UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF NEW YORK; STATE OF CONNECTICUT; STATE OF ILLINOIS; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF MAINE; STATE OF MARYLAND; STATE OF MICHIGAN; 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; and STATE OF WISCONSIN, Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States; PAMELA JO BONDI, in her official capacity as United States Attorney General; and the UNITED STATES DEPARTMENT OF JUSTICE; Defendants.	Case No.: 25-cv-12162

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, the Commonwealth of Massachusetts, State of California, State of New York, State of Connecticut, State of Illinois, State of Delaware, District of Columbia, State of Hawai'i, State of Maine, State of Maryland, State of Michigan, 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, and State of Wisconsin, allege as follows:

INTRODUCTION

1. Since taking office on January 20, 2025, President Donald J. Trump and his administration have relentlessly, cruelly, and unlawfully targeted transgender individuals. The Trump administration has sought to deny their very existence, banish transgender residents from the public square, and refuse them medically necessary healthcare through unlawful Executive Orders (EOs) and a raft of federal agency actions implementing those EOs. What's more, the Attorney General has not minced words that she will use the Department of Justice to "bring [] an end" to gender-affirming care for transgender adolescents. The result is an atmosphere of fear and intimidation experienced by transgender individuals, their families and caregivers, and the medical professionals who seek only to provide necessary, lawful care to their patients.

2. This lawsuit challenges one of President Trump's Executive Orders—E.O. 14,187, referenced herein as the "Denial of Care" Order—and two implementing actions taken by the Department of Justice that aim to eliminate the provision of medically necessary healthcare to transgender individuals under age 19—a category that includes not only minors, but also eighteen-year-olds who have reached the age of majority—by intimidating providers into ceasing care through threats of civil and criminal prosecution under laws unconnected to the lawful provision of this care.[1] These threats have no basis in law. No federal law prohibits, much less criminalizes, the provision or receipt of gender-affirming care for transgender adolescents.[2] In fact, federal healthcare programs have reimbursed the provision of such care for years.

[1] Although this Complaint focuses primarily on one Executive Order and related memoranda from the Department of Justice, the Administration has engaged in additional conduct to create an environment of fear and to coerce providers to cease care. The Administration has issued additional "guidance" and sent threatening letters and requests for sensitive patient information to providers in our states.

[2] As used in this Complaint, "adolescent" refers to individuals between the ages of 10 and 19, consistent with the World Health Organization's definition of the term.

3. Furthermore, these actions interfere with weighty state interests. Specifically, the regulation of medicine is a core traditional police power belonging to the States and protected by the Tenth Amendment. Yet through the challenged actions, the Defendants seek to trammel on State power and eliminate this care, even in those States where such care is supported, and indeed protected, by law.

4. The Defendants' actions have had the intended effect of chilling providers from gender-affirming care to individuals under 19 years old—care that is lawful and protected in Plaintiff States. The administration has explicitly threatened civil and criminal prosecution of providers of this care and launched criminal investigations into children's hospitals that provide this care in California, Colorado, and Massachusetts, and demanded extensive data—including patient medical records—regarding the provision of this care from hospitals across the country, without any reason to believe those hospitals have violated the statutes being invoked. Facing threats to their licenses, livelihoods, and liberty, some providers in Plaintiff States have announced that they will cease providing this longstanding, medically necessary, often lifesaving care to their patients. These actions have been touted by Defendants as precisely what was intended by their unlawful and disingenuous targeting, including explicit acknowledgement as much by Defendant Trump[3]: In a press release, attached hereto as Exhibit A, the White House crowed that "President Trump Promised to End Child Sexual Mutilation—and He Delivered."

[3] *See* Exhibit A, News Release, The White House, President Trump Promised to End Child Sexual Mutilation – and He Delivered (July 25, 2025), https://www.whitehouse.gov/articles/2025/07/president-trump-promised-to-end-child-sexual-mutilation-and-he-delivered/ (touting closures or changes in practice at 21 clinics nationwide, including in Plaintiff States California, New York, and Illinois); *see also* News Release, The White House, President Trump Marks Six Months in Office with Historic Successes (July 20, 2025), https://www.whitehouse.gov/articles/2025/07/president-trump-marks-six-months-in-office-with-historic-successes/ ("President Donald J. Trump celebrates the most successful first six months in office for any President in modern American history," including where 'Hospitals and hospital systems across the country have halted so-called "gender-affirming care' for minors following President Trump's executive order 'protecting children from chemical and surgical mutilation.'").

5. In many of the Plaintiff States, transgender individuals are protected by state laws that prohibit discrimination in, among other things, the provision of healthcare services, and which enable them to live healthy lives consistent with their gender identity. Many Plaintiff States' legislatures and administrative agencies have enacted statutes, laws, and regulations consistent with that fundamental principle. The federal threat of civil and criminal investigations and prosecutions restricts Plaintiff States' ability to regulate the healthcare that would otherwise be accessible to their own residents. Through their multi-faceted campaign to pressure providers to cease providing this medically necessary care to transgender adolescents, Defendants have coerced hospitals, individual providers, and others to potentially violate Plaintiff States' anti-discrimination and age-of-majority state laws.

6. Certain Plaintiff States' hospitals, clinics, and universities also provide this medically necessary care and face a credible threat of civil and criminal subpoenas and prosecutions. In addition, diminished access to this care will result in unnecessary pain, anguish, and despair for transgender adolescents experiencing gender dysphoria in Plaintiff States.

7. None of the Administration's actions challenged by this suit have any legal basis. They should be declared unlawful and vacated in their entirety. This Court should declare Section 8 of the Denial of Care Order unconstitutional, vacate and set aside the two final agency actions that flow from that section, declare that the provision of medically necessary care to adolescents subject to the requirements of a state's regulatory system is lawful, and enjoin enforcement of Section 8 of the Denial of Care Order and of the two DOJ directives.

JURISDICTION

8. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the Constitution and laws of the United States and further has jurisdiction

to render declaratory relief under 28 U.S.C. § 2201. This Court also has jurisdiction pursuant to 8 U.S.C. § 1346, as a civil action against the United States founded upon the Constitution, an Act of Congress, or an executive regulation, and 28 U.S.C. § 1361, as an action to compel an officer or employee of the United States or an agency to perform a duty owed to the plaintiff. Jurisdiction is also proper under the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. § 702.

9. Declaratory and injunctive relief is sought consistent with 5 U.S.C. §§ 705 and 706, and as authorized in 28 U.S.C. §§ 2201 and 2202.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(2) and (e)(1). Defendants are United States agencies or officers sued in their official capacities. Plaintiff Commonwealth of Massachusetts is a resident of this judicial district, and a substantial part of the events or omissions giving rise to this Complaint occurred and continue to occur within this district.

PARTIES

11. Plaintiff the Commonwealth of Massachusetts, represented by and through its Attorney General Andrea Joy Campbell, is a sovereign state of the United States of America. Attorney General Campbell is authorized to pursue this action under Mass. Gen. Laws ch. 12, §§ 3, 10.

12. Plaintiff the State of California is a sovereign state in the United States of America. California is represented by Attorney General Rob Bonta, who is the chief law enforcement officer of California.

13. Plaintiff the 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.

14. Plaintiff the 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.

15. Plaintiff, the State of Illinois, represented by and through its Attorney General Kwame Raoul, is a sovereign state of the United States of America. Attorney General Raoul is authorized to pursue this action under Illinois law. *See* 15 ILCS 205/4.

16. Plaintiff State of Delaware is a sovereign state of the United States of America. 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.

17. Plaintiff the 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.

18. 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.

19. Plaintiff the State of Maine, represented by and through its Attorney General Aaron M. Frey, is a sovereign state of the United States. As the State's chief law officer, the Attorney General is authorized to act on behalf of the State in this matter pursuant to 5 Me. Rev. Stat. Ann. § 191.

20. The State of Maryland is a sovereign state of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Anthony G. Brown.

21. Plaintiff the State of Michigan is a sovereign state of the United States of America. Michigan is represented by Attorney General Dana Nessel, who is the chief law enforcement officer of Michigan.

22. 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 of the State of Nevada and is authorized to pursue this action under Nev. Rev. Stat. 228.110 and Nev. Rev. Stat. 228.170.

23. 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 of New Jersey.

24. The State of New Mexico is a sovereign state of the United States of America. New Mexico is represented by Attorney General Raúl Torrez, who is the State's chief law enforcement officer.

25. 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 P.S. §§ 732-204(c), 732-301(6), 732-303.

26. The State of Rhode Island is a sovereign state in the United States of America. Rhode Island is represented by Attorney General Peter F. Neronha, who is the chief law enforcement officer of Rhode Island.

27. The State of Wisconsin is a sovereign state in the United States of America. Wisconsin is represented by Joshua L. Kaul, the Attorney General of Wisconsin. Attorney General Kaul is authorized under Wis. Stat. § 165.25(1m) to pursue this action on behalf of the State of Wisconsin.

28. Defendant Donald J. Trump is the President of the United States, charged under Article II of the Constitution to "take Care that the Laws be faithfully executed." U.S. Const. Art. II § 3. He is sued in his official capacity.

29. Defendant Pamela Jo Bondi is the Attorney General of the United States. She is sued in her official capacity. Attorney General Bondi is responsible for all aspects of the operation and management of the United States Department of Justice (DOJ), including implementing and fulfilling DOJ's duties under the United States Constitution and statutory law.

30. Defendant DOJ is a cabinet agency within the executive branch of the United States government. 28 U.S.C. § 501. DOJ has several divisions, including the Civil and Criminal Divisions. The Federal Bureau of Investigation (FBI) is the principal investigative arm of DOJ.

31. Defendants Attorney General Bondi and DOJ are referred to collectively as the "Agency Defendants."

FACTUAL ALLEGATIONS

I. Gender Identity and the Provision and Protection of Healthcare

A. Transgender Identity, Gender Dysphoria, Intersex Identity, and Healthcare

32. Gender identity refers to a person's internal sense of belonging to a particular gender.[4] Everyone has a gender identity, and a person's gender identity cannot be altered by coercion or medical intervention.

33. Sex is based on anatomical and physiological traits that include external genitalia, secondary sex characteristics (i.e., traits that are sex-linked but not part of the reproductive system), gonads, chromosomes, and hormones.[5]

34. Transgender individuals are people whose gender identity differs from their sex assigned at birth. A transgender boy is someone whose sex assigned at birth was female but has a male gender identity. A transgender girl is someone whose sex assigned at birth was male but

[4] "Gender refers to the characteristics of women, men, girls and boys that are socially constructed. This includes norms, behaviours and roles associated with being a woman, man, girl or boy, as well as relationships with each other. As a social construct, gender varies from society to society and can change over time." *Gender and health*, World Health Organization, https://www.who.int/health-topics/gender#tab=tab_1 (last accessed Jul. 16, 2025).
[5] National Academies of Sciences, Engineering, and Medicine, Introduction and Background, *in* Measuring Sex, Gender Identity, and Sexual Orientation 17, 20 (Nancy Bates, Marshall Chin, & Tara Becker eds., 2022).

has a female gender identity. Non-binary individuals have a gender identity that does not fit within the binary construction of either "male" or "female."

35. In addition to transgender individuals (whose gender identity is different than their sex assigned at birth), other people who do not fit into a binary sex classification may be intersex. Individuals who are intersex "have reproductive or sexual anatomy that doesn't fit into an exclusively male or female (binary) sex classification."[6] Some individuals present with intersex traits at birth, while others may not notice until during or after puberty; some may even "never notice their intersex traits externally."[7] Intersex traits include combinations of chromosomes and mixed genitals and sex organs.[8] There are dozens of medically recognized combinations of intersex traits.[9] Individuals may, for example, be born with "female" external genitalia but experience "male" puberty (such as hair growth and voice deepening).[10]

36. According to recent estimates, approximately 1.3 million adults in the United States (about 0.5%) identify as transgender. Approximately 300,000 youth ages 13 to 17 in the United States (about 1.4% of that age group) identify as transgender.[11] And even the lowest estimates of individuals with intersex traits include hundreds of thousands of people in the United States alone.[12]

37. The health and wellbeing of all people, including those who are transgender and intersex, depends on their ability to live in a manner consistent with their gender identity.

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[6] *Intersex*, Cleveland Clinic, https://my.clevelandclinic.org/health/articles/16324-intersex (last visited July 29, 2025).
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *17-beta Hydroxysteroid Dehydrogenase 3 Deficiency*, Medline Plus, https://medlineplus.gov/genetics/condition/17-beta-hydroxysteroid-dehydrogenase-3-deficiency/ (last visited July 29, 2025).
[11] Jody L. Herman et al., Williams Inst., How Many Adults And Youth Identify As Transgender In The United States? 4 (June 2022), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Pop-Update-Jun-2022.pdf.
[12] United Nations Human Rights Office, Intersex People Fact Sheet, https://www.unfe.org/sites/default/files/download/Intersex%20factsheet%202024%20EN%20-%20CLEARED.pdf (last accessed July 29, 2025) (noting that experts estimate between 0.05% and 1.7% of the global population is born with intersex traits).

38. For some transgender people, the incongruence between their gender identity and sex assigned at birth can cause clinically significant distress, recognized by the American Psychiatric Association's *Diagnostic & Statistical Manual of Mental Disorders, Fifth Edition, Text Revision* ("DSM-5-TR") as "gender dysphoria."[13] To be diagnosed with gender dysphoria, the incongruence must persist for at least six months and be accompanied by clinically significant distress or impairment in social, occupational, or other important areas of functioning.[14]

39. Healthcare for transgender adolescents with gender dysphoria is medically necessary healthcare. Gender dysphoria is a serious medical condition.[15] Treatment for gender dysphoria aims to resolve the distress associated with the incongruence between a transgender person's sex assigned at birth and their gender identity.

40. Treatment for gender dysphoria comes in a number of forms. For example, "social transitioning" is the process by which transgender or non-binary people begin to live in a manner consistent with their gender identity. This can include using a new name and pronoun that corresponds to their gender identity, and adopting dress, hair, or cosmetic styles that more authentically reflect their gender identity. Social transitioning is typically the first—and, in some cases, the only—step a transgender adolescent takes in assuming their gender identity.

41. Individuals experiencing gender dysphoria may also seek medical intervention to address gender dysphoria. Medical intervention for adolescents comes after a long assessment process by a licensed physician and licensed mental health provider to ensure that any such

[13] Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders 513 – 14 (5th ed., text rev. 2022).
[14] *Id.* at 512 – 13.
[15] *See* Eric Yarbrough et al., Am. Psych. Ass'n, Gender Dysphoria Diagnosis, *in* A Guide for Working With Transgender and Gender Nonconforming Patients (2017).

intervention is medically necessary for the patient, and that the patient and their family are adequately informed of any risks that accompany such treatment.

