-wmc (W.D. Wis.), the United States District Court for the Western District of Wisconsin issued a decision finding that administrative rules that excluded coverage of gender-affirming care services violated federal law, and it issued a permanent injunction enjoining the Wisconsin Department of Health Services from enforcing

[3] EOHHS Gender Dysphoria/Gender Nonconformity Coverage Guidelines (October 28, 2015), https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf.

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this exclusion. As a result of this permanent injunction, and since October 31, 2019, Wisconsin Medicaid provides coverage for gender-affirming care for individuals, including those under nineteen years old.

B. Defendants

~~32.~~34. Defendant Robert F. Kennedy, Jr., is the Secretary of the Department of Health and Human Services, and that agency's highest ranking official. He is charged with the supervision and management of all decisions and actions of that agency. 42 U.S.C. §§ 3501a, 3502. He is sued in his official capacity.

~~33.~~35. Defendant Thomas March Bell is Inspector General of the Department of Health and Human Services. He is sued in his official capacity.

~~34.~~36. Defendant Office of Inspector General is a component of the Department of Health and Human Services. 5 U.S.C. §§ 401, 402.

~~35.~~37. Defendant the United States Department of Health and Human Services is a Department within the Executive Branch of the United States government. 42 U.S.C. §§ 3501, 3501a.

IV. FACTUAL BACKGROUND

A. Gender-Affirming Care Is Medically Necessary Health Care Protected by State Laws

~~36.~~38. The Kennedy Declaration targets so-called "sex-rejecting procedures," a category of medical interventions known by medical professionals as "gender-affirming care." Gender-affirming care includes puberty-blocking medications, hormone therapy, and gender-affirming surgery. Gender-affirming care is medically appropriate, necessary health care backed by overwhelming medical consensus, including the support of the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Medical Association, the American Psychological Association, the Endocrine Society, and other American medical organizations.

~~37.~~39. Research and clinical data support gender-affirming care as a safe and effective treatment for gender dysphoria in adolescents. Patients receiving gender-affirming care have

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high rates of satisfaction and low incidence of regret compared with other medical treatments. Conversely, untreated gender dysphoria can have devastating impacts to the mental health and wellbeing of those youth and adolescents, and can lead to increased incidence of anxiety, depression, eating disorders, substance abuse, self-harm, and suicidality. For many patients, medically necessary gender-affirming care is life-saving.

B. The Kennedy Declaration

~~38.~~40. On December 18, 2025, Secretary Kennedy issued a "Declaration of the Secretary of the Department of Health and Human Services," subtitled, "RE: Safety, Effectiveness, and Professional Standards of Care for Sex-Rejecting Procedures on Children and Adolescents." A copy of the Kennedy Declaration is attached as Exhibit A to the Complaint.

~~39.~~41. The Kennedy Declaration purports to be issued pursuant to the Secretary's "authority and responsibilities under federal law, and pursuant to 42 C.F.R. § 1001.2." The cited regulation, 42 C.F.R. § 1001.2, is a definitional provision governing decisions to exclude health care providers from participation in Medicare and Medicaid. *See* 42 C.F.R. § 1001.1(b). This regulation does not confer any authority to the Secretary. *See Biden v. Missouri*, 142 S. Ct. 647, 656 (2022) (Thomas, J., dissenting) (refusing to find vast powers hidden in definitional provisions). The provision only refers to situations in which HHS or one of its component agencies has made a determination regarding a treatment modality's safety and efficacy—it does not purport to confer authority to the Secretary to make such pronouncements. *See* Department of Health and Human Services, Office of Inspector General, Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting From Public Law 104–191, 62 Fed. Reg. 47,182, 47,185, 47.189 (Sep. 8, 1997) (agency's explanation of the language). An agency has no power to confer authority on itself. *See New York v. FERC*, 535 U.S. 1, 18 (2002) ("[A]n agency literally has no power to act … unless and until Congress confers power upon it.") (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355 (1986)).

~~40.~~42. The Kennedy Declaration is purportedly based on a report that HHS issued in May 2025, and subsequently revised in November 2025, titled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" (the "HHS Review"). The Kennedy

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Declaration creates a new term, "sex-rejecting procedures," which is never used in the HHS Review, and defines it to include both pharmaceutical interventions like puberty blockers and hormone therapy, as well as surgeries such as mastectomies and vaginoplasties. The Kennedy Declaration then states that these "'sex-rejecting procedures' 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." The Declaration expressly purports to supersede "Statewide or national standards of care," including those backed by medical consensus with support from national medical organizations.

41.43. The Kennedy Declaration then threatens that HHS 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." While the Kennedy Declaration states only that providers "may" be excluded, and that a separate determination would be made under 42 C.F.R. § 1001.701, the Declaration itself establishes an HHS policy that the provision of any gender-affirming medical care to adolescents categorically fails to meet professionally recognized standards of care, and therefore is sufficient grounds to exclude a health care provider from participation in the Medicare and Medicaid programs.