42. Medical intervention to address gender dysphoria may include puberty-delaying medication, hormone treatment, and surgery—healthcare that has been referred to collectively as "gender-affirming care." Puberty-delaying medications, sometimes called "puberty blockers," are used to delay the changes of puberty in transgender and some intersex adolescents who have already started puberty in order to prevent changes to those individuals' bodies that are inconsistent with their gender identity and that, if they were to proceed, could exacerbate the individuals' gender dysphoria. Puberty blockers are administered through injections several times a year, or through a subcutaneous implant that continuously administers the medication for approximately one year. Puberty blockers are also a medically accepted treatment that is prescribed for precocious puberty.

43. Hormone therapy typically consists of testosterone for transgender boys, and estrogen in addition to medicine to suppress testosterone for transgender girls. Hormone therapy allows transgender adolescents to develop physical characteristics consistent with their gender identity. Hormone therapy is a medically appropriate treatment for some individuals with gender dysphoria that is also routinely prescribed for non-transgender adolescents with delayed puberty.

44. Some older adolescents suffering severe gender dysphoria may require and be offered surgical options such as masculinizing chest surgery for transgender boys. The same surgery is commonly performed on non-transgender boys as a treatment for gynecomastia. This surgery is considered medically appropriate for treating some individuals with gender dysphoria and is only performed in extremely rare circumstances for transgender individuals under the age of 19.

45. Left untreated, gender dysphoria can substantially affect quality of life, including causing "symptoms of depression and anxiety, substance use disorders, a negative sense of well-being and poor self-esteem, and an increased risk of self-harm and suicidality."[16] Indeed, in the wake of the Executive Orders, providers expressed deep concern over the imminent "spike in acute mental health crises" anticipated by interruptions in care.[17]

46. Decisions about healthcare services for adolescents with gender dysphoria are made in consultation with medical professionals, who consult with individual patients and their families or caregivers, where required, and recommend an appropriate course of treatment. The patient must always consent to receive care. For individuals under the age of 18, such decisions are made consistent with state law, which generally requires that such treatment decisions occur only with the consent and participation of parents or legal guardians.

47. In all Plaintiff States, residents who are 18 years old are legal adults who have legal authority to make medical decisions for themselves.

48. Forcing adolescents diagnosed with gender dysphoria to wait until they turn 19 to access medically necessary healthcare services can cause significant harm. Not only are they denied medical treatment that could alleviate their anxiety, depression, and other symptoms of their clinically diagnosed gender dysphoria, but their clinical distress is also likely to worsen while they wait. Without treatment, transgender adolescents will undergo puberty and the associated physiological changes typical of those with their sex assigned at birth, which do not correspond to their gender. That experience may amplify their gender dysphoria and may

[16] Garima Garg et al., *Gender Dysphoria*, StatPearls (July 11, 2023), https://www.ncbi.nlm.nih.gov/books/NBK532313/.

[17] Charlotte Rene Woods, *VCU Health resumes gender-affirming care – but only for some*, Virginia Mercury (Feb. 25, 2025), https://virginiamercury.com/briefs/vcu-health-resumes-gender-affirming-care-but-only-for-some/ ("'I know many of us are anticipating a large spike in children who are in acute mental health crises,' wrote Dr. Frank Petruzella, division chief of emergency pediatric medicine, in an email sent shortly after Trump's order.").

unnecessarily increase the costs and complications associated with obtaining such healthcare after they turn 19.

49. Transgender adolescents who are denied access to this medically necessary healthcare are also denied the irreplaceable opportunity to mature and grow with their peers, and in their schools and communities, as their authentic selves.

50. Some intersex individuals experience gender dysphoria and require treatment to alleviate it. And many of the same treatments used to treat transgender individuals with gender dysphoria may be used to treat intersex individuals who need specialized medical care.[18] For instance, in consultation with an array of specialists and medical providers, some intersex individuals receive medically necessary hormone therapy to "induce secondary sex characteristics," "affirm gender identity if sex assigned at birth does not correspond with gender identity," or "replace sex hormones after surgical removal of gonads."[19]

B. Standards of Care for Treating Individuals Under 19 with Gender Dysphoria

51. Many major medical organizations—including the American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American Society for Reproductive Medicine, American College of Physicians, American Medical Association, the American Psychiatric Association, and the Endocrine Society—relying on extensive clinical experience and research findings have recognized the benefits of providing medical care when appropriate to improve the symptoms of gender dysphoria. Recognizing that denying or interrupting such medically necessary care can have tragic consequences for the physical and

[18] National LGBTQIA+ Health Education Center, Affirming Primary Care for Intersex People (Aug. 6, 2020) ("While many intersex people do not need any specialized medical care, some require care at specific developmental junctures, and others have lifelong needs related to their individual variation").
[19] *Id.* at 7.

mental well-being of transgender adolescents diagnosed with gender dysphoria, they have in many cases created detailed, evidence-based clinical practice guidelines. With minor variations, those guidelines broadly promote a uniform standard of care.

52. In Plaintiff States, healthcare providers in hospitals and other medical facilities follow and continue to use evidence-based, well-researched clinical practice and medical guidelines to assess, diagnose, and treat patients with gender dysphoria. Like all medical treatments, the benefits and risks must be carefully weighed in every individual circumstance, and patients (and minor patients' parents or legal guardians) must provide informed consent.

53. Providers who deliver this care to transgender patients under 19 are dedicated professionals who hold themselves to stringent guidelines based on the most current scientific evidence available. Under the existing standard of care, teams of expert specialists engage in a holistic model of care that considers the patient's mental health, internal identity, developmental journey, goals and aspirations, and other medically relevant factors such as comorbidities. Guided by their families and providers, adolescent patients are at the center of any treatment plan, and decisions as to the trajectory of that care are their own.

54. The treatment of gender diverse adolescents is a multidisciplinary effort, and the standard of care calls, at minimum, for an appropriately trained diagnosing clinician and a mental health provider for the patient, in addition to primary care providers. The care team must pay particular attention to the patient's developmental stage, neurocognitive function, and language skills and include a supporting adult in decision-making to ensure that the patient is fully informed about the options for treatment and the associated risks and benefits.

55. The first step in accessing treatment is a comprehensive assessment by qualified providers who specialize in both gender identity and adolescent health. This assessment includes

physical evaluations, mental health screenings, and discussions about the patient's gender identity and its impact on the patient's well-being. To meet the diagnostic criteria of gender dysphoria, a patient must have experienced a "marked incongruence" between their gender identity and sex assigned at birth for at least six months. That incongruence must manifest in at least two of a number of criteria indicating that the patient has experienced strong desires to have the physical characteristics or social role of a different gender, and the conviction that their lived experience aligns more with the lived experience of a different gender.[20]

56. Only after the patient has undergone this thorough diagnostic process can they begin to contemplate further interventions, with the help of their primary care physician, mental health provider, endocrinologist, gender specialist, as well as any other relevant specialists for that particular patient. These expert provider teams work with patients and their supporting adult(s) to develop treatment plans designed to address the specific needs of each individual.

57. Often, treatment plans begin with social transition, such as by supporting the patient in using a chosen name and pronouns that correspond more closely with their gender identity at home, school, or in other social environments. This alone has been shown to improve mental health outcomes and reduce suicidality in gender diverse youth when the young person lives in a supportive environment.[21] Because some young people may face increased harassment or bullying due to social transition, care guidelines recommend that providers discuss these risks and benefits so that the individual can make an informed choice.[22]

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[20] Am. Psychiatric Ass'n, Diagnostic and Statistical Manual of Mental Disorders 512 – 14 (5th ed., text rev. 2022).
[21] Stephen T. Russell et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behavior Among Transgender Youth*, 63 J. Adolescent Health 503, 505 (2018), https://pubmed.ncbi.nlm.nih.gov/29609917/.
[22] Jack L. Turban et al., *Timing of Social Transition for Transgender and Gender Diverse Youth, K-12 Harassment, and Adult Mental Health Outcomes*, 69 J. Adolescent Health 991, 996 (Dec. 2021), https://www.sciencedirect.com/science/article/abs/pii/S1054139X21002834?dgcid=coauthor; 2021) Min Kyung Lee et al., *The Impact of Gender Affirming Medical Care During Adolescence on Adult Health Outcomes Among Transgender and Gender Diverse*

58. For adolescents who have not started puberty, social transition is the only clinically recommended form of gender-affirming care. This is because age is the most important factor in determining what kind of care is appropriate. Indeed, providers are encouraged to recognize that gender diversity in children is not a pathology and may not result in adult gender incongruence; rather, providers are encouraged to support a young person's gender exploration so as to empower the individual to come to an autonomous understanding of their own identity, from childhood, through adolescence, and into adulthood.[23]

59. Moreover, certain medical interventions are categorically proscribed by age. For example, hormone treatment of any kind is not recommended for young people who have not started puberty. For adolescents under 14, hormone agonists, commonly referred to as "puberty blockers," may be initiated as a monotherapy; however, young people 16 and over who have used or anticipate using hormone agonists for an extended period of time typically are both eligible for and recommended to use hormone replacement therapy in addition to puberty blockers. [24] This is both to mitigate the risks associated with suppressing sex hormones during a critical developmental period, and because adolescents aged 16 and older typically have the mental capacity to make an informed decision about this kind of care.

60. Providers who deliver hormone treatments to patients under 19 are expected to regularly monitor the patient through physical assessments every three to six months and laboratory tests every six to twelve months.

Individuals in the United States: The Role of State-Level Policy Stigma, 11 LGBT Health 111, 112 (Mar. 2024), https://www.liebertpub.com/doi/10.1089/lgbt.2022.0334?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed.

[23] E. Coleman et al., Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 23 Int'l J. Transgender Health S1, S67 (2022) ("[G]ender diversity is an expected aspect of general human development.").

[24] *See* Janet Y. Lee & Stephen M. Rosenthal, *Gender-Affirming Care of Transgender and Gender-Diverse Youth: Current Concepts*, 74 Annual Rev. Med. 107, 108 – 109 (2023), https://www.annualreviews.org/content/journals/10.1146/annurev-med-043021-032007.

61. Surgical interventions for gender diverse adolescents under the age of 18 are exceptionally rare, and those surgeries that do occur are almost entirely chest masculinization procedures, often referred to as "top surgery."[25] It is further recommended that the patient have undergone a year of gender-affirming hormone treatment prior to any surgery. Other surgeries are generally not recommended by either the Endocrine Society or World Professional Association for Transgender Health (WPATH) guidelines for patients under 18. As with any other medical procedure, in determining whether top surgery may be appropriate for a patient, a provider should consider their physical and mental health status.

62. As with all medical care, these treatments for transgender patients carry certain risks and providers are expected to discuss these and other risks with patients and their families in order to ensure that the adolescent and their parents or caregivers understand the risks such that the patient is able to make a fully informed decision to proceed with treatment.

C. Plaintiff States' Efforts to Protect Transgender Individuals From Discrimination and Ensure the Availability of Healthcare for Their Residents

63. Many Plaintiff States have enacted laws, policies, and protections for transgender residents, including transgender and intersex people under 19 years of age, in an appropriate and lawful exercise of their traditional police power to regulate the practice of medicine within their borders.[26] These protections include the right to access medically necessary healthcare, regardless of gender identity.[27]

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[25] Dannie Dai et al., *Prevalence of Gender-Affirming Surgical Procedures Among Minors and Adults in the US*, 7 JAMA Network Open 1, 3 (June 27, 2024), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820437.

[26] *See, e.g.*, Mass. Gen. Laws c. 12, § 11 I 1/2 (a)-(d); N.Y. Const. art. 1, § 11(a); N.Y. Exec. Law § 296 et. seq.; 775 Ill. Comp. Stat. 5/1-102; 775 Ill. Comp. Stat. 5/1-103(O), (O-1); 775 Ill. Comp. Stat. 5/5-101(A)(6); Unruh Civil Rights Act, Cal. Civ. Code § 51.

[27] *See, e.g.*, Mass. Gen. Laws c. 272, §§ 92A, 98; Mass. Div. of Ins. Bulls. 2021-11, 2014-03; N.Y. Pub. Health L. § 2803(1)(g); N.Y. Comp. Civ. R. Regs. tit. 9, § 466.13, tit. 10, §§ 405.7(b)(2), (c)(2), 505.2(l)(2); 410 Ill. Comp. Stat 50/3(a); 735 Ill. Comp. Stat 40/28-10; 215 Ill. Comp. Stat 5/356z.60(a); 50 Ill. Admin. Code § 2603.35(a); Conn. Ins. Dept. Bull. IC-34.

64. Access to healthcare services is a right secured by the constitution and laws of the Commonwealth of the Massachusetts. Mass. Gen. Laws c. 12, § 11 I ½(b).[28] Any 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 c. 12, § 11 I ½(a) & (d). Massachusetts prohibits discrimination on the basis of gender identity in the provision of healthcare services and insurance coverage. *See* Mass. Gen. Laws c. 272, §§ 92A, 98; Mass. Division of Insurance Bulletins 2021-11 and 2014-03 (interpreting Mass. Gen. Laws c. 175, §§ 4C, 24A, and 120F).

65. In California, healthcare is a right secured by state law. Cal. Civ. Code § 1798.301. California law also prohibits discrimination on the basis of gender identity, gender expression, transgender status, gender dysphoria diagnosis, or intersex status in the provision of healthcare services. Cal. Civ. Code § 51; Cal. Gov't Code §§ 11135, 12926; Cal. Code Regs. tit. 2, §§ 14000 *et seq*. In California, healthcare for transgender residents is "medically necessary health care that respects the gender identity of the patient, as experienced and defined by the patient." Cal. Welf. and Inst. Code § 16010.2(b)(3); Cal. Civ. Code § 1798.300(c).

66. 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, healthcare 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 to access healthcare without discrimination on the basis of

[28] Gender-affirming healthcare services are defined by Mass. Gen. Laws c. 12, § 11 I ½(a) to include "all supplies, care and services of a medical, behavioral health, mental health, surgical, psychiatric, therapeutic, diagnostic, preventative, rehabilitative or supportive nature relating to the treatment of gender dysphoria."

sex, gender identity, gender expression, transgender status, or diagnosis of gender dysphoria and 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 L. § 2803(1)(g).

67. Connecticut likewise prohibits discrimination on the basis of gender identity in public accommodations, including hospitals, and insurance coverage. *See* Conn. Gen. Stat. § 46a-64; Conn. Insurance Dept. Bulletin IC-34. Connecticut also prohibits discrimination on the basis of gender identity in the provision of medical care. *See* P.A. 25-154, Sec. 1.

68. Illinois law prohibits discrimination on the basis of sex or gender identity by hospitals, pharmacies, and healthcare providers, among others. 775 ILCS 5/1-102; 775 ILCS 5/1-103(O), (O-1); 775 ILCS 5/5-101(A)(6). The Illinois Insurance Code further prohibits discrimination based on an individual's actual or perceived gender identity, or on the basis that an individual is transgender, and requires coverage of, *inter alia*, "hormonal treatment administered to treat gender dysphoria." 215 ILCS 5/356z.60(a); 50 Ill. Admin. Code 2603.20, 2603.35(a), 2603.40. In Illinois, residents have "the right of each patient to care consistent with sound nursing and medical practices[.]" 410 ILCS 50/3(a).

69. The Delaware "Transgender Identity Nondiscrimination Act of 2013," referred to as SB 97 (2013), made gender identity a protected class and banned discrimination against a person based on gender identity in housing, employment, public works contracting, public accommodations, and insurance. Delaware law prohibits blanket policy exclusions for gender-affirming care and requires that insurance companies provide coverage for gender-affirming care on an equivalent basis with similar care provided for other diagnoses and impose equal premiums for those seeking or receiving gender-affirming care. 18 Del. C. § 3571N; 18 Del. C.

§ 7207. Delaware law bans conversion therapy for youth. 24 Del. C. § 1702. On June 20, 2025, Governor Matthew Meyer issued Executive Order 11, Protecting Gender-Affirming Care In Delaware, which declared, in pertinent part, that "'gender-affirming care' means any medically necessary healthcare or treatment consistent with current clinical standards of care prescribed by a licensed healthcare provider for the treatment of a condition related to the individual's gender identity and that is legal under Delaware law." Executive Order 11 further prohibits state professional regulation boards from disciplining a healthcare professional solely on the basis of providing or assisting with gender-affirming care that is or would otherwise be lawful in Delaware.

70. In the District of Columbia, healthcare providers are prohibited from denying services to a person based on the person's perceived or actual sex or gender identity or expression. D.C. Code § 2-1402.31 *et seq.* Specifically, a "place of public accommodation" is prohibited from "deny[ing], directly or indirectly, any person the full and equal enjoyment of the goods, services, facilities, advantages, and accommodations of any place of public accommodation." *Id.* at § 2-1402.31(a)(1). A "place of public accommodation" is defined as "any person or place that provides, to a person in the District, access to an accommodation, service, or good, whether or not that person or place maintains a physical location in the District or charges for those goods or services," and expressly includes "clinics" and "hospitals" in its definition. *Id.* at § 2-1401.02(24).

71. Maine law prohibits healthcare providers from denying services to or discriminating against any individual based on gender identity. 5 MRS §4551 *et seq.* State laws expressly protect access to gender-affirming care in Maine. 22 MRS §1508 (minors' access to gender-affirming care); 22 MRS §3174-MMM (coverage for gender-affirming care).

72. In Maryland, state-regulated health insurance carriers are barred from discriminating against individuals on the basis of their sex or gender identity. Md. Code Ann., Ins. § 15-1A-22. This includes prohibitions on refusing, withholding, or denying coverage because of the individual's sex or gender identity. *Id.* § 15-1A-22(d). Maryland's Medical Assistance Program, a state public health program for eligible low-income adults, children, pregnant women, elderly adults, and people with disabilities, is required by state law to cover all medically necessary gender-affirming treatment prescribed to a Program recipient in accordance with current clinical standards of care. Md. Code Ann., Health-Gen, § 15-151(c).

73. In Michigan, individuals cannot be denied healthcare services based on, among other classifications, sex or gender identity or expression. Mich. Compl. Laws § 37.2302.

74. The New Jersey Law Against Discrimination prohibits discrimination and harassment based on gender identity or expression in public accommodations, including clinics, hospitals, and other medical settings. *See* N.J. Stat. Ann. 10:5-5(*l*), (rr), 10:5-12(f). New Jersey law also prohibits health insurance carriers from discriminating "on the basis of a covered person's or prospective covered person's gender identity or expression or on the basis that the covered person or prospective covered person is a transgender person." N.J. Stat. Ann. § 17B:26-2.1*ii*.; *see also* N.J. Stat. Ann. § 17:48A-7*ll*; N.J. Dep't of Banking & Ins., Bulletin No. 23-05.

75. New Mexico's Reproductive and Gender-Affirming Health Care Freedom Act prohibits discrimination based on a person's use of or refusal to use gender-affirming health care services. NMSA 1978, § 24-34-3(A) (2023). New Mexico also prohibits restriction or interference "with a person's ability to access or provide reproductive health care or gender-affirming care within the medical standard of care." NMSA 1978, § 24-34-3(B) (2023).

Additionally, New Mexico's Reproductive and Gender-Affirming Health Care Protection Act protects the State's healthcare providers from "foreign investigation[s] or proceeding[s] that seek[] to impose civil or criminal liability or professional disciplinary action" for engaging in the provision of gender-affirming care. *See* NMSA 1978, §§ 24-35-1 through 8 (2023).

76. Pennsylvania law prohibits discrimination against individuals in public accommodation because of a person's sex assigned at birth, gender identity or expression, or differences of sex development (i.e., intersex characteristics). 43 P.S. §§ 952, 954; 16 Pa. Code §§ 41.204, 41.206. Pennsylvania health care facility regulations mandate nondiscriminatory practices in patient care. 28 Pa. Code §§ 51.11-51.13. The Pennsylvania State Board of Medicine; State Board of Osteopathic Medicine; State Board of Nursing; State Board of Social Workers, Marriage and Family Therapists, and Professional Counselors; and State Board of Psychology have each issued a statement of policy stating that use of conversion therapy—i.e., the wide range of interventions by mental health professionals that seek to change an individual's sexual orientation or gender expression—may constitute unprofessional conduct when directed at minors. 49 Pa. Code § 16.63, 25.218, 21.416, 47.5, 48.5, 49.5, 41.62. The Pennsylvania Insurance Department has issued guidance that health insurance policies should not exclude services based on gender identity and must provide coverage for medically necessary services regardless of an individual's gender identity. Pa. Insurance Dep't Notice Regarding Nondiscrimination, 46 Pa.B. 2251 (Apr. 30, 2016).

77. Rhode Island 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. R.I. Gen. Laws § 23-17-19.1; *see also* 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-RICR-80-05-1 (regulations further detailing these obligations of health care facilities, including obligations to admit patients without discriminating on the basis of "gender identity or expression" and implement employment policies that prohibit discrimination on the basis of "sex" or "gender identity or expression"). Rhode Island further prohibits discrimination on the basis of gender identity, expression, or gender dysphoria diagnosis in the provision of health insurance regulated by the state. Health Insurance Bulletin 2015-3, Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity or Expression (November 23, 2015).

78. In Wisconsin, under Wis. Stat. § 36.12(1), "[n]o student may be denied admission to, participation in or the benefits of, or be discriminated against in any service, program, course or facility of the [University of Wisconsin System] or its institutions because of the student's … sex [or] … sexual orientation …" This same antidiscrimination provision applies to students in Wisconsin's Technical College System under Wis. Stat. § 38.23, and public students in K-12 under Wis. Stat. § 118.13. Discrimination based on sex is also prohibited in employment (Wis. Stat. §§ 111.31-111.36); in open housing (Wis. Stat. §106.50(1m)(h)); and in public places of accommodation or amusement (Wis. Stat. § 106.52(3). Also, Wisconsin law prohibits insurers from discriminating among policyholders by offering different terms of coverage except on the basis of classifications related to the nature and the degree of the risk, or to deny benefits on the basis of sex. *See* Wis. Stat. § 628.34(3); Wis. Stat. § 632.746(10), Wis. Stat. § 632.748(2); Wis. Admin. Code § Ins 6.55)). These laws have been interpreted to prohibit the exclusion of health treatments based on gender identity that would otherwise be covered, and to prohibit the exclusion, limitation, or denial of covered benefits based on an insured's gender identity by self-

funded, non-federal governmental plans. *See* Wis. Stat.§ 632.746 (10)(b)2. Finally, in January 2019, Governor Tony Evers issued Executive Order #1, which prohibits discrimination on the basis of gender identity in government employment.

79. Many Plaintiff States also have "shield laws" that are intended to protect patients and providers who provide or access this medically necessary and lawful healthcare within our states from criminal and civil liability in an out-of-state-jurisdiction that outlaws it.[29]

80. Many Plaintiff States also require that transgender and gender diverse individuals in state custody have access to medically necessary care, without unnecessary delays, requirements, or barriers.[30]

81. Many of the States' agencies are also subject to laws and regulations that prohibit discrimination on the basis of gender identity and expression and have adopted nondiscrimination policies that further prohibit such discrimination. For example, the New York State Office of Children and Family Services (NY OCFS) is bound by state regulations governing foster care, juvenile justice facilities, and programs for runaway and homeless youth that prohibit discrimination based on gender identity or expression and disability, and state statutes and a state constitutional provision which further prohibit such discrimination. NY OCFS policy also forbids discrimination by employees, contractors, and volunteers on the basis of gender identity or expression. Accordingly, NY OCFS is required to treat adolescents seeking

[29] *See, e.g.*, 735 ILCS 40/28-5, *et seq.*; Mass. Gen. Laws c. 12, § 11 I ½(c); Conn. Gen. Stat. §§ 19a-17e, 52-146w, 52-571m, 54-82i, 52-155a, 54-155a, and 54-162; House Bill 205, 153rd Delaware General Assembly (2025); 14 MRS §9901 (Maine); N.J. Exec. Order No. 326 (Apr. 4, 2023) (ordering application of New Jersey shield law, N.J. Stat. Ann. § 2A:160-14, to "protect people or entities in New Jersey providing, receiving, assisting in providing or receiving, seeking, or traveling to obtain gender-affirming health care services").

[30] *See, e.g.,* DCF Policy 2021-01: Gender-affirming Medication Consent Policy, DYS Policy on the Prohibition of Harassment and Discrimination Against Youth, DYS Guidelines for Practices with LGBTQI and gender non-conforming Youth (Massachusetts); DCFS Procedure, Rule 302, Appendix K, P.T. 2023.07 (Illinois); N.J. Dep't of Children & Families, *LGBTIA Policy*, Policy Manual, Vol. I, ch. A (rev. Sept. 3, 2024) (New Jersey).

this medically necessary care no differently than adolescents seeking other medically necessary care.

82. Some of the States' agencies have legal obligations to ensure youth in the custody or care of the States can access medically necessary healthcare. For example, NY OCFS is required by law to provide comprehensive medical, health, and behavioral health services to every child in its care or custody. 18 CRR-NY 441.22. This includes all medically necessary care for transgender adolescents. The agency's policies and practices reflect this obligation.

D. State Regulation of the Practice of Medicine

83. States exercise their power to regulate medicine in various ways. Perhaps most significantly, states regulate the practice of medicine by defining the scope and contours of medical practice and requiring medical licenses for practitioners.

84. Since 1895, all states have had boards that oversee the licensing of medical professionals. Fundamental and consistent requirements for obtaining a medical license across states include graduation from an accredited medical school, completing one or more years of residency or fellowship, and passing a licensing examination. Additional requirements can include interviews, a documented lack of criminal history, and malpractice insurance coverage documentation. State boards also regulate medical practice by disciplining licensees who act illegally or unethically and by "enact[ing] laws and regulations that directly circumscribe how licensed practitioners conduct medical practice," such as reporting, disclosure, and timeframe rules.[31]

85. The Massachusetts Board of Registration in Medicine (BORIM) is a state governmental body that is responsible for licensing, regulation, and discipline of Massachusetts

[31] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 S.D. L. Rev. 427, 450-52 (2015).

physicians and acupuncturists. BORIM's mission is to ensure that only qualified and competent physicians of good moral character are licensed to practice in the Commonwealth of Massachusetts and that those physicians and healthcare institutions in which they practice provide to their patients a high standard of care, and support an environment that maximizes the high quality of healthcare in Massachusetts.

86. The Medical Board of California is a state government agency that is responsible for the licensure and discipline of medical doctors. The mission of the Medical Board of California is to protect consumers of healthcare in California and to prevent harm through licensing and regulations of physicians, surgeons, and other healthcare professionals. The Medical Board of California enforces the Medical Practice Act to ensure quality medical care in California.

87. In New York, the New York State Department of Education is responsible for licensing physicians by setting the requirements for licensure, including education and examinations. *See* N.Y. Educ. L. §§ 6520 *et seq.* The New York State Department of Health is responsible for disciplining physicians. *See* N.Y. Educ. L. 6530 *et seq.*; N.Y. Pub. Health L. §§ 230 *et seq.* The Office of Professional Medical Conduct of the New York State Department of Health is responsible for investigating all complaints of misconduct, coordinating disciplinary hearings that may result from an investigation, and monitoring physicians who are the subject of disciplinary action. Disciplinary hearings are held before the Board for Professional Medical Conduct.

88. The Connecticut Medical Examination Board is the state government body that is responsible for licensing and discipline of physicians in Connecticut. The Board ensures that physicians licensed to practice in Connecticut provide care within the scope of their practice and

the acceptable standard of care. The board may take disciplinary actions against a physician who, among other things, prescribes medication without a therapeutic or medically proper purpose. Conn. Gen. Stat. § 20-13c.

89. The Illinois Department of Financial and Professional Regulation regulates various professions in Illinois, including healthcare professionals. The Illinois State Medical Board advises the Department on qualifications for physician licensure. 225 ILCS 60/3. Among other things, the Board sets minimum education standards and investigates allegations of physician misconduct.

90. The Delaware Board of Licensure and Discipline, a Board within the Delaware Division of Professional Regulation, is the state government body that is responsible for licensing and disciple of physicians in Delaware. The Board develops standard for professional competency and ensures that physicians licensed to practice in Delaware provide care within the scope of their practice and the acceptable standard of care. 24 Del. C. §1700. The board may take disciplinary actions against a physician who, among other things, performs unnecessary medical procedures, fraudulently bills for medical services or willfully fails to treat a person under their care. 24 Del. C. §1731(b)(3).

91. The District of Columbia Department of Health's Board of Medicine is the District agency authorized to license and regulate physicians as part of the Department of Health's overall mission to "promote[] health, wellness, and equity across the District, and protect[] the safety of residents, visitors, and those doing business in our nation's capital." D.C. Code § 3-1201 *et seq*.; D.C. Mun. Reg. § 17-4600 *et seq.* The Board of Medicine has broad jurisdiction to regulate the practice of medicine in the District of Columbia, including the licensure and discipline of physicians. D.C. Code § 3-1202.03; § 3-1205.14 *et seq.*

92. The Maine Board of Licensure in Medicine is the state agency responsible for protecting the health and safety of the public by determining who may be licensed for medical practice in Maine and by regulating the medical practice of those licensees. The Board monitors the practice of medicine to ensure the integrity of the profession and to maintain high professional standards and conduct. It may discipline and/or sanction licensees who violate the standards of conduct or whose performance is below minimum acceptable standards of proficiency. 32 MRS § 3263 et. seq.

93. The Maryland Board of Physicians is the state governmental agency authorized to license and regulate physicians and allied health providers pursuant to Md. Code Ann., Health Occ. §§14-101 *et seq.,* §§14-5A-01 *et seq.* through §§ 14-5G-01 *et seq.,* and §§ 15-101 *et seq.*, and to discipline licensees who violate relevant grounds of the Health Occupations Article. In addition to establishing qualifications for licensure, the Board is responsible for investigating complaints against licensees and for taking action against the licenses of those who fail to maintain Maryland's high standards for the delivery of quality medical care.