42.44. The Declaration thus purports to bind the HHS Office of the Inspector General (OIG), as well as "Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG." 42 C.F.R. § 1001.1. The authority to exclude individuals or entities from participation in Medicare is set out in sections 1128 (42 U.S.C. § 1320a-7) and 1156 (42 U.S.C. § 1320c-5) of the Social Security Act. OIG is statutorily authorized to exclude individual providers only upon notice and due process of law, with such decisions appealable to the HHS Departmental Appeals Board, and subject to judicial review. The Department's regulations do not give the Secretary authority to predetermine exclusion decisions. 42 C.F.R. §§ 1001.2001 *et seq*.

43.45. Exclusion is an exceedingly serious punishment. "The effect of an OIG exclusion is that no Federal health care program payment may be made for any items or services furnished

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(1) by an excluded person or (2) at the medical direction or on the prescription of the excluded person." Office of the Inspector General, Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs at 6 (May 8, 2013). To give an example of the consequences of exclusion, the OIG explained, "no payment may be made to a hospital for the items or services furnished by an excluded nurse to Federal health care program beneficiaries, even if the nurse's services are not separately billed and are paid for as part of a Medicare diagnosis-related group payment received by the hospital." *Id.*

~~44.~~46. The exclusion also prohibits "payment for items or services furnished by an excluded individual … beyond patient care." *Id.* "[P]reparation of surgical trays," "review of treatment plans," and even "transportation services" are included in the exclusion. *Id.* at 7. "[A]dministrative and management services" are also prohibited, such that "an excluded individual may not serve in an executive or leadership role … at a provider that furnishes items or services payable by Federal health care programs." *Id.*

~~45.~~47. Violating an exclusion by furnishing items or services for which Federal health care program payment is sought can result in penalties including civil monetary penalties, civil actions, and criminal prosecutions. *Id.* at 9. And civil monetary penalties can be imposed on providers that employ or enter into contracts with excluded persons to provide items or services payable by Federal health care programs. *Id.* at 10. The OIG makes public the List of Excluded Individuals and Entities (https://exclusions.oig.hhs.gov) that employers can use to make employment decisions. *Id.* at 11; *see also* Office of the Inspector General, Search the Exclusions Database.

~~46.~~48. The Kennedy Declaration was issued with apparent immediate effect without prior notification to members of the public or to the health care providers it purports to regulate, despite statutory mandates that "no rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" under the Medicare program shall take effect unless it is promulgated by

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regulation with notice of the proposed regulation in the Federal Register and at least 60 days for public comment. 42 U.S.C. §§ 1395hh(a)(2), (b)(1).

~~47.~~49. The Kennedy Declaration offers no attempt to justify legislative rulemaking outside statutorily mandated notice and comment procedures and cites no exception or exemption to these requirements. Only certain limited exceptions to this notice and comment requirement apply, including where "a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment," "a statute establishes a specific deadline" for the regulation's requirements that is less than 150 days after the date of the enactment of that statute, or certain other exceptions codified in the APA. None of these exceptions apply here.

~~48.~~50. By contrast, on the very same day that HHS issued the Kennedy Declaration, it announced two other notices of proposed rulemaking seeking to amend certain program requirements under Medicare and Medicaid to restrict the expenditure of federal funds for medically necessary healthcare for transgender youth and to exclude hospitals that deliver these services from participation in the Medicare and Medicaid programs. These notices were published in the Federal Register and provided for a 60-day period of public comment. *See* Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicaid Program, Prohibition on Federal Medicaid and Children's Health Insurance Program Funding for Sex-Rejecting Procedures Furnished to Children, 90 Fed. Reg. 59,441 (Dec. 19, 2025); Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs, Hospital Condition of Participation: Prohibiting Sex-Rejecting Procedures for Children, 90 Fed. Reg. 59,463 (Dec. 19, 2025).

~~49.~~51. The Kennedy Declaration also purports to establish a standard of care and supersede other standards of care, despite the Medicare statute's clear "prohibition against any Federal interference," that restricts Federal officers or employees from "exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided[.]" 42 U.S.C. § 1395.

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~~50.~~52. To Plaintiff States' knowledge, HHS has never before issued a "declaration" or other sub-regulatory guidance document purporting to apply a categorical definition of "safety and effectiveness" to any medical intervention. The Kennedy Declaration is the first, and it does so for an array of interventions recognized as valid treatment modalities by medical professionals in the Plaintiff States.

C. Plaintiff States Administer State Medicaid Programs

~~51.~~53. The Medicaid health insurance program was created by federal law and is funded by the federal government. Medicaid is the federally matched medical aid program created under Title XIX of the Social Security Act in which the federal government provides matching funds to States to help pay for health care for low-income and other eligible individuals. State Medicaid programs provide health insurance for individuals, including children, whose household incomes fall below certain eligibility thresholds that vary by state. Plaintiff States administer their Medicaid programs and receive federal matching funds to provide healthcare services to Medicaid-insured residents.