94. The Michigan Board of Medicine is a state governmental body that is responsible for licensing, regulation, and discipline of Michigan physicians. The Board ensures that physicians licensed to practice in Michigan provide care within the scope of their practice and the acceptable standard of care.

95. The New Jersey Board of Medical Examiners (NJBOM) is a state body that is responsible for the licensing, regulation, and discipline of New Jersey medical professionals. The NJBOM's "paramount responsibility" is "the protection of the public's health, safety and welfare," and it meets this "responsibility by licensing medical professionals, adopting regulations, determining standards of practice, investigating allegations of physician misconduct,

and disciplining those who do not adhere to requirements - thereby assuring the public that the physicians are qualified, competent, and honest."[32]

96. The New Mexico Medical Board (NMMB) and the New Mexico Board of Nursing (NMBN) are state governmental bodies responsible for the regulation and licensing of healthcare providers. The NMMB was created in the interest of public health, safety, and welfare to protect the public from the improper, unprofessional, incompetent, and unlawful practice of medicine. The NMBN's mission is to protect the public safety through effective regulation of nursing care and services.

97. The Pennsylvania State Boards of Medicine and Osteopathic Medicine are governmental entities responsible for the licensure, regulation, and discipline of medical physicians, osteopathic doctors, and certain allied health professionals in the Commonwealth of Pennsylvania. *See* 63 P.S. §§ 422.1 – 422.51a; *id.* §§ 271.1 – 271.19. By law, medical and osteopathic doctors must be licensed to engage in the practice of medicine, surgery, and osteopathic medicine in Pennsylvania. *See* 63 P.S. §§ 422.28, 442.10; *id.* § 271.3. Medical physicians and osteopathic doctors must meet minimum qualifications for licensure, including education, training, and examination requirements. *See* 63 P.S. § 422.22; *id.* § 271.6. The Boards play a central role in ensuring that physicians and osteopathic doctors deliver competent, ethical, and legally compliant care throughout the Commonwealth. Through their regulatory and disciplinary authority, the Boards protect public health and maintain high standards of medical practice in Pennsylvania. The Boards have the authority to refuse, suspend, or revoke a license for "unprofessional or immoral conduct" or for "incompetence, gross negligence, or repeated

[32] About the Board, State Bd. of Med. Exam'rs, https://www.njconsumeraffairs.gov/bme/Pages/about.aspx (last visited July 24, 2025).

acts of negligence or incompetence in the practice of medicine or surgery." *See* 63 P.S. §§ 422.41(8)–(9); *id.* § 271.15; 49 Pa. Code § 16.61.

98. The Rhode Island Board of Medical Licensure and Discipline is the body that oversees medical licensing and discipline in the State of Rhode Island. R.I. Gen. Laws §§ 5-37-1 *et seq.* The purpose of this board is to uphold standards for medical licensure and ensure the clinical competence of licensed physicians in the state.

99. The Wisconsin Medical Examining Board (MEB) is the state board responsible for regulating the practice of medicine and osteopathy in Wisconsin. It is created in Wis. Stat. § 15.405(7) and has authority as outlined in Wis. Stat. ch. 448. MEB plays a vital role in safeguarding public health by ensuring that only qualified, competent, and ethical physicians and healthcare providers are licensed to practice medicine in Wisconsin. This includes setting high standards for medical licensing, overseeing the conduct of medical professionals, and ensuring ongoing education and compliance with medical laws and regulations.

100. Additionally, each state has its own standards and regulations in place to ensure patients receive care consistent with evidence-based medicine. These protections are sufficient to ensure patients enter into medical procedures or begin new medications with their eyes open to potential side effects and impacts.

II. Executive Orders Targeting Transgender Individuals and Their Medical Care

101. In the first days of his administration, President Trump issued two Executive Orders aimed at limiting recognition of the existence of transgender individuals by the federal government and restricting their care. While this lawsuit specifically challenges Section 8 of the Denial of Care Executive Order, as well as final agency actions that flow from that section, both

Executive Orders demonstrate the administration's hostility to transgender individuals more broadly.

102. On January 20, 2025, President Trump issued Executive Order No. 14,168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 20, 2025) (the "Gender Identity Order," attached hereto as Exhibit B). The Gender Identity Order declares that it is now "the policy of the United States to recognize two sexes, male and female," and defines "sex" as "an individual's immutable biological classification as either male or female." Decrying what the Administration deems an "ongoing and purposeful attack against the ordinary and longstanding use and understanding of biological and scientific terms," the Gender Identity Order denies the existence of gender identity as distinct from biological sex and seeks to prohibit the use of federal funds to promote what it dubs "gender ideology."

103. Section 3 of the Gender Identity Order specifies actions to be taken by each federal agency to implement the Order. As relevant here:

a. Section 3(b) orders each agency to "enforce laws governing sex-based rights, protections, opportunities, and accommodations to protect men and women as biologically distinct sexes."

b. Section 3(e) of the Gender Identity Order states: "Agencies shall remove all statements, policies, regulations, forms, communications, or other internal and external messages that promote or otherwise inculcate gender ideology, and shall cease issuing such statements, policies, regulations, forms, communications or other messages. Agency forms that require an individual's sex shall list male or female, and shall not request gender identity. Agencies shall

take all necessary steps, as permitted by law, to end the Federal funding of gender ideology."

c. Section 3(g) states: "Federal funds shall not be used to promote gender ideology. Each agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology."

104. On January 28, 2025, President Trump issued Executive Order No. 14,187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8,771 (Jan. 28, 2025) (the "Denial of Care Order," attached hereto as Exhibit C), which expanded on the Gender Identity Order.

105. Section 1 of the Denial of Care Order asserts, among other things: "Across the country today, medical professionals are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions. This dangerous trend will be a stain on our Nation's history, and it must end . . . Accordingly, it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called 'transition' of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures." 90 Fed. Reg. 8771 (Feb. 3, 2025).

106. Section 2 of the Denial of Care Order sets out the following definitions:

a) The term "child" or "children" means "an individual or individuals under 19 years of age";

b) The term "pediatric" means "relating to the medical care of a child"; and

c) The phrase "chemical and surgical mutilation" means "the use of puberty blockers, including GnRH agonists and other interventions, to

> delay the onset or progression of normally timed puberty in an individual who does not identify as his or her sex; the use of sex hormones, such as androgen blockers, estrogen, progesterone, or testosterone, to align an individual's physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex or that attempt to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions."

107. Though the Denial of Care Order purports to protect "children," it defines "child" or "children" as an individual or individuals under 19 years of age"—including individuals who are 18 years old, which is the age of majority in the Plaintiff States.

108. Section 2 of the Denial of Care Order conflates, without evidence, the offensive and inaccurate term "chemical and surgical mutilation" with "gender-affirming care," which is known to comprise a wide range of individualized, patient-specific care, including the use of puberty blockers and sex hormones as well as non-medical interventions.[33]

109. The phrase "chemical and surgical mutilation" is not a medically recognized term, and the American Academy of Pediatrics has issued a statement contesting the claims found in Section 2 of the Denial of Care Order and subsequent administration reports.[34]

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[33] Phie Jacobs, *Researchers slam HHS report on gender-affirming care for youth*, Science (May 2, 225), https://www.science.org/content/article/researchers-slam-hhs-report-gender-affirming-care-youth.

[34] The statement criticized the Administration's interference with the physician-patient relationship, asserting that the "report misrepresents the current medical consensus and fails to reflect the realities of pediatric care" and "prioritizes opinions over dispassionate reviews of evidence." *AAP speaks out against HHS report on gender dysphoria, infringement on physician-patient relationship*, AAP News (May 1, 2025), https://publications.aap.org/aapnews/news/32145/AAP-speaks-out-against-HHS-report-on-gender.

110. Section 8 of the Denial of Care Order, which is titled "Directives to the Department of Justice," states in part: "The Attorney General shall:

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

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

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

111. Both Executive Orders use inaccurate, cruel, demeaning, and inflammatory language designed to deter and interfere with the provision and regulation of medical care. The Denial of Care Order refers to this medically necessary care for transgender adolescents as "chemical and surgical mutilation" and defines 18-year-old adults as "children." 90 Fed. Reg. at 8771. And the Gender Identity Order denies that gender identity exists distinct from biological sex, and thus by implication denies the existence of transgender people.

112. The Executive Orders also promulgate a definition of biological sex that is divorced from biology itself, ignoring the complex interplay of genetics and hormones that sometimes results in variations in primary and secondary sex characteristics. As a result, the Executive Orders deny—with no basis in science or medicine—the very existence and lived experiences of intersex people.

113. Critically, the Denial of Care Order states that it is the policy of the federal government that the provision of medically necessary gender-affirming care to transgender adolescents should be forbidden: Section 1 calls such care "a stain on our Nation's history[that] must end."

III. Agency Actions Directing the Use of Investigations and Enforcement Actions to Advance the Ideological Priorities Identified in the Denial of Care Order and to Restrict the Provision of Medically Necessary Care for Transgender Adolescents

114. The Agency Defendants have now implemented Section 8 of the Denial of Care Order in order to accomplish the President's stated policy that this medically necessary care for transgender adolescents "must end." The DOJ defendants have issued two directives outlining DOJ's interpretation of the legality of this care under several federal statutes. The directives represent the consummation of DOJ's decision-making process and additionally instruct DOJ staff to use investigations and enforcement actions to advance this interpretation of the law and the priorities identified in the Denial of Care Order. DOJ has issued these directives notwithstanding the fact that there is no lawful basis for it to do so. On the contrary, these directives reverse and conflict with the law, as well as years of practice. In other words, DOJ has improperly weaponized its authority by issuing a novel and atextual legal interpretation that has intimidated providers, pressuring them to stop offering lawful, necessary, and often lifesaving medical care to transgender adolescents.

A. The Bondi Directive

115. On April 22, 2025, U.S. Attorney General Bondi issued a "memorandum" titled "Preventing the Mutilation of American Children" ("Bondi Directive," attached hereto as Exhibit D). The Bondi Directive is directed to all U.S. DOJ employees—40 separate component

organizations and more than 115,000 employees.[35] Without citing any legal authority to support its claims, the Bondi Directive describes the provision of this medically necessary care as "fraud" and "exploitation" by the medical community at the expense of the patients receiving care and their families. And it states that the "medical community" can act as a "bulwark" against "[g]ender ideology" in the form of "life-altering chemical and surgical intervention."

116. The Bondi Directive directs the following actions regarding the investigation and prosecution of medical providers who provide medically necessary care for transgender adolescents.

117. First, in a section titled "Enforcement of Laws Outlawing Female Genital Mutilation," the Bondi Directive orders U.S. Attorneys to engage in the criminal prosecution of medically necessary care for transgender minors as purported violations of the laws against female genital mutilation. Specifically, the Bondi Directive "direct[s] all U.S. Attorneys to investigate all suspected cases of [female genital mutilation] FGM—under the banner of so called 'gender-affirming care' or otherwise—and to prosecute all FGM offenses to the fullest extent possible." This directive tracks Section 8(a) of the Denial of Care EO.[36]

118. The FGM statute, which was passed in 1996 and contains not one but two carveouts for medical care provided by a licensed physician, has never been interpreted or enforced to include this care.

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[35] *About DOJ*, U.S. Dept. of Justice, https://www.justice.gov/about#:~:text=the%20taxpayers'%20dollars.-,Organization,50%20countries%20around%20the%20world (last visited July 29, 2025).

[36] *See* 18 U.S.C. § 116. The full statutory definition of FGM is as follows: "any procedure performed for non-medical reasons that involves partial or total removal of, or other injury to, the external female genitalia, and includes— (1) a clitoridectomy or the partial or total removal of the clitoris or the prepuce or clitoral hood; (2) excision or the partial or total removal (with or without excision of the clitoris) of the labia minora or the labia majora, or both; (3) infibulation or the narrowing of the vaginal opening (with or without excision of the clitoris); or (4) other procedures that are harmful to the external female genitalia, including pricking, incising, scraping, or cauterizing the genital area." *Id.*

119. Second, the Bondi Directive directs the civil investigation of the manufacturing and distribution of pharmaceuticals supporting medical care for transgender adolescents. It states that U.S. DOJ "will investigate and hold accountable medical providers and pharmaceutical companies that mislead the public about the long-term side effects of chemical and surgical mutilation." To that end, the memo "direct[s] the Civil Division's Consumer Protection Branch to undertake appropriate investigations of the Food, Drug, and Cosmetic Act by manufacturers and distributors engaged in misbranding by making false claims about the on- or off-label use of puberty blockers, sex hormones, or any other drug used to facilitate a child's so-called 'gender transition.'" The Bondi Directive further asserts that "[e]ven if otherwise truthful, the promotion of off-label uses of hormones . . . run afoul of the FDA's prohibitions on misbranding and mislabeling." This directive directly tracks Section 8(c) of the Denial of Care EO.

120. The Bondi Directive cites no evidence to suggest that the above-mentioned conduct is actually occurring, i.e., that manufacturers, distributors, or physicians have been making misleading or false claims about hormone replacement therapy or puberty blockers. Indeed, the Bondi Directive appears to order the investigation based purely on the fact that these therapies are critical components of this necessary medical care.

121. Third, the Bondi Directive directs the civil investigation of False Claims Act violations in connection with the provision of medical care for transgender adolescents. The Bondi Directive "direct[s] the Civil Division's Fraud Section to pursue investigations under the False Claims Act of false claims submitted to federal healthcare programs for any non-covered services related to radical gender experimentation." It further states that "[f]alsely billing the

government for the chemical or surgical mutilation of a child is a violation of the False Claims Act and is subject to treble damages and severe penalties."

122. This care has been and is currently covered under Medicare on a patient-by-patient basis, and under Medicaid per each state's regulatory program.[37]

123. In its final paragraph, the Bondi Directive makes clear that its aim is to end the provision of gender-affirming care to transgender adolescents by leveraging these criminal and civil statutes to achieve the Administration's desired policy outcomes, regardless of what the statutes actually say: "Every day, we hear more harrowing stories about children who will suffer for the rest of their lives because of the unconscionable ideology behind 'gender-affirming care.' Under my leadership, the Department of Justice will bring these practices to an end." Said another way, DOJ under Bondi's leadership will bring an end to lifesaving medical treatment for transgender and intersex adolescents.

124. On June 2, 2025, the Federal Bureau of Investigation ("FBI"), the principal law enforcement arm of DOJ, published a tweet on X stating: "Help the FBI protect children. As the Attorney General has made clear, we will protect our children and hold accountable those who mutilate them under the guise of gender-affirming care. Report tips of any hospitals, clinics, or practitioners performing these surgical procedures on children."[38] The tweet links to an FBI tip line that requests information "to report federal crimes."[39]

[37] *Gender Dysphoria and Gender Reassignment Surgery*, CAG-00446N (CMS Aug. 30, 2016), https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282; *Medicaid Coverage of Transgender-Related Healthcare*, MAP, https://www.lgbtmap.org/equality-maps/medicaid (last visited July 29, 2025).
[38] @FBI, X (June 2, 2025, 1:15PM), https://x.com/FBI/status/1929587710894739567.
[39] *Electronic Tip Form*, FBI, https://tips.fbi.gov/home (last visited July 19, 2025).

B. The Shumate Directive

125. On June 11, 2025, Assistant Attorney General Brett A. Shumate issued a memorandum to all U.S. DOJ civil division employees with the subject "Civil Division Enforcement Priorities" (the "Shumate Directive," attached hereto as Exhibit E).

126. The Shumate Directive describes the policy objectives and directives in the Denial of Care Order, the Gender Identity Order, and the Bondi Directive, and "directs Civil Division attorneys to prioritize investigations and enforcement actions advancing those priorities."

127. Specifically, the Shumate Directive directs the Civil Division to "use all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities" to pursue alleged violations "of the Food, Drug, and Cosmetic Act and other laws by (1) pharmaceutical companies that manufacture drugs used in connection with so-called gender transition; and (2) dealers such as online pharmacies suspected of illegally selling such drugs." The Shumate Directive provides no indication that pharmaceutical companies that manufacture therapies used in this care have committed, or are more likely to commit, violations of the Food, Drug, and Cosmetic Act.

128. The Shumate Directive further directs the Civil Division to "aggressively pursue claims under the False Claims Act against healthcare providers that bill the federal government for impermissible services. This includes, for example, providers that attempt to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes." Again, the Shumate Directive provides no indication that providers of this care are engaged in misbilling and simply requires attorneys to scrutinize such providers "aggressively."

C. Implementation of the DOJ Directives

129. The DOJ directives implement a new interpretation of the law and, in accordance with such, threaten baseless civil and criminal prosecution, as well as onerous investigations and data demands. These actions interfere with state regulation of the provision of medical care and intimidate providers of this important medical care into reducing or eliminating medically necessary services. Indeed, the providers are faced with an impossible choice in light of these directives: either (1) continue providing lawful care and risk being subject to (and incurring the time and expense of defending oneself against) baseless investigations and, potentially, prosecution, or (2) cease providing care that is consistent with federal law, protected under state law, and medically appropriate.

130. These efforts to chill the provision of healthcare for adolescents—even in states where such care is legal and protected—show that the Agency Defendants have adopted and are engaged in a systematic effort to leverage the threat of criminal and civil enforcement to eliminate medically necessary care for transgender adolescents in the United States.

131. In developing and implementing these directives, the Agency Defendants have interfered with numerous critical aspects of the provision of this medically necessary healthcare, including (but not limited to) the States' role as the regulators of the practice of medicine within their borders, the benefits that patient-centered care provides to transgender and intersex patients, the consensus among all major American medical organizations in favor of the availability of such care, and the informed consent and decision-making process of patients, their families, and their doctors.

132. On July 9, 2025, following the issuance of the Bondi and Shumate Directives, DOJ issued a press release announcing that it had issued more than twenty subpoenas to doctors

and clinics that provide this care.[40] While the release stated that the subpoenas relate to investigations that "include healthcare fraud, false statements, and more"—paralleling the statutes identified in Section 8(c) of the Denial of Care Order—the release also makes clear that DOJ's intent in issuing the subpoenas is not enforcement of the specific prohibitions of those laws but the chilling of medical care with which the administration disagrees ideologically. In the release, Attorney General Bondi states that "[m]edical professionals and organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice."

133. Neither Attorney General Bondi nor Shumate point to any evidence of specific marketing practices for off-label uses of medication or the use of improper billing codes, as is prohibited by the statutes listed in Section 8(c) of the Denial of Care Order. Rather, these statements make plain that the subpoenas are intended to subject providers to the threat of prosecution solely because they have provided legal and essential medical care to adolescents diagnosed with gender dysphoria.

134. According to the New York Times, the subpoenas demand that providers produce to the federal government a significant amount of private, confidential, and HIPAA-protected patient information. It characterized the subpoenas as "part of a coordinated effort between the Justice Department and the White House to fulfill President Trump's promises to curtail pediatric gender care."[41]

[40] Press Release, U.S. Dep't of Just., Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children (Jul. 9, 2025), https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical.

[41] Azeen Ghorayshi & Glenn Thrush, *Justice Dept. Demands Patient Details From Trans Medicine Providers*, N.Y. Times (Jul. 10, 2025), https://www.nytimes.com/2025/07/10/health/transgender-medicine-minors-trump-subpoena.html.

135. Further, the Federal Trade Commission (FTC) held a workshop on July 9, 2025 "devoted to the question of whether providers of transgender medical treatments were engaging in unfair or deceptive trade practices."[42] At the workshop, one panelist "argued that doctors providing [medical care to transgender adolescents] should be prosecuted to create a chilling effect across the country," suggesting that "'[t]hen these people will be held accountable … and there's a very good chance this will stop even in blue states.'" A fellow panelist presently working at DOJ stated that he was "[w]orking on it."

136. The Consumer Protection Branch of the Civil Division is tasked with working with the FTC to investigate "[u]nscrupulous business practices": "The Branch, working in partnership with the FTC, brings cases against such practices under the FTC Act and regulations promulgated by the FTC."[43] Thus, the FTC's focus on the provision of essential medical care to transgender adolescents as a fraudulent trade practice is closely tied to the aims outlined in the Bondi memo and the directive to investigate such care.

137. In addition to civil subpoenas, upon information and belief, DOJ has initiated criminal investigations of providers of this care as well: On June 24, 2025, Fox News reported that the FBI launched criminal investigations into Boston Children's Hospital, Children's Hospital Colorado, and Children's Hospital Los Angeles pursuant to the FGM criminal statute.[44] Upon information and belief, DOJ has no basis to believe that the targets of these criminal investigations have engaged in any misconduct under the FGM criminal statute. The only basis

[42] *See* Fed. Trade Comm'n, *The Dangers of "Gender-Affirming Care" for Minors* (Jul. 9, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-Transcript.pdf.
[43] *Consumer Protection Branch Practice Areas*, U.S. Dep't of Just., https://www.justice.gov/civil/consumer-protection-branch-practice-areas (last visited Jul. 29, 2025).
[44] Alec Schemmel, *FBI launches probes into 3 children's hospitals for alleged genital mutilation of minors*, Fox News (June 24, 2025), https://www.foxnews.com/politics/fbi-launches-probes-against-3-childrens-hospitals-genital-mutilation-minors.

for the investigation is the agency's adopted belief that the provision of this medically necessary care, which is provided in accordance with the laws of the states where such care takes place, violates that federal statute.

IV. Inapplicability of Statutes Identified by DOJ to Medically Appropriate Healthcare for Transgender Patients

138. The Denial of Care Order, Bondi Directive, and Shumate Directive set forth a legal interpretation that is designed to intimidate providers of gender-affirming care for transgender adolescents by threatening action under the False Claims Act, the Female Genital Mutilation Statute, and the Food, Drug, and Cosmetic Act. However, the provision of medically appropriate care for transgender individuals with gender dysphoria does not—on its own—facially violate any of these federal statutes. Furthermore, this novel legal interpretation departs from longstanding practice.

A. The False Claims Act ("FCA")

139. The FCA was created to prevent fraud on the United States government. The FCA imposes civil liability on any person or entity that submits a false or fraudulent claim for payment to the United States government.[45] A person or entity may be liable under the FCA if that person or entity "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[46]

140. The Bondi Directive directs the Civil Division's Fraud Section to "pursue investigations under the False Claims Act of false claims submitted to federal healthcare programs for any non-covered services related to radical gender experimentation." The Bondi

[45] 31 U.S.C. §§ 3729 - 3733.
[46] *Id.* at § 3729.

Directive also directs investigations into false claims submitted for "the chemical or surgical mutilation of a child."

141. Absent a change in federal law about covered services, accurately billing federal programs for the provision of health care for transgender patients on its own is not a violation of the False Claims Act. In fact, federal programs including Medicare have explicitly allowed for the reimbursement of health care for transgender patients for a wide range of treatments including hormone therapy and surgery.

142. The threat of FCA enforcement against providers who properly bill and code their services speaks to the broader goal of the Defendants to paint all medically necessary healthcare for transgender patients as "fraudulent" in and of itself.[47]

B. The Female Genital Mutilation Act ("FGM Act")

143. The FGM Act was passed in 1996 as part of the United States's commitments to its international partners and the United Nations in their efforts to safeguard the rights of women and girls. It takes a two-pronged approach, codified at 18 U.S.C. § 116 and 22 U.S.C. § 262K-2, imposing criminal penalties and financial consequences for violations of the Act.

144. "FGM," as reflected in its statutory definition, refers to a broad range of cultural practices across many groups that involve inflicting varying degrees of injury to women and girls. These are non-medical procedures performed by individuals with no professional training,

[47] *See* Fed. Trade Comm'n, *The Dangers of "Gender-Affirming Care" for Minors* (Jul. 9, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-Transcript.pdf. During the FTC workshop titled 'The Dangers of "Gender-Affirming Care' for Minors," DOJ Chief of Staff Chad Mizelle said the following: "The DOJ also has numerous civil and criminal tools to root out fraud. We are focusing these tools on everyone who's involved in the multi-billion-dollar industry of harming our kids…We're investigating violations such as healthcare fraud, false statements, all of this which could result in either civil or criminal liability for these clinics. We have also investigations into hospitals and other providers related to fraudulent billing, false claims under Medicaid fraud and the False Claims Act. We're going after false and deceptive claims by non-profits and medical associations that have provided false, deceptive or scientifically dubious assertions about transition related medical interventions, allegedly is cover for the clinics and the hospitals to be able to do what they're doing." *Id.* at 49.

and often performed without access to medical equipment, sterile environments, or medications to prevent infections. As a result, individuals subjected to these practices can endure lifelong or even fatal complications. The FGM Act is not designed to criminalize the provision of medically necessary care to transgender individuals. Nor did Congress understand the law to criminalize such care at the time of its adoption, and it has never been so interpreted in the 30 years it has been in force. Indeed, in those 30 years, DOJ has pursued only two criminal prosecutions under the Act. The Act has primarily had implications in asylum and immigration law.[48]

145. The FGM Statute defines FGM as follows: any procedure performed upon a person under 18 for non-medical reasons that involves partial or total removal of, or other injury to, the external female genitalia, and includes— (1) a clitoridectomy or the partial or total removal of the clitoris or the prepuce or clitoral hood; (2) excision or the partial or total removal (with or without excision of the clitoris) of the labia minora or the labia majora, or both; (3) infibulation or the narrowing of the vaginal opening (with or without excision of the clitoris); or (4) other procedures that are harmful to the external female genitalia, including pricking, incising, scraping, or cauterizing the genital area.[49]

146. The FGM statute also provides that "[a] surgical operation is not a violation of this section if the operation is— (1) necessary to the health of the person on whom it is performed, and is performed by a person licensed in the place of its performance as a medical practitioner; or (2) performed on a person in labor or who has just given birth and is performed for medical purposes connected with that labor or birth by a person licensed in the place it is

[48] *See generally* Michelle A. McKinley, *Cultural Culprits*, 24 Berkeley J. Gender L. & Just. 91 (2009); Erika Sussman, *Contending with Culture: An Analysis of the Female Genital Mutilation Act of 1996*, 31 Cornell Int'l L.J. 193 (1998).
[49] *See* 18 U.S.C. § 116.

performed as a medical practitioner, midwife, or person in training to become such a practitioner or midwife."[50]

147. The provision of medically necessary healthcare for transgender patients does not—and cannot—fit into the definition of FGM for a variety of reasons. First and foremost, by its nature, the care has been determined by providers and patients to be "necessary to the health of the person on whom it is performed," excluding it from the statutory definition. Indeed, the federal government has consistently reimbursed healthcare provided to transgender patients under 18 as medically necessary. Second, as described herein, performing gender-affirming surgeries of any kind on patients under 18 is exceedingly rare, and performing surgeries that would impact external genitalia are even more rare. Third, the provision of hormones or puberty blockers are given orally, through an injection, or through an implant in a patient's limbs; there is no surgical change to the genitals as a result. Thus, it is incredibly unlikely that any provider in the Plaintiff States has engaged in any conduct that conceivably could be captured by the FGM statute.

C. The Food, Drug, and Cosmetic Act ("FDCA")

148. The FDCA creates protections against deficits in the safety and efficacy of food, drugs, devices, and cosmetics in the United States. The primary purpose of the FDCA is to prevent adulterated or misbranded food, drugs, devices, or cosmetics from entering the market and to provide remedies for harm caused if they do.

149. The Bondi Directive states that "[e]ven if otherwise truthful, the promotion of off-label uses of hormones . . . run afoul of the FDA's prohibitions on misbranding and mislabeling."

[50] *Id.*

150. However, the FDCA does not prohibit off-label prescribing by a provider, and, according to the FDA, "healthcare providers generally may prescribe [a] drug for an unapproved use when they judge that it is medically appropriate for their patient."[51] This is because a medication that is prescribed "off label" has already gone through rigorous regulatory review such that it is considered safe for delivery in humans. Indeed, the prescription of medications for off-label use is quite common,[52] especially in pediatric medicine. Depending on the medication, anywhere from 20% to 100% of pediatric prescriptions may be written for "off-label" uses.[53]

151. The FDCA also does not prohibit physicians from prescribing or providing certain treatments. Rather, it primarily aims to prevent manufacturers from promoting medications or medical devices in ways that may be harmful to consumers.

V. Other Agencies' Support for DOJ Directives and the Denial of Care Order

152. That DOJ's directives represent the consummation of its decision-making process and the adoption of a new legal interpretation is only underscored by the fact that other agencies are following these directives and, in certain instances, coordinating with DOJ to implement them.

153. By way of example, on July 2, 2025, the Department of Health and Human Services (HHS) announced a new working group in partnership with DOJ to "make referrals to DOJ of potential violations of the FCA that reflect Working Group priorities." The

[51] *Understanding Unapproved Use of Approved Drugs "Off Label,"* FDA, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (last visited Jul. 28, 2025).
[52] Carolyn M. Clancy, *Off-Label Drugs: What You Need to Know*, AHRQ Archive (Apr. 21, 2009), https://archive.ahrq.gov/news/columns/navigating-the-health-care-system/042109.html.
[53] H. Christine Allen et al., *Off-Label Medication use in Children, More Common than We Think: A Systematic Review of the Literature*, 111 J. Okla. State. Med. Ass'n 776 (Oct. 2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6677268/.

announcement specifically cites the Shumate Directive as identifying "priority FCA matters" to be addressed by the working group.

154. Even before the announcement of the working group, HHS and its subsidiary agencies took a range of actions to collect information and data to be used to support potential action by DOJ to intimidate providers into ceasing the provision of this medical care to adolescents.