~~52.~~54. CHIP is a related state-federal cooperative healthcare program authorized by section 2103 of the Social Security Act that offers coverage for certain low-income children and pregnant women. Thousands of children rely on CHIP for comprehensive coverage, including those that fall outside Medicaid eligibility but are unable to afford private or group health coverage. States are enabled to design their CHIP plan as a program separate from their state Medicaid plan, as an expansion of their Medicaid plan, or both. In all three instances, States retain significant discretion to determine which services and care are included, and which providers may participate, in their CHIP plans. Each of the Plaintiff States has a CHIP program.

~~53.~~55. Medicaid affords "substantial discretion" to participating states. *Alexander v. Choate*, 469 U.S. 287, 303 (1985). That commitment to state discretion is apparent from the text and structure of the Medicaid statute itself. States can choose whether to participate in Medicaid in the first place. *See* 42 U.S.C. § 1396a. And even after states sign up, Medicaid is not a take-it-or-leave-it proposition. Instead, the statute affords each participating state "substantial discretion

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to choose the proper mix of amount, scope, and duration limitations on coverage." *Alexander*, 469 U.S. at 303.

~~54.~~56. Although states' participation in Medicaid is voluntary, since "1982 every State ha[s] chosen to participate …." *NFIB v. Sebelius*, 567 U.S. 519, 542 (2012). Once states choose to participate, states must comply with federal statutory and regulatory requirements, including the creation of a State Plan outlining the administration of their respective Medicaid programs. 42 C.F.R. § 431.10. Congress has delegated policy decisions about what services should be covered to participating states by allowing them to develop their own State Plans that specify, among other things, the particular covered services within the broad categories of inclusions in the Act. 42 U.S.C. § 1396a(a)(10); 42 C.F.R. § 431.10.

~~55.~~57. As relevant here, State Plans also describe the state-specific standards to determine provider qualifications. The Medicaid Act provides that any individual eligible for assistance under a state Medicaid program may choose, as relevant here, any provider "qualified to perform the service or services required … who undertakes to provide him such services." 42 U.S.C. § 1396a(a)(23). By leaving the term "qualified" undefined, the Act leaves substantial discretion to states—exercising their traditional role regulating health and safety—in determining providers' qualifications for inclusion in their Medicaid programs. *See Medina v. Planned Parenthood South Atlantic*, 606 U.S. 357, 364 (2025).

~~56.~~58. Pursuant to 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320c-5, Defendants have limited authority to determine which providers may participate in Medicaid programs as qualified providers. Neither section authorizes HHS to exclude providers from participation in Medicaid based solely on their provision of medically necessary gender-affirming care. And neither section authorizes the Secretary of HHS to set professionally recognized standards of care to be used to exclude providers.

~~57.~~59. Moreover, if HHS seeks to exclude a provider based on these sections, it must provide specific process to the provider as set forth in the Social Security Act and implementing regulations. *See* 42 C.F.R. §§ 1001.1 *et seq.* These processes include but are not limited to issuance of a Notice of Intent to Exclude and an opportunity to respond to and challenge any

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determinations by HHS. Any exclusion may be appealed to an Administrative Law Judge and the resulting decision may be appealed to the HHS Departmental Appeals Board. 42 C.F.R. § 1001.2007(c).

~~58.~~60. HHS has continuously provided payments for gender-affirming care for minors. For example, the Oregon Health Plan, ensures "[c]omprehensive coverage for children under a Medicaid Section 1115 demonstration waiver." Under Oregon's 1115 waiver, Oregon may use a "Prioritized List of Health Services" to determine the services covered under state Medicaid and CHIP plans. Oregon's Prioritized List of Health Services, in turn, includes coverage for Gender Affirming Treatment, including medical and surgical treatment/psychotherapy. The Oregon Health Plan also provides coverage for gender-affirming care for individuals under nineteen years old through the Early and Periodic Screening, Diagnosis, and Treatment Program, which provides benefits for members of Oregon Health Plan under the age of 21 (or members who are under 26 and have Young Adults with Special Health Care Needs benefits) and covers medically necessary services as defined in Section 1905(a) of the Social Security Act (42 U.S.C. § 1396d). Those covered services include gender-affirming medical treatment.

~~59.~~61. For further example, Washington's Apple Health program has successfully sought reimbursement from the federal government for gender-affirming care for decades, and it claims millions of dollars annually for reimbursement for gender-affirming care provided as a part of Apple Health, including to adolescents. There are almost 6,000 distinct providers that provide gender-affirming care in Washington through the Medicaid program.