155. First, on February 19, 2025, HHS issued guidance for federal agencies "implementing Executive Order 14168," notably "expanding on the sex-based definitions set forth in the Executive Order." In furtherance of the Section Five mandate within the Denial of Care Order to "take all appropriate actions to end" this healthcare, the HHS guidance states that there are "only two sexes, female and male" and that sex is "determined genetically at conception (fertilization)." The guidance issued definitions for a number of terms. On a website promoting this guidance, HHS noted that it is "promot[ing] policies to end the chemical and surgical mutilation of children."[54]

156. On May 1, HHS published a 409-page, unattributed report titled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices" (the "HHS Report"). The report questions the methodologies used by studies that support the efficacy and safety of certain treatments for gender dysphoria including puberty blockers and surgery.[55] The HHS Report recommends further research into psychotherapy as a treatment option. However, it also asserts that "[t]his document is not intended to serve as a clinical practice guideline and does not aim to

[54] *Protecting Women and Children*, Off. on Women's Health, https://womenshealth.gov/protecting-women-and-children (last visited Jul. 29, 2025).
[55] *See* U.S. Dep't of Health & Hum. Servs., Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices (May 1, 2025), https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf.

issue treatment recommendations."[56] The HHS Report has been criticized by the majority of mainstream medical organizations, including the American Psychological Association, which criticized the lack of attributed authorship and weak methodology, as well as the American Academy of Pediatrics, which stated that the report "misrepresents the current medical consensus and fails to reflect the realities of pediatric care."[57]

157. On May 28, 2025, HHS published a letter on X (formerly Twitter) from HHS Secretary Robert F. Kennedy, Jr. addressed to "Health Care Providers, Health Care Risk Managers, and State Medical Boards."[58] The letter advises those entities "to read with care" the HHS Report and—contrary to the assessment of the mainstream medical community—claimed that the report was a "methodologically rigorous assessment of evidence" concerning the provision of this medical care and "employs the tools of evidence-based medicine."

158. The HHS letter further told providers of this care for adolescents that "HHS expects you promptly to make the necessary updates to your treatment protocols and training for care for children and adolescents with gender dysphoria to protect them from these harmful interventions."[59] The letter also notes that HHS published guidance "to protect whistleblowers who make reports concerning these harmful interventions for minors, including for fraud, waste, and abuse in HHS-funded programs, and created a portal to receive complaints at www.hhs.gov/protect-kids."

159. On the same day, the Centers for Medicare and Medicaid Services (CMS), a subsidiary agency of HHS, published a letter from Administrator Dr. Mehmet Oz that it sent to

[56] *Id*. at 261.
[57] News Release, Susan J. Kressly, Am. Acad. of Pediatrics President, AAP Statement on HHS Report Treatment for Pediatric Gender Dysphoria (May 1, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-hhs-report-treatment-for-pediatric-gender-dysphoria/.
[58] *See* @HHSGov, X (May 28, 2025, 2:17PM), https://x.com/HHSGov/status/1927791449476567043.
[59] *Id*.

hospitals across the country, including in the Plaintiff States.[60] Titled "Urgent Review of Quality Standards and Gender Transition Procedures," the CMS letter states that "the United States government has serious concerns with medical interventions for gender dysphoria in children."[61] After describing puberty blockers, hormone therapy, and surgeries as the medical interventions in question, the letter states that "CMS believes that these interventions were initiated with an underdeveloped body of evidence, lack reliable evidence of benefits to minors, and are now known to carry serious risks of long-term and irreparable harm."

160. The CMS letter further requested that—within 30 days—hospitals provide CMS with information on: (1) "*The adequacy of informed consent protocols for children* with gender dysphoria, including how children are deemed capable of making these potentially life-changing decisions and when parental consent is required; (2) *Changes to clinical practice guidelines and protocols* that your institution plans to enact in light of the [May 1 HHS Report] and corresponding guidance released by the Department; and (3) *Any adverse events* related to these procedures, particularly children who later look to de-transition" (emphasis original).[62]

161. The CMS letter further requested (within 30 days) that the hospitals "provide complete financial data for all pediatric sex modifications performed at your institution and paid, in whole or in part, by the federal government." The requested financial data includes: (1) all billing codes used for "pediatric sex trait modifications"; (2) facility and provider-level revenue (or utilization data) generated directly or indirectly from these procedures (from 2020 to the present); (3) facility and provider-level operating and profit margins for each procedure type (both for the institutions themselves and for directly or indirectly owned and/or affiliated

[60] *See* Letter from Dr. Mehmet Oz, Administrator, Ctrs. for Medicare & Medicaid Servs. (May 28, 2025), https://www.cms.gov/files/document/hospital-oversight-letter-generic.pdf.
[61] *Id*.
[62] *Id*.

providers); and (4) projected revenue forecasts for these service lines.[63] The letter also provides a "non-exhaustive list of potentially relevant diagnosis and procedure codes" as a reference point. That list includes 134 distinct diagnosis and procedure codes.[64] The letter cited no authority for its sweeping financial data production demands.

162. Coupled with the threat of criminal and civil investigations hanging over providers, these requests for information and instructions to conform longstanding protocols and standards of care with the HHS Report are not benign. Rather, they are additional evidence of the increasing pressure and outsized scrutiny transgender patients and medical professionals have suffered since January 20, 2025.

VI. The Impact of the Denial of Care Order, the DOJ Directives, and The Actions Implementing Them

163. The Denial of Care Order, the DOJ directives, and DOJ's actions to implement them are having the desired effect. These actions are causing chaos, confusion, and fear among medical care providers and stoking anxiety and dread among transgender and intersex adolescents and their families, guardians, and caregivers. These actions have been decried by the mainstream medical community, including the American Academy of Pediatrics, which has lamented the insertion of politics into the examination room, interfering with the provider-patient relationship:

> We reiterate that all patients must have access to evidence-based, comprehensive medical care, and that physicians must be able to practice medicine that is informed by their education, training, and experience without threat of criminalization. Politics should not get in the way of evidence-based care and a strong patient-physician relationship.[65]

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[63] *Id.*
[64] *Id.*
[65] News Release, Am. Acad. of Pediatrics, Leading Physician Groups Oppose Infringements on Medical Care, Patient-Physician Relationship (May 1, 2025), https://www.aap.org/en/news-room/news-releases/aap/2025/leading-physician-groups-oppose-infringements-on-medical-care-patient-physician-relationship/?_gl=1*11vciwm*_ga*NDY0Njc3ODI3LjE3NTM2NDI2Nzg.*_ga_FD9D3XZVQQ*czE3NTM2NDI2NzgkbzEkZzAkdDE3NTM2NDI2NzgkajYwJGwwJGgw.

164. In the immediate aftermath of the Denial of Care Order, some Plaintiff States' Attorneys General responded to the overwhelming demand for guidance and clarity by issuing public guidance relating to health care providers' obligations to provide care consistent with state laws, and reminding providers of the limited legal authority of an executive order.[66] State health agencies also issued statements reminding both public and private providers that the Denial of Care EO did not require them to stop treatments and reminding them of their ethical and legal obligations to ensure continuity of care.[67]

165. Unfortunately, other entities were actively promoting the opposite message. Other states' Attorneys General issued a not-so-subtle threat that "[h]ospitals and institutions that continue to mutilate children place themselves at significant legal risk and face substantial financial exposure."[68] The White House celebrated the panicked initial reaction by providers and organizations to cancel appointments, boasting that this was the Denial of Care Order's "intended effect."[69]

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[66] *See, e.g.*, Letter from Letitia James, Attorney General of New York, on New York State Law Obligations after Executive Order 14187 (Feb. 3, 2025), https://ag.ny.gov/sites/default/files/letters/ag-james-to-hc-providers-re-tro-letter-2025.pdf; Press Release, Rob Bonta, Attorney General of California, Cal. Dep't of Justice, Attorney General Rob Bonta Reminds Hospitals and Clinics of Anti-Discrimination Laws Amid Executive Order on Gender Affirming Care (Feb. 5, 2025), https://oag.ca.gov/news/press-releases/attorney-general-bonta-reminds-hospitals-and-clinics-anti-discrimination-laws; Press Release, Andrea Joy Campbell, Attorney General of Massachusetts, AG Campbell Leads 14 AGs In Issuing Statement On Protecting Access To Gender-Affirming Care (Feb. 5, 2025), https://www.mass.gov/news/ag-campbell-leads-14-ags-in-issuing-statement-on-protecting-access-to-gender-affirming-care#:~:text=Health%20care%20decisions%20should%20be,living%20as%20their%20authentic%20selves.

[67] Letter from Mark Hennessey, Director, N.Y. Dep't of Health, on Continuity of Care (Feb. 18, 2025), https://health.ny.gov/professionals/hospital_administrator/letters/2025/docs/dal_25-02.pdf.

[68] Letter from John Miyares, Attorney General of Virginia, to University of Virginia and Virginia Commonwealth University (Jan. 30, 2025) https://ewscripps.brightspotcdn.com/6e/61/442bb4c04f47afe33ef1470856fc/file-3674.pdf ("Any state institution that continues to chemically and surgically mutilate children risks violating [the Actions'] and being terminated from participation in the Medicare and Medicaid programs . . . The chemical and surgical mutilation of children must stop immediately.").

[69] News Release, The White House, President Trump is Delivering on His Commitment to Protect our Kids (Feb. 3, 2025), https://www.whitehouse.gov/articles/2025/02/president-trump-is-delivering-on-his-commitment-to-protect-our-kids/; *see also* News Release, The White House, President Trump is Protecting America's Children (Mar. 4, 2025), https://www.whitehouse.gov/articles/2025/03/president-trump-is-protecting-americas-children/.

166. Under the cumulative weight of these targeted actions against medical care providers—which baselessly threaten civil and criminal prosecution and demand burdensome production of financial and patient data—some providers are scaling back or halting this care altogether. Not only have these federal actions harmed transgender and intersex individuals suffering from gender dysphoria, as well as their families and caregivers, but the actions are harming Plaintiff States as well. The Denial of Care Order, the DOJ directives, and the actions implementing them are impairing Plaintiff States' authority to regulate the practice of medicine in their states and their authority to protect and enhance the health and well-being of their residents.

167. The Administration has boasted that this intended result—vital healthcare being shut off—is coming to fruition because of its actions, explaining that "Hospitals and hospital systems across the country have halted so-called 'gender-affirming care' for minors following President Trump's executive order 'protecting children from chemical and surgical mutilation.'"[70]

A. Impact on Providers and Recipients of Healthcare for Transgender Adolescents

168. The Denial of Care Order, the DOJ directives and the agency actions implementing them seek to completely eliminate access to this medically necessary care for anyone under the age of 19. And they are succeeding.

169. As a result of the Agency Defendants' concerted efforts at intimidation, several providers of this care in the Plaintiff States have already scaled back the services they offer to transgender adolescent patients or have shut down their gender care clinics entirely in an attempt

[70] News Release, The White House, President Trump Marks Six Months in Office with Historic Successes (Jul. 20, 2025), https://www.whitehouse.gov/articles/2025/07/president-trump-marks-six-months-in-office-with-historic-successes/.

to avoid groundless civil or criminal investigations or actions. This reduction in services has caused significant harm to transgender adolescents in the Plaintiff States, depriving them of essential care at a critical time in their development.

170. In California, Children's Hospital Los Angeles (CHLA) is the largest provider of this care for adolescents. CHLA's Center for Transyouth Health and Development (CTYHD) was one of the country's oldest and largest providers of this care for adolescents and young adults, having provided "high-quality, evidence-based, medically essential care" for transgender adolescents for more than 30 years.[71] CTYHD was among the few facilities in the country providing puberty blockers, hormone replacement therapy, and surgical procedures for transgender adolescents on public insurance.[72]

171. On June 12, 2025, CHLA wrote to nearly 3,000 patient families, announcing the complete closure of CTYHD due to "significant operational, legal, and financial risks stemming from the shifting policy landscape at both the state and federal levels."[73] CHLA announced July 22, 2025 as the closure date of CTYHD, "to give patient families adequate time to plan for moving care to providers less impacted by the legal and financial pressures our health system faces."[74]

172. Upon information and belief, and to illustrate the kind of impact these closures can have, remaining providers in the Los Angeles region do not have capacity to quickly absorb thousands of additional patients. It can take an average of at least one month for a patient and

[71] *Children's Hospital Los Angeles*, CHLA, https://www.chla.org/adolescent-and-young-adult-medicine/center-transyouth-health-and-development (last visited Jul. 30, 2025).
[72] Sonja Sharp, *Children's Hospital Los Angeles halts transgender care under pressure from Trump*, Los Angeles Times (June 12, 2025), https://www.latimes.com/california/story/2025-06-12/childrens-hospital-of-los-angeles-transgender-care#:~:text=The%20hospital's%20Transyouth%20center%20is,the%20state%20Department%20of%20Justice.
[73] Julie Sharp, *Children's Hospital Los Angeles to close trans youth center*, CBS News (June 13, 2025), https://www.cbsnews.com/losangeles/news/childrens-hospital-los-angeles-close-trans-youth-center/.
[74] *Id.*

their family to identify a new provider and obtain insurance approval to establish care with the new provider. Additionally, patients that transition to new providers often must spend months on wait lists prior to having their first appointment with the new provider. As one parent of two longtime patients of CTYHD shared, the consequences of CTYHD's closure will be "life and death" for some of the transgender individuals who will no longer have access to care.[75]

173. In Chicago, Illinois, one provider has stopped providing this care—specifically, puberty blockers and hormone replacement therapy—for new patients under 18.[76] Another Chicago hospital explained that, "in response to continued federal actions, it will discontinue all gender-affirming pediatric care effective immediately."[77]

174. In Connecticut, the two primary providers of care for transgender adolescents have elected to stop providing medical care—including puberty blockers and hormone replacement therapy—to patients under 19.[78] Both hospitals highlighted federal pressures, with one noting the "federal executive orders and administrative actions relating to gender-affirming care for patients under age 19." The winding down of these programs may leave hundreds of young people without access to lifesaving care.

175. As of July 8, 2025, Nemours Children's Hospital in Delaware is no longer offering gender-affirming care beyond behavioral health services for new patients. A

[75] Nico Lang, *Children's Hospital LA shuts down trans youth clinic, leaving families scrambling*, Los Angeles Public Press (June 13, 2025), https://lapublicpress.org/2025/06/chla-shuts-down-trans-youth-clinic/.
[76] Mack Liederman, *Rush Medical Center Rolls Back Gender-Affirming Care For Minors*, Block Club Chicago (Jul. 15, 2025), https://blockclubchicago.org/2025/07/15/rush-medical-center-rolls-back-gender-affirming-care-for-minors-as-pressure-from-trump-mounts/.
[77] *Trans CARE (Clinic for Affirmation and Reproductive Equity): Important Update to Gender-Affirming Pediatric Care Services*, UChicago Med., https://www.uchicagomedicine.org/conditions-services/transgender-care-services/trans-care (last updated Jul. 18, 2025).
[78] Kaitlin McCallum, *Yale follows Connecticut Children's in gutting pediatric gender care*, Hartford Courant (Jul. 24, 2025), https://www.courant.com/2025/07/24/yale-follows-connecticut-childrens-in-gutting-pediatric-gender-care/.

spokesperson for the hospital stated, "This change reflects evolving communications and actions from federal agencies directed at healthcare providers related to gender-affirming care."[79]

176. In a press release titled "President Trump Promised to End Child Sexual Mutilation — and He Delivered," *see* Exhibit A, the White House published a list of providers who have been forced to change their practices as a result of the onslaught of pressure from the Defendants, including:

a. **Phoenix Children's Hospital**: Within days of the issuance of the Denial of Care Order, Phoenix Children's Hospital "indefinitely paused" the provision of hormone therapy to adolescents in its gender clinic "to ensure . . . full compliance with the recent executive order." Other Arizona clinics followed suit.[80] Though some clinics in Arizona resumed hormone therapy after enforcement of the Denial of Care Order was enjoined, Phoenix Children's Hospital has not.[81]

b. **Stanford Medicine**: Effective June 2, 2025, in order to "protect providers and patients," and "[a]fter careful review of the latest actions and directives from the federal government and following consultations with clinical leadership, including our multidisciplinary LGBTQ+ program and its providers, Stanford Medicine paused providing gender-related surgical procedures as part of [its] comprehensive range of medical services for LGBTQ+ patients under the age of 19."[82]

c. **Denver Health**: Immediately following the issuance of the Denial of Care Order, Denver Health in Colorado indefinitely suspended gender-affirming surgeries for minors, citing the "criminal and financial consequences for those that do not comply" with the Order.[83]

d. **University of Colorado Health**: On February 2, 2025, UCHealth announced that in order to comply with the Denial of Care Order, it updated its policy only

[79] Aubrey Whelan, *Nemours Children's Hospital cuts back on gender-affirming care for new patients*, The Philadelphia Inquirer (Jul. 8, 2025), https://archive.ph/c6YyL.
[80] Stephanie Innes, *Phoenix medical providers halt some gender-affirming care for teens because of Trump order*, AZ Central (Feb. 13, 2025), https://www.azcentral.com/story/news/politics/arizona/2025/02/13/trump-executive-order-halts-gender-affirming-care-for-arizona-kids/78418545007/.
[81] Stephanie Innes, *Phoenix clinic to resume gender-affirming care for children paused by Trump order*, AZ Central (Feb. 15, 2025), https://www.azcentral.com/story/news/local/arizona-health/2025/02/15/az-clinic-to-resume-gender-affirming-care-transgender-people-under-19/78625587007/.
[82] Clara Harter, *Stanford Medicine ends surgeries for transgender minors amid pressure from Trump administration*, Los Angeles Times (June 25, 2025), https://archive.ph/GY2fX.
[83] Sydney Isenberg, *Denver Health suspends gender-affirming surgeries for people under 19 following Trump executive order*, Denver7 (Jan. 30, 2025), https://www.denver7.com/news/pride/denver-health-suspends-gender-affirming-surgeries-for-minors-following-trump-executive-order.

allowing for gender-affirming surgeries "for appropriate patients who are 18 or older" to only allow such services for patients 19 or older. It also suspended the provision of "the specific medical therapies outlined in the executive order" to patients under 19.[84]

e. **University of Chicago Medicine**: A week after DOJ issued a press release announcing that it had issued over 20 subpoenas to providers, UChicago made the "difficult decision" to suspend gender-affirming surgeries for patients under 19.[85]

f. **Rush Medical Center**: On July 16, 2025, Rush University Medical Center in Chicago announced that it had paused the provision of hormone therapy to patients under 18, but remained committed to advocating for the LGBTQ+ community in these "unprecedented times." Rush stated that it is "doing what it can under mounting pressure from the federal government."[86]

g. **New York City, Mount Sinai**: Within days of the issuance of the Denial of Care Order, Mount Sinai and other New York hospitals reportedly cancelled scheduled surgical procedures for patients under 19 and informed parents that they would not provide hormone therapy treatments to new patients under 19.[87]

h. **New York-Presbyterian:** In early February, New York Presbyterian hospital removed references to the provision gender-affirming care to adolescents from its website, stating that it was "working to comply with applicable state and federal laws."[88]

i. **Pennsylvania**: In April 2025, shortly after the release of the Bondi Directive, three major Pennsylvania hospital systems, Penn State Health, the University of Pittsburgh Medical Center, and the University of Pennsylvania Health System, all announced they would no longer provide gender-affirming surgeries to

[84] *Statement form UCHealth on GAC, 2-5-2025*, U. Colo. Anschutz Med. Campus (Feb. 5, 2025), https://www.cuanschutz.edu/federaltransition/updates/statement-from-uchealth-on-gac---2-5-2025#:~:text=UCHealth%20respects%20the%20important%2C%20private,as%20they%20navigate%20these%20changes.. Children's Hospital of Colorado also suspended the provision of puberty blockers and hormone therapy to patients under 19, citing the Denial of Care Order. *Id.* CHCO never provided gender affirming surgical services to patients under 19. *Children's Hospital Colorado (CHOCO) Federal Transition Update, 2-5-25*, U. Colo. Anschutz Med. Campus (Feb. 5, 2025), https://www.cuanschutz.edu/federaltransition/updates/chco-federal-transition-update---2-5-25.

[85] Violet Miller, *UChicago discontinues gender-affirming care for minors*, Chicago Sun-Times (Jul. 18, 2025), https://chicago.suntimes.com/health/2025/07/18/uchicago-discontinues-gender-affirming-care-for-minors.

[86] Mary Norkol, *Rush Medical Center halts gender-affirming care for new patients under 18*, Chicago Sun-Times (Jul. 16, 2025), https://chicago.suntimes.com/lgbtq/2025/07/16/rush-medical-center-rolls-back-gender-affirming-care-for-minors.

[87] Emily Witt, *Where Do Trans Kids Go from Here?*, New Yorker (Feb. 19, 2025), https://www.newyorker.com/news/the-lede/where-do-trans-kids-go-from-here.

[88] Kelsey Butler & Laura Nahmias, *NYC Hospitals Halt Some Gender Affirming Care After Trump Order*, Bloomberg (Feb. 5, 2025), https://www.yahoo.com/news/nyc-hospitals-halt-gender-affirming-222456366.html.

patients under 19. Penn State Health and UPMC also suspended the provision of hormone therapy to patients under 19.

j. **The Hospital of Richmond at VCU Health**: Immediately following the issuance of the Denial of Care Order, the Hospital of Richmond paused the provision of gender-affirming care to patients under 19. It resumed that care in February 2025 but does not offer it to new patients.

k. **Children's Hospital of The King's Daughters**: Upon the advice of the Attorney General of Virginia, CHKD suspended the use of hormone therapy and puberty blockers in order to treat gender dysphoria in patients under 19.[89]

l. **Seattle Children's Hospital**: Immediately following the issuance of the Denial of Care Order, Seattle Children's suspended the provision of gender-affirming surgical services to patients under 19. Though the hospital briefly resumed surgical services, news outlets report that surgeries are again on hold.[90]

m. **Children's National Hospital**: Citing "increasing legal and regulatory risks," on July 21, 2025, Children's National Hospital in Washington, D.C. announced that it will "discontinu[e] the prescription of gender-affirming medications," effective August 25, 2025.[91]

n. **Kaiser Permanente**: On July 23, 2025, California healthcare giant Kaiser Permanente announced that it would pause all gender-affirming surgeries for patients under 19, effective August 29, 2025.[92]

177. Nowhere in the post from the White House is there an acknowledgement of the thousands of patients and families who will be impacted by these closures and terminations of care.

B. Impact on Plaintiff States

178. Defendants' efforts to stop the provision of gender-affirming care to adolescents through the intimidation of care providers undeniably causes harm to providers, patients, and their families—but it inflicts manifold injuries on the Plaintiff States as well.

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[89] *CHKD suspends hormone therapy, puberty blockers for gender-affirming care following Trump exec. order*, WTKR (Feb. 3, 2025), https://www.wtkr.com/news/health/chkd-suspends-hormone-therapy-puberty-blockers-for-gender-affirming-care.
[90] Id.
[91] *Gender Development Program*, Children's Nat'l, https://www.childrensnational.org/get-care/departments/gender-development-program (last visited Jul. 30, 2025).
[92] Leif Le Mahieu, *Health Care Provider Puts Stop To Trans Surgeries On Kids*, Daily Wire (Jul. 23, 2025), https://www.dailywire.com/news/health-care-puts-stop-to-trans-surgeries-on-kids.

1. Injury to States as Payors and Providers of Healthcare

179. Apart from the injury to their sovereign interests, discussed below, some Plaintiff States are injured directly as providers of healthcare. Just as the Bondi and Shumate Directives and their follow-on actions threaten to interfere with private healthcare providers' provision of care, so too do they interfere in those Plaintiff States where state-run or state-affiliated entities provide medically necessary care to transgender adolescents and thus are potential targets of the threatened federal enforcement. This interference ranges from possible significant financial penalties to criminal prosecution of state employees, and it also promises to drain significant state resources in responding to or accommodating these threats.

180. The injuries to States as providers and payors of healthcare go beyond direct responses to Defendants' unlawful actions. The inability to access this care for transgender adolescents has been linked to significant mental and physical health impacts. Transgender adolescents who are denied this care are likely to require additional, more costly physical and mental healthcare, now and down the road.[93]

181. As noted above, the lack of access to this care can increase rates of depression and anxiety among transgender adolescents. Treatment for depression and anxiety can be costly and would result in Plaintiff States expending additional funds to care for these residents, including through providing additional mental health counseling, crisis services, and hospital admissions, when the treatment that could potentially alleviate the source of such depression and anxiety remains unavailable.

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[93] Landon D. Hughes et al., *"These Laws Will Be Devastating": Provider Perspectives on Legislation Banning Gender-Affirming Care for Transgender Adolescents*, 69 J. Adolescent Health 976 (2021) ("[P]roviders described how denial of evidence-based, gender-affirming care for [transgender and gender-diverse youth] will necessitate more serious and costly interventions including avoidable surgeries later in life"); *Outlawing Trans Youth: State Legislatures and the Battle over Gender-Affirming Healthcare for Minors,* 134 Harv. L. Rev. 2163 (2021) (explaining how puberty blockers and hormone replacement therapies allow transgender adolescents to avoid intense psychological distresses, including anxiety, depression, and suicidal behavior).

182. Further, the lack of access to this medical care, particularly treatments like puberty-delaying medications, can force transgender individuals to complete endogenous puberty, which causes their bodies to undergo physical changes that they may seek to reverse later in life. Puberty-delaying medications also have the potential to improve mental well-being, ease depression and anxiety, and improve social interactions with others.

183. The more costly procedures and treatments for the consequences of being denied this medical care will be borne by the States, which are providers of State Medicaid plans and which have enacted protections to ensure such healthcare is covered by state-offered health insurance.

184. In addition, if Defendants succeed in intimidating providers of this medical care to adolescents into closing their doors, many Plaintiff States could be unable to satisfy their own legal obligations to provide minors in their custody with the medical care they need.

2. Injury to States' Sovereign Interests

185. The Constitution vests the States with traditional police powers, which include the ability to regulate the medical profession, license medical professionals, and the authority to make policy judgments regarding the health, wellbeing, dignity, and autonomy of their residents and people within their borders.

186. The Tenth Amendment reserves for the states all rights and powers "not delegated to the United States" federal government.[94] Commonly referred to as "traditional state police powers," the rights and powers of the states include the exercise of control over the "health, safety, and welfare of state citizens."[95]

[94] U.S. CONST. amend. X.
[95] U.S. CONST. amend. X; Slaughterhouse Cases, 83 U.S. 36, 62 (1873) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons…within the State").

187. Such powers reserved to the States include the authority to regulate the practice of medicine, which dates back to at least 1889. Courts have upheld a broad set of "state medical practice laws against constitutional challenges, making clear that states are generally authorized to legislate in the medical practice area."[96] Such powers also include the States' authority to make policy judgments regarding the health and wellbeing of their residents.

188. Defendants' efforts to chill this medically necessary care out of existence functionally supersedes the Plaintiff States' authority to regulate the practice of medicine and their considered judgment that access to this medical care for adolescents should be protected.

189. For example, the Denial of Care Order explicitly calls this care for adolescents "a stain on our Nation's history [that] must end."

190. DOJ's actions, similar and pursuant to the Denial of Care Order, also reflect an unconstitutional attempt to infringe on the States' power to regulate medicine. To illustrate, Attorney General Bondi justified the subpoenas that issued pursuant to the Bondi and Shumate Directives by stating that "[m]edical professionals and organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice," and she promised in the Bondi Directive that her Justice Department would "bring []an end" to this medical care for adolescents. Thus, rather than being animated by particular marketing practices for off-label uses of medication or the use of improper billing codes—the particular misconduct that is prohibited by the statutes listed in Section 8(c) of the Denial of Care Order—the subpoenas are intended to subject providers to the threat of prosecution simply because they have provided a form of medical care that is explicitly provided for and legal under the laws of their respective States.

[96] Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 S.D. L. Rev. 427, 448 (2015).

191. The Denial of Care Order, the DOJ directives, and the agency actions implementing them also injure many Plaintiff States' abilities to give full effect to their own laws protecting residents' health, safety, and rights, harming their sovereign interests and intruding on an area traditionally left to the province of the States.

192. As detailed above, Plaintiff States have enacted numerous laws to protect transgender residents and ensure access to medically necessary healthcare. These enactments reflect the policy judgments by many Plaintiff States that continued access to this care is vital to the health, wellbeing, dignity, and autonomy of their residents and people within their borders.

193. The Denial of Care Order, the DOJ directives, and the agency actions implementing them will make this medical care difficult or impossible to obtain for patients under 19. But many of the States' agencies are obligated under state law to provide medically necessary healthcare to minors in their care or custody. The effects of these federal actions will render many State agencies unable to fulfill their legal duty. Additionally, it will force state agencies to treat transgender adolescents seeking this medically necessary care differently from adolescents seeking other forms of medically necessary healthcare, in violation of state laws and regulations. This frustrates the States' ability to effectuate and enforce their own laws and policies, including in the regulation of medicine, and injures the States' sovereign interests.

194. The collective effect of the Executive Order, the DOJ directives, and their implementation is to pressure providers to cease providing healthcare that they deem medically necessary. This puts providers in the untenable position of risking either substantial financial and legal liability for baseless federal claims or running afoul of many Plaintiff States' anti-discrimination laws if they decline to provide medically necessary care while providing the same treatments to cisgender individuals.

195. Because the Denial of Care Order, DOJ directives, and agency actions implementing them address this medical care provided to individuals aged 19 and under, they also force providers to violate state laws allowing 18-year-olds to make their own medical decisions.

CAUSES OF ACTION

COUNT ONE
(Against the Agency Defendants)
Administrative Procedure Act, 5 U.S.C. § 706(2)(A):
Arbitrary and Capricious Agency Action

196. Plaintiff States repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

197. Defendant DOJ is an agency under the APA, 5 U.S.C. § 551(1), and the DOJ directives are an "agency action" under the APA, *id.* § 551(13).