~~60.~~62. For further example, New York's Medicaid program, including Child Health Plus, provides coverage for medically necessary gender-affirming care for both minors and adults who meet defined criteria. *See* 18 NY Code R. Regs. 505.2; NYS Dep't of Health, Office of Health Insurance Programs, *Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria*, https://www.health.ny.gov/health_care/managed_care/plans/docs/treat_gender_dysphoria.pdf; NYS Dep't of Health, Office of Health Insurance, *Physician Surgery Procedure Codes; New York State Medicaid Provider Procedure Code Manual*,

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https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf. *See also Cruz v. Zucker*, 218 F. Supp. 3d 246, 249 (S.D.N.Y. 2016) (entering judgement for plaintiffs where undisputed facts showed exclusion of treatment of gender dysphoria for people under 18 and blanket ban on coverage of medically necessary cosmetic procedures for gender dysphoria under previous regulatory regime violated Medicaid's Availability and Comparability Provisions). Participating providers across New York who provide this care bill Medicaid and Child Health Plus for covered services, including medically necessary transgender health care for people under 18, in the same manner as they do for other forms of medically necessary health care. NYS DOH then obtains reimbursement for the federal matching share for this care from CMS Consistent with other services and benefits covered under the approved state plan.

D. Plaintiff States Regulate the Medical Professions

~~61.~~63. The Plaintiff States license or otherwise establish qualifications and discipline for physicians and other medical professionals operating in their states. *See generally, e.g.*, Or. Rev. Stat. ch. 677; Or. Admin. R. ch. 847; Wash. Rev. Code ch. 18.71, ch. 18.79; Wash. Admin. Code tit. 246; N.Y. Educ. L. §§ 6520 *et seq.*; D.C. Code §§ 3-1201 *et seq.*; D.C. Mun. Reg. tit. 17 §4600 *et seq.*; Colo. Rev. Stat. § 12-240-101, *et seq.*; 3 Colo. Code Reg. § 713-1; 225 Ill. Comp. Stat. 60/1 *et seq.*; Mass. Gen. Laws ch. 13, §§ 9-11; Mass. Gen. Laws ch. 112, §§ 2-12DD, 61; 243 Mass. Code. Reg. 2.00 *et seq.*; Mich. Comp. Laws §§ 333.17001 *et seq.*; N.J. Stat. Ann. § 45:9-1 *et seq.*; 63 Pa. Cons. Stat. §§ 422.1–51a; *id.* §§ 271.1–19; R.I. Gen. Laws §§ 5-37-1 *et seq.*, 5-34-1 *et seq.*, 5-44-1 *et seq.*, 5-54-1 *et seq.*, 216 R.I. Code R. §§ 40-05-1, 40-05-3, 40-05-15, 20-05-24; Wis. Stat. § 15.08; Wis. Stat. ch. 448; Wis. Admin. Code Med. chs. 1–27. Medical professionals are subject to regulation, oversight, and discipline by the Plaintiff States. *See, e.g.*, Or. Rev. Stat. §§ 675.070, .540, .745, 677.190; Wash. Rev. Code § 18.130.040; N.Y. Educ. L. §§ 6524, 6530 *et seq.*; N.Y. Pub. Health L. §§ 230 *et seq.*; Colo. Rev. Stat. §§ 12-240-115, -120, -121; Conn. Gen. Stat. § 20-13c; 225 Ill. Comp. Stat. 60/7.1, 7.5, 22; Mich. Comp. Laws §§ 333.16221, 333.16226, .17011, .17033; N.J. Stat. Ann. § 45:9-6; R.I. Gen. Laws §§ 5-37-6.3, 5-34-24, 5-44-18, 5-54-13; Wis. Stat. §§ 20-13c; Wis. Stat. §§ 448.02; .05, .40, .978.

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~~62.~~64. Similarly, the Plaintiff States license and regulate hospitals. *See, e.g.*, Or. Admin. R. ch. 333; Wash. Rev. Code ch. 70.41; NY Pub. Health §§ 2800 *et seq.*; Colo. Rev. Stat. § 25-3-101 *et seq.*; 210 Ill. Comp. Stat. 85/1 *et seq.*; Mass. Gen. Laws c. 111, §§ 3, 51-56, 70; 105 Mass. Code. Regs. § 130.00 *et seq.*; N.J. Admin. Code § 8:43G-1.1 *et seq.*; 35 Pa. Stat. §§ 448.801a–448.822; R.I. Gen. Laws §§ 23-17-1 *et seq.*; 216 R.I. Code R. § 40-10-4; Wis. Stat. ch. 50, subch. II; Wis. Admin. Code § DHS 124.03.

V. THE KENNEDY DECLARATION HARMS THE PLAINTIFF STATES

A. The Kennedy Declaration Harms the Plaintiff States' Medicaid programs

~~63.~~65. The Plaintiff States administer their respective state Medicaid programs and are harmed by the Kennedy Declaration as administrators of those programs.

~~64.~~66. The Social Security Act does not define what makes a provider "qualified" to perform services under Medicaid pursuant to 42 U.S.C. § 1396a(a)(23), and instead leaves that determination to the States as program administrators, and in their traditional role as regulators of health and safety. *See Medina*, 606 U.S. at 364.

~~65.~~67. Each state must develop a process by which providers may enroll in Medicaid as covered or participating providers, and through which each state approves or rejects providers for enrollment. See 42 C.F.R. § 455.400 *et seq*. This process must follow all screening and categorization procedures outlined in the regulations.

~~66.~~68. HHS OIG has limited authority to determine which providers may participate in Medicaid programs as qualified providers. If HHS OIG seeks to exclude a provider based on the Social Security Act sections 1128 (42 U.S.C. § 1320a-7) or 1156 (42 U.S.C. § 1320c-5), it must follow the process set forth in the Social Security Act and its implementing regulations. This process includes, among other things, issuance of a Notice of Intent to Exclude and an opportunity to respond to and challenge any determinations by HHS. Any exclusion may be appealed to an Administrative Law Judge and the resulting decision may be appealed to the HHS Departmental Appeals Board. 42 C.F.R. § 1001.2007.

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~~67.~~69. Exclusion from the Medicaid program carries significant collateral consequences, such as reputational stigma; the inability to work at institutions that rely on Medicaid or Medicare; exclusion from private insurance panels; emergency suspension of the provider's license (in some States); and difficulties obtaining loans for office space or equipment.

~~68.~~70. The Kennedy Declaration announces a binding rule of decision that the provision of medically necessary transgender healthcare constitutes legally sufficient grounds for exclusion from the Medicaid program. As result, Plaintiff States are likely to face a loss of Medicaid-enrolled providers in critical specialties (such as pediatrics and endocrinology) and higher hurdles in persuading new and existing providers to participate in Medicaid. It is foreseeable that existing qualified providers will voluntarily depart from the Medicaid program rather than face the impossible choice of restricting care to their patients or risking career-ending consequences. This is particularly problematic where States already face significant barriers to attracting and retaining high-quality providers to their Medicaid programs at a time when reliance on State-funded health care is growing.

~~69.~~71. The Kennedy Declaration also directly impairs the Plaintiff States' administration of state Medicaid and CHIP programs under the very terms agreed and guaranteed by HHS. Each Plaintiff State has adopted a state Medicaid plan that provides coverage for gender-affirming care. *See* 42 C.F.R. §§ 430.10 *et seq*. Each of these Plans has been approved by the Centers for Medicare and Medicaid Services, and each Plaintiff State has sought, and received, reimbursement for medically necessary gender-affirming care that the Kennedy Declaration now seeks to prohibit by excluding providers of that care. The Kennedy Declaration thus unilaterally and retroactively discards the state plans without proper procedure, harming the Plaintiff States. *See generally* 42 C.F.R. §§ 430.10 *et seq*. (describing procedures for establishing and amending State Medicaid Plans).

~~70.~~72. For example, the statutory guarantees of coverage under the Oregon Health Plan for gender-affirming care directly conflict with and are undermined by the Kennedy Declaration. The Kennedy Declaration forces the administrator of Oregon Health Plan into an impossible position, regardless of whether participating providers decide to continue providing gender-

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affirming care to patients under the age of nineteen or cease such care. If providers choose to continue providing care, Oregon faces losing the largest providers of health care in the state from participation in state health care plans, including OHSU and Legacy Health. That loss would significantly harm health care networks covered by state health plans, limit the availability of health care for all residents on a state health plan, and strain Oregon's health care system. And if providers cease care, patients under a state health plan will lose access to gender-affirming care for which they are statutorily guaranteed coverage, and the State of Oregon would lose its ability to fulfill its mission as a Medicaid administrator.

~~71.~~73. The Kennedy Declaration similarly harms all Plaintiff States by threatening to exclude providers from participation in Medicare and Medicaid. It threatens provider networks by forcing providers to choose between cessation of gender-affirming care or subjecting themselves to exclusion from participation in federally funded health care programs, including all of the incidental and collateral consequences such an exclusion would entail.

B. The Kennedy Declaration Harms the Plaintiff States as Regulators of the Practice of Medicine

~~72.~~74. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cnty., Fla. v. Auto. Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) *(*citing *Rice v. Sante Fe Elevator Corp*., 331 U.S. 218 (1947)). "The licensing and regulation of physicians is a state function." *P*a. *Med. Soc. v. Marconis*, 942 F.2d 842, 847 (3d Cir. 1991); *see also Dent v. West Virginia*, 129 U.S. 114, 122 (1889) (recognizing the state's powers to regulate medical professions from "time immemorial"). Congress did not delegate to the Secretary of HHS the authority to exercise control over the practice of medicine, *Rasulis v. Weinberger*, 502 F.2d 1006 (7th Cir. 1974), and Congress went out of its way to state that no provision of the Social Security Act should be construed as authorizing the Secretary to exercise such control, *see* 42 U.S.C. § 1395.