198. Under the APA, a Court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). "An agency action qualifies as 'arbitrary' or 'capricious' if it is not reasonable and reasonably explained." *Ohio v. EPA*, 603 U.S. 279, 292 (2024) (quotation marks omitted). "In reviewing an agency's action under that standard," courts ask whether the agency "has offered 'a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.'" *Id.* (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Further, "an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider [or] entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n.*, 463 U.S. at 43.

199. The Bondi and Shumate Directives are final agency actions that, both individually and collectively, are arbitrary and capricious.

200. The DOJ directives are arbitrary and capricious because they rely on factors that Congress has not intended the Agency Defendants to consider. These collective actions by the Agency Defendants explicitly threaten civil and criminal prosecution of medical care providers under the FGM statute; the Food, Drug, and Cosmetic Act; and the False Claims Act. But the Agency Defendants have made clear that the actions they are taking under those statutes are not designed to combat the problem Congress enacted those statutes to address or any conduct that the text of the statutes enacted by Congress prohibits; rather, these actions flow directly from President Trump's directive to intimidate and chill providers into ceasing the provision of medical care for adolescents suffering from gender dysphoria.

201. The DOJ directives are arbitrary and capricious because the Agency Defendants have failed to engage in reasoned consideration of their actions, and have failed to offer a reasoned justification for their actions beyond the unsupported assertions and directives in the Denial of Care Order.

202. The DOJ directives are arbitrary and capricious because the Agency Defendants, in adopting and implementing them, have failed to consider several important aspects of the issues before them, including: (1) the longstanding reliance interests in the availability of this medically necessary care, on the part of individuals suffering from gender dysphoria, the healthcare providers treating them, and the Plaintiff States dedicated to the health and well-being of their residents; and (2) the severe economic and health impacts on Plaintiff States and their residents from the use of DOJ enforcement threats to reduce or curtail the provision of this medically necessary care.

203. Accordingly, Plaintiff States are entitled to an order and judgment, and to a permanent injunction, holding unlawful and setting aside the Challenged Directives and enjoining any action taken to enforce or implement the Challenged Directives.

COUNT TWO
(Against the Agency Defendants)
Administrative Procedure Act, 5 U.S.C. § 706(2)(A) & (C)
Contrary to Law and in Excess of Statutory Authority

204. Plaintiff States repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

205. Defendant DOJ is an agency under the APA, 5 U.S.C. § 551(1), and the DOJ directives are an "agency action" under the APA, *id.* § 551(13).

206. Under the APA, an agency action must be set aside if it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C), or is "otherwise not in accordance with law," *id.* § 706(2)(A).

207. The Bondi and Shumate Directives state expressly or imply that the provision of medical care to treat gender dysphoria in adolescents violates the FGM statute, FDCA, or FCA, and is therefore subject to criminal and civil enforcement.

208. These statements are contrary to the clear text, scope and meaning of each of these three statutes. The provision of medically necessary healthcare to treat gender dysphoria in adolescents does not fall within the scope of these statutes. Indeed, no federal law criminalizes such medical care.

209. The FGM statute, 18 U.S.C. § 116, defines "female genital mutilation" as limited to procedures performed for "non-medical reasons." 18 U.S.C. § 116(e). Surgical operations do not violate the statute when, inter alia, they are "necessary to the health of the person on whom [they are] performed, and [are] performed by a person licensed in the place of . . .performance as

a medical practitioner." 18 U.S.C. § 116(b)(1). The provision of medically necessary healthcare to treat gender dysphoria in adolescents, provided by licensed healthcare providers, does not violate the FGM statute.

210. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. ch. 9, governs, among other things the manufacturing, distribution, and sale of drugs and medical devices. The FDCA sets forth the process by which drugs are approved by the federal government for distribution, and requires drug manufacturers to submit evidence of drug safety and effectiveness. The FDCA does not make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender dysphoria in adolescents.

211. The federal False Claims Act, 31 U.S.C. §§ 3729-3733, governs liability for submitting false claims to the federal government. The FCA provides that any person who knowingly submits, or causes to submit, false claims to the government is liable for three times the government's damages plus a penalty linked to inflation. The FCA does not make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender dysphoria in adolescents and to accurately bill for such treatments, nor does it suggest that such care is inherently fraudulent.

212. The Agency Defendants' invocation of these three statutes as legal authority for prosecuting the provision of medical care to treat gender dysphoria in adolescents is therefore contrary to law.

213. The DOJ directives are also contrary to state law, as state law—not the federal FGM, FDCA or FCA statutes—governs the practice of medicine. The Agency Defendants' attempt to invoke these federal statutes as grounds for policing the provision of a category of

medical care is contrary to Plaintiff States' statutes and regulations governing the licensing, regulation, and supervision of medical care in their States.

214. Accordingly, Plaintiff States are entitled to an order and judgment, and to a permanent injunction, holding unlawful and setting aside the DOJ directives and enjoining any action taken to enforce or implement the DOJ directives.

COUNT THREE
(Against the Agency Defendants)
Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
Contrary to Constitutional Right, Power, Privilege or Immunity: Tenth Amendment

215. Plaintiff States repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

216. Defendant DOJ is an agency under the APA, 5 U.S.C. § 551(1), and the DOJ directives are an "agency action" under the APA, *id.* § 551(13).

217. Under the APA, an agency action must be set aside if it is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

218. The Bondi Directive, the Shumate Directive, and the actions that flow from them violate the Tenth Amendment.

219. The Tenth Amendment of the U.S. Constitution reserves to the Plaintiff States the sovereign authority to regulate their internal affairs, to exercise their powers of self-government, and to legislate under their police powers to protect the health and safety of their residents. Accordingly, it has been well-established for over a century that "direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925); *see also Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (holding that the Controlled Substances Act did not intend to "regulate the practice of medicine," which is traditionally a core police power of the states).

220. Though Congress may legislate to regulate interstate activities, which may include the promulgation of criminal and regulatory laws, the Executive may not amend or adopt novel interpretations of statutes in order to disrupt a state's medical regulatory scheme or invent criminal activity. *See Gonzales*, 546 U.S. at 269-70 (holding that Controlled Substances Act did not prohibit Oregon doctors from prescribing medication for the purpose of physician-assisted suicide, where such care had been codified through voter ballot measure).

221. Plaintiff States have the authority and exercise the authority to regulate the practice of medicine within their States.

222. Moreover, the regulation of healthcare and of the practice of medicine is a core function of state authority under our system of federalism. *Linder*, 268 U.S. at 18. The States—not the federal government—are empowered to regulate the practice of medicine and the medical profession, including by licensing medical professionals ensuring that evidence-based medical care is available to their residents. Defendants' efforts to leverage unrelated and inapplicable statutes to institute a de facto national regime barring the provision of this care to adolescents flatly disregards this long-established state authority and seeks to impose a federal standard of medical care on every medical provider in the country, effectively usurping a core state police power.

223. Also, as detailed above, many Plaintiff States have enacted numerous laws to protect transgender residents and to ensure their access to medically necessary care. These enactments reflect the sovereign policy judgments by Plaintiff States that continued access to this care is vital to the health, wellbeing, dignity, and autonomy of their residents and people within their borders.

224. The DOJ directives and the actions implementing them undermine many Plaintiff States' abilities to give full effect to their own laws protecting residents' health, safety, and rights, harming their sovereign interests and intruding on an area traditionally left to the province of the States. The collective and intended effect of the Denial of Care Order and agency actions is to intimidate providers to cease providing this medically necessary care. But if providers cease providing this care to avoid substantial financial and legal liability for baseless federal claims, they risk running afoul of many Plaintiff States' anti-discrimination and age-of-majority and consent state laws. Those laws prohibit discrimination on the basis of sex, gender identity, gender expression, transgender status, diagnosis of gender dysphoria, or intersex status, require the coverage and provision of medically necessary care, and grant 18-year-olds the right to make their own medical decisions. *See, e.g.*, N.Y. Pub. Health L. § 2803(1)(g); Mass. Gen. Laws c. 12, § 11 I ½(b); Cal. Fam. Code § 6500; 775 ILCS 5/1-102; 775 ILCS 5/1-103(O), (O-1); 775 ILCS 5/5-101(A)(6); 755 ILCS 5/11-1. The Denial of Care Order, the DOJ directives, and the actions implementing them render it impossible for hospitals, providers, pharmacies, and others to comply with their legal obligations in the Plaintiff States.

225. None of the statutes relied on in the Directives as the legal basis for them—the FGM statute, the FDCA and the FCA—authorize Defendants to intrude on an area "traditionally supervised by the States' police power." *Gonzales*, 546 U.S. at 274.

226. The DOJ directives and the actions implementing them impermissibly intrude on the Plaintiff States' sovereign authority to enforce their own laws and/or effectuate their policy choices regarding the provision of this care. They violate the Tenth Amendment.

227. These constitutional violations provide an independent basis for the Court to vacate and set aside the challenged agency actions.

228. Accordingly, Plaintiff States are entitled to an order and judgment, and to a permanent injunction, holding unlawful and setting aside the DOJ directives and enjoining any action taken to enforce or implement the DOJ directives.

COUNT FOUR
(Against All Defendants)
U.S. Constitution, Tenth Amendment

229. Plaintiff States repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

230. For the reasons stated above, the Denial of Care Order, the DOJ directives, and the actions implementing them violate the Tenth Amendment's protections of the Plaintiff States' sovereign authority to regulate their internal affairs, to exercise their powers of self-government, and to legislate under their police powers to protect the health and safety of their residents.

231. Plaintiff States have the authority under the Tenth Amendment, and exercise the authority, to regulate the practice of medicine within their States.

232. As detailed above, many Plaintiff States have enacted numerous laws to protect transgender residents and ensure access to this medical care. These enactments reflect the sovereign policy judgments by many Plaintiff States that continued access to this medical care is vital to the health, wellbeing, dignity, and autonomy of their residents and people within their borders.

233. The Denial of Care Order, the DOJ directives, and the actions implementing them undermine Plaintiff States' abilities to give full effect to their own laws protecting residents' health, safety, and rights, harming their sovereign interests and intruding on an area traditionally left to the province of the States.

234. The Denial of Care Order, the DOJ directives, and the actions implementing them impermissibly intrude on the Plaintiff States' sovereign authority to enforce their own laws and/or effectuate their policy choices regarding the provision of this care. They violate the Tenth Amendment.

235. Accordingly, Plaintiff States are entitled to an order and judgment, and to a permanent injunction, holding unlawful and setting aside Section 8 of the Denial of Care Order and the DOJ directives, and enjoining any action taken to enforce or implement Section 8 of the Denial of Care Order and the DOJ directives.

COUNT FIVE
(Against All Defendants)
Declaratory Judgment, 28 U.S.C. § 2201

236. Plaintiff States repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

237. The Denial of Care Order, the DOJ directives, and their implementing final agency actions seek to weaponize a variety of federal statutes—the FGM statute, the FDCA, and the FCA—and the threat of investigation or prosecution under these statutes to intimidate providers out of offering medically necessary care to adolescents. None of these statutes address such care, let alone proscribe it.

238. An actual and substantial controversy exists between Plaintiff States and the Defendants about whether the FGM statute, the FDCA, and the FCA make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender dysphoria in adolescents.

239. This action is presently justiciable because Defendants have asserted that the FGM statute, the FDCA, and the FCA make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender dysphoria in adolescents.

240. The FGM statute, 18 U.S.C. § 116, defines "female genital mutilation" as limited to procedures performed for "non-medical reasons." 18 U.S.C. § 116(e). Surgical operations do not violate the statute when, inter alia, they are "necessary to the health of the person on whom [they are] performed, and [are] performed by a person licensed in the place of [their] performance as a medical practitioner." 18 U.S.C. § 116(b)(1). The provision of medically necessary healthcare to treat gender dysphoria in adolescents, provided by licensed health providers, does not violate the FGM statute.

241. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. ch. 9, governs, among other things the manufacturing, distribution and sale of drugs and medical devices. The FDCA sets forth the process by which drugs are approved by the federal government for distribution, and requires drug manufacturers to submit evidence of drug safety and effectiveness. The FDCA does not regulate the physician-patient relationship, and does not make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender dysphoria in adolescents, including providing or prescribing drugs off-label.

242. The federal False Claims Act, 31 U.S.C. §§ 3729-3733, governs liability for submitting false claims to the federal government. The FCA provides that any person who knowingly submits, or causes to submit, false claims to the government is liable for three times the government's damages plus a penalty linked to inflation. The FCA does not make it unlawful for healthcare providers to provide medically necessary healthcare to treat gender

dysphoria in adolescents and to accurately bill for that treatment, nor does it deem such care inherently fraudulent.

243. This Court should issue a declaratory judgment stating that the FGM statute, 18 U.S.C. § 116, does not make it a crime for properly licensed persons, performing in their capacity as medical practitioners, to provide medically necessary healthcare to treat gender dysphoria in adolescents.

244. This Court should issue a declaratory judgment stating that the Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9, does not make it unlawful for healthcare providers to provide medically necessary healthcare, including pharmaceutical and surgical therapies, to treat gender dysphoria in adolescents.

245. This Court should issue a declaratory judgment stating that the False Claims Act, 31 U.S.C. §§ 3729-3733, does not make it unlawful for healthcare providers (i) to provide medically necessary healthcare, including prescribing or providing drugs off-label, to treat gender dysphoria in adolescents or (ii) to communicate about this care with adolescents or their caregivers in the context of a provider-patient relationship.

246. Declaratory relief will clarify the rights and obligations of the parties and, therefore, pursuant to 28 U.S.C. § 2201, is appropriate to resolve this controversy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff States request that the Court grant the following relief:

A. Declare pursuant to 28 U.S.C. § 2201 that Section 8 of the Denial of Care Order is unconstitutional and unlawful;

B. Declare pursuant to 28 U.S.C. § 2201 that the provision of gender-affirming healthcare to a person under 19-years old that is in the good faith medical judgment of the treating

healthcare provider medically necessary (and the accurate billing for such treatment) does not, standing alone, violate the Female Genital Mutilation statute (18 U.S.C. § 116); the Food, Drug, and Cosmetic Act (21 U.S.C. ch. 9 §§ 301 *et seq.*); or the False Claims Act (31 U.S.C. § 3729);

C. Enter an order pursuant to 5 U.S.C. § 706(2) holding unlawful and setting aside the following final actions undertaken by the Agency Defendants:

   a. The April 22, 2025 Bondi Directive titled "Preventing the Mutilation of American Children," and

   b. The June 11, 2025 Shumate Directive to all Civil Division Employees, titled "Civil Division Enforcement Priorities," to the extent that it threatens to use "all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies" and others who provide medically necessary care to adolescents;

D. Issue injunctive relief enjoining defendants from enforcing the FGM, FDCA, or the FCA in violation of the declaratory relief set forth above; and

E. Grant any other and further relief that this Court may deem just and proper and that the interests of justice may require.

Dated: August 1, 2025

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