~~73.~~75. The Kennedy Declaration infringes on the Plaintiff States' role as regulators of the practice of medicine by attempting to impose coercive conditions on its providers' participation

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in federal health care programs, and retroactive and coercive conditions on the Plaintiff States' access to federal health care funding. *See Arizona v. Yellen*, 34 F.4th 841, 851–53 (9th Cir. 2022).

~~74.~~76. The Kennedy Declaration also infringes on the Plaintiff States' traditional role in regulating the practice of medicine within the Plaintiff States by declaring substantive standards of care that conflict with state law and undermine state civil rights protections. *E.g.*, Or. Rev. Stat. § 743A.325. The Kennedy Declaration thereby impairs Plaintiff States' authority to "exercise … sovereign power over individuals and entities within [its] jurisdiction, including the power to create and enforce a legal code." *Washington v. U.S. Food & Drug Admin.*, 108 F. 4th 1163, 1176 (9th Cir. 2024) (internal quotation marks omitted). That interest "is sufficient to convey standing to … challenge a federal statute that preempts or nullifies state law." *Id.* The Kennedy Declaration obstructs compliance with state law and effectively nullifies those state laws.

C. The Kennedy Declaration's Harm to the Plaintiff States is Immediate and Ongoing

~~75.~~77. The Kennedy Declaration has immediate harmful effect upon the Plaintiff States. The Kennedy Declaration threatens to exacerbate an already serious shortage of providers willing to participate in Plaintiff States' Medicaid programs, especially in critical specialties like pediatrics and endocrinology, including the provision of medically necessary gender-affirming care. It also immediately disrupts the Plaintiff States' regulation of the practice of medicine by creating a separate and legally unsupported standard of care that purports to displace state standards.

VI. CAUSES OF ACTION

COUNT 1
Violation of APA — Without Observance of Procedure Required by Law (5 U.S.C. § 706(2)(D)) — Violation of Medicare Rulemaking and Notice and Comment Requirements (42 U.S.C. §§ 1302, 1395hh)

~~76.~~78. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

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~~77.~~79. Defendants include "agenc[ies]" under the APA, 5 U.S.C. § 551(1), and the Kennedy Declaration is a final agency action subject to review under the APA. The Kennedy Declaration marks the consummation of HHS's decision-making process because it announces the agency's decision to immediately implement a policy that will dramatically change the agency policy regarding gender-affirming care. The Kennedy Declaration announces that the provision of medically necessary healthcare for transgender minors "will be deemed not to meet the professionally recognized standards of health care" and thus allows exclusion of the provider from Medicare and Medicaid.

~~78.~~80. When HHS seeks to change a substantive legal standard under the Medicare Act, it must first allow the public 60 days to comment on the proposed regulation. "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title subchapter shall take effect unless it is promulgated by the Secretary by regulation." 42 U.S.C. § 1395hh(a)(2). Subject to exceptions not applicable here, "before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." *Id.*

~~79.~~81. The Kennedy Declaration violates Medicare notice and comment requirements because it changes a substantive legal standard and was not a "previously published notice of proposed rulemaking or interim final rule." 42 U.S.C. § 1395hh(a)(4). HHS has no "lawful excuse for neglecting its statutory notice-and-comment obligations," and thus HHS's "new policy cannot stand." *Azar v. Allina Health Servs.*, 587 U.S. 566, 568 (2019).

COUNT 2
Violation of APA —
Without Observance of Procedure Required by Law (5 U.S.C. § 706(2)(D)) —
Violation of APA Rulemaking and Notice and Comment Requirements
(5 U.S.C. § 553; 42 U.S.C. § 1302)

~~80.~~82. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

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~~81.~~83. Under the APA, a court "shall … hold unlawful and set aside agency action, findings and conclusions found to be … without observance of procedure required by law[.]" 5 U.S.C. § 706(2)(D).

~~82.~~84. The Kennedy Declaration constitutes a rule for purposes of the APA because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4).

~~83.~~85. Subject to express exceptions not applicable here, federal agencies must complete the process of agency rulemaking before issuing a rule. *Id.* § 553(b). The Kennedy Declaration is subject to notice and comment because it is a substantive, legislative rule. "Legislative rules … create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp Indus. Ass'n v. Drug Enf't Admin.*, 333 F.3d 1082, 1087 (9th Cir. 2003). Thus, the Kennedy Declaration is not exempt from notice-and-comment rulemaking as an "interpretative rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A).

~~84.~~86. When the APA was enacted in 1947, it exempted from its notice-and-comment requirements any "matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts." 5 U.S.C. § 553(a)(2). Case law interpreted that provision to exclude Medicaid as a "benefit" program. *See, e.g.*, *Cubanski v. Heckler*, 781 F.2d 1421, 1428–29 (9th Cir. 1986), *vacated sub nom. on other grounds, Bowen v. Kizer*, 485 U.S. 386 (1988). Subsequent statutory changes, however, have removed Medicaid regulations from that general exemption. In 1987, Congress enacted legislation requiring each notice of proposed rulemaking affecting Medicaid or Medicare "that may have a significant impact on the operations of a substantial number of small rural hospitals" to include an "initial regulatory impact analysis" on these hospitals, and each final rule to include a final regulatory impact analysis. 42 U.S.C. § 1302(b) (P.L. 100-203, Dec. 22, 1987). That requirement is inconsistent with a blanket exemption of Medicaid regulations from the APA's notice-and-comment requirements.

~~85.~~87. In 1971, HHS waived any exemption from rulemaking requirements, which determined "[t]he public participation requirements prescribed by 5 U.S.C. § 553(b) and (c) will

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be followed by all agencies of the Department in rulemaking relating to … grants, benefits, or contracts." 36 Fed. Reg. 13,804 (1971). This commitment, known as the "Richardson Waiver," is enforceable. *Cubanski*, 781 F.2d at 1428–29; *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 356–57 (D.C. Cir. 2017).

~~86.~~88. In March of this year, HHS attempted to disavow the Richardson Waiver in a one-page Federal Register notice. 90 Fed. Reg. 11,029 (March 3, 2025). That revocation is ineffective, because it is arbitrary and capricious: HHS's departure from its decades' old policy lacks "a rational connection between the facts found and the choice made." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

~~87.~~89. Regardless of whether notice and comment are required, a substantive rule must be published in the Federal Register at least 30 days before its effective date. 5 U.S.C. § 553(d).

~~88.~~90. Because the Kennedy Declaration did not follow these required procedures, as required by the APA and the Richardson Waiver, it is procedurally invalid.

COUNT 3
Violation of APA — In Excess of Statutory Authority
(5 U.S.C. § 706(2)(C))

~~89.~~91. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

~~90.~~92. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be … in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

~~91.~~93. The Kennedy Declaration exceeds the Secretary's authority because it purports to set a national standard of care, but there is no statute that permits the Secretary of HHS to do so. No statute allows the Secretary to unilaterally declare that a treatment modality is not safe and effective and thus grounds for exclusion from the program.

~~92.~~94. Under the Medicare statute, Federal officers or employees are prohibited from "excercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. This provision explicitly states the intent "to

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minimize federal intrusion" into state healthcare regulation. *Mass. Med. Soc. v. Dukakis*, 815 F.2d 790, 791 (1st Cir. 1987) (opinion of Breyer, J.).

~~93.~~95. "An agency literally has no power to act … unless and until Congress confers power upon it." *FERC*, 535 U.S. at 18. The Kennedy Declaration does not identify any statutory authority for "declaring" a national standard of care. And although the Kennedy Declaration states that it is "informed by" a regulation, 42 C.F.R. § 1001.2, an agency cannot grant itself authority to create substantive law by promulgating a regulation. In any event, the cited regulation is a definitional provision that does not provide any substantive grant of authority at all.

~~94.~~96. The Kennedy Declaration threatens to invoke 42 U.S.C. § 1320a-7(b)(6)(B), which provides that "[t]he Secretary may exclude … from participation in any Federal health care program … [a]ny individual or entity that the Secretary determines … 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 …." But that statute is a limitation on, not an expansion of, the Secretary's authority to identify a standard of care, because it empowers the Secretary to exclude providers who violate "*professionally recognized* standards of health care"—not standards of care that he declares by edict. Moreover, that provision contemplates actions based on the "quality" of "items or services," not a categorical prohibition on a disfavored category of care.

~~95.~~97. Because the Kennedy Declaration exceeds the Secretary's statutory authority, it is invalid.

COUNT 4
Violation of APA (5 U.S.C. § 706(2)(A)) —
Not in Accordance with Law

~~96.~~98. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

~~97.~~99. ***Regulation of the practice of medicine.*** The Kennedy Declaration violates 42 U.S.C. § 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or

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employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided ….").

~~98.~~100. The Secretary's actions violate multiple, substantive statutory requirements for Medicaid programs.

~~99.~~101. ***Altering the terms of federally approved Medicaid state plans.*** Pursuant to 42 U.S.C. § 1396b, "the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved" amounts specified by statute. Pursuant to 42 U.S.C.§ 1396a, the Secretary has approved state Medicaid and CHIP plans for each Plaintiff State under which each state provides health services to eligible individuals. "The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program." 42 C.F.R. § 430.10. The Kennedy Declaration purports to unilaterally amend a state plan by threatening to drastically reduce the number of eligible providers by deeming them presumptively excluded from participation, and by curtailing the states' traditional authority under the Medicaid Act to determine which providers are eligible. Accordingly, Defendants' action is ultra vires and contrary to law.

~~100.~~102. ***Free Choice of Provider.*** The Kennedy Declaration's prohibition of medical providers who provide medically necessary gender-affirming care from participating in the Medicaid program violates the requirement that Medicaid beneficiaries have a free choice of provider. The Medicaid statutes gives states the authority to set qualifications for providers who may participate in their State Plan. 42 U.S.C. § 1396a(a)(23); 42 C.F.R. § 431.51; *see also Medina*, 606 U.S. at 364 ("States have traditionally exercised primary responsibility over … regulation of the practice of medicine.").

~~101.~~103. ***Comparability requirement.*** The Kennedy Declaration's denial of medically necessary services to Medicaid recipients violates Medicaid's comparability requirement by effectively forcing plans to offer a service to one category of patients (individuals with "a verifiable disorder of sexual development" or other purposes unrelated to such disorders), but to deny the same service to a different category (namely those with a diagnosis of

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gender dysphoria or gender incongruence), on the basis of medical diagnosis. 42 U.S.C.§ 1396a(a)(10)(B); 42 C.F.R. § 440.240. It similarly forces plans to offer services to some patients (those above a certain threshold age), while denying the same services to a different category (those under the threshold age).

~~102.~~104. ***Medical necessity requirement.*** The Kennedy Declaration's effect of denying medically necessary services to Medicaid enrollees violates the Medicaid Act's requirement that medically necessary services be made available to Medicaid enrollees. 42 U.S.C. § 1396a(a)(10)(B); 42 C.F.R. §§ 440.210, 440.220, 440.230.

~~103.~~105. Because the Kennedy Declaration is not in accordance with law, it is invalid.

COUNT 5
Violation of APA (5 U.S.C. § 706(2)(A)) —
Arbitrary and Capricious and an Abuse of Discretion

~~104.~~106. Plaintiff States incorporate by reference the allegations contained in the preceding paragraphs.

~~105.~~107. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

~~106.~~108. The Kennedy Declaration is arbitrary and capricious because it departs from CMS's past practice of allowing States to include gender-affirming care in their Medicaid state plans and never prohibiting providers from providing gender-affirming care as a condition of participation. This abrupt reversal disrupts the Plaintiff States' settled expectations, and those of patients already undergoing care, based on CMS's approval of their state plans and CMS's implementation of those state plans through ongoing payments for gender-affirming care. The agency failed to adequately address these "serious reliance interests" engendered by its prior policy while also failing to "show that there are good reasons for the new policy." *Encino Motorcars, LLC*, 579 U.S. at 221 (citation modified).

~~107.~~109. The Kennedy Declaration also fails to include consideration of important aspects of the problem the Declaration creates, namely, the shortage of Medicaid providers,

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particularly in the fields of pediatrics and endocrinology; the reliance interests of Plaintiff States in structuring their Medicaid Programs based on the availability of providers who meet statutory criteria for eligibility; and the harms to patients and providers within Plaintiff States that would be caused should this rule be implemented. And Defendants failed to adequately consider alternatives.

~~108.~~110. The Kennedy Declaration also fails to include consideration of reasonable alternatives. For example, nowhere in the Kennedy Declaration does Secretary Kennedy claim that provision of gender-affirming care to each and every child or adolescent with gender dysphoria results in harmful outcomes, nor does he cite a single study making such a claim. For example, he cites a study from Sweden recommending that "[h]ormonal interventions may serve as last-resort measures for select youth." But the Kennedy Declaration seeks the extreme outcome of eliminating gender-affirming care entirely without considering less extreme actions, like restricting such care to a "last resort" measure.

~~109.~~111. The Kennedy Declaration also fails to explain its rationale adequately, particularly with respect to the statutory authority upon which it is based. It cites no statute as a basis upon which the Secretary may declare a certain treatment modality or protocol to fall below professionally recognized standards of care and thus fails to explain the Secretary's authority to promulgate the declaration in the first place.

~~110.~~112. Accordingly, the Kennedy Declaration is arbitrary and capricious and an abuse of the Secretary's discretion, and therefore invalid. *See* 5 U.S.C. § 706(2)(A).

VII. PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs pray that the Court:

a. Declare and hold unlawful the Kennedy Declaration;

b. Stay, vacate, and set aside the Kennedy Declaration;

c. Preliminarily and permanently enjoin Defendants; their officers, agents, servants, employees, and attorneys; and anyone acting in concert or participation with Defendants from implementing, instituting, maintaining, enforcing, or giving effect to the Kennedy Declaration in any form;

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d. Postpone the effective date of the Kennedy Declaration pending judicial review;

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e. Award Plaintiffs' costs of suit and reasonable attorneys' fees and expenses pursuant to any applicable law; and

f. Award such additional relief as the interests of justice may require.

DATED: ~~December 23~~January 6, 2025

Respectfully submitted,

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