

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

In Re: Administrative Subpoena
25-1431-032 to Rhode Island Hospital

Misc. Action No. _____

**EMERGENCY MOTION TO QUASH
SUBPOENA DUCES TECUM**

**REQUEST FOR EXPEDITED
RELIEF PURSUANT TO LR CV 9**

INTRODUCTION

The Child Advocate for the State of Rhode Island brings this motion to quash to protect the constitutional privacy rights and well-being of vulnerable children in the care, custody, or treatment of the Rhode Island Department of Children, Youth & Families (DCYF), and in fulfillment of her legal obligation to secure and ensure the legal and civil rights of children in DCYF care or custody. The United States Department of Justice (DOJ) served a subpoena, Administrative Subpoena 25-1431-032, on Rhode Island Hospital (RI Hospital), commanding production of information and documents relating to RI Hospital's provision of medical care for gender dysphoria (the Subpoena). The sweeping Subpoena seeks an extraordinarily broad set of sensitive medical records—including the identities, diagnoses, clinical assessments, and intimate personal details—of minor patients who received gender-affirming medical care, including children in DCYF care or custody. This unprecedented intrusion into

the private medical information of children, many of whom are among the most vulnerable in our state's care, cannot be justified by any legitimate law enforcement purpose.

On April 30, 2026, though the Subpoena was issued to RI Hospital in Providence, Rhode Island, and from DOJ's Consumer Protection Branch/Enforcement and Affirmative Litigation Branch in Washington, D.C., the government filed a Petition for Enforcement of the Subpoena in the United States District Court for the Northern District of Texas. *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026). The district court in Texas granted the government's motion to compel the same day, hours later, without any filed opposition, ordering RI Hospital to "provide all records responsive to each request in the subpoena within 14 days of the entry of this order." *Id.* at ECF No. 2. This Court's intervention is therefore immediately necessary, before May 13, 2026, to protect the constitutional privacy rights of Rhode Island's children.

DOJ does not have a legitimate law enforcement purpose for the Subpoena, as its own statements make clear. To the contrary, DOJ issued the Subpoena as part of a coordinated campaign by the Trump Administration to eliminate access to medical care for gender dysphoria, lifesaving care that is recognized as medically necessary by every major medical association, even where it is expressly protected by state law, as it is in Rhode Island. The Administration has made no secret of its true goal: to end medical care for gender dysphoria through intimidation, harassment, and the threat of criminal prosecution. Indeed, the Administration intends to eliminate the

recognition of transgender people it deems to fall outside a new “immutable biological reality of sex” it seeks to impose.¹ Incredibly, after another court quashed an identical subpoena, on the very ground that DOJ issued the subpoena not to investigate legal violations but instead to intimidate and coerce providers into abandoning lawful medical care, DOJ issued a public response eliminating any doubt about its improper purpose: “As Attorney General Bondi has made clear, this Department of Justice will use every legal and law enforcement tool available to protect innocent children from being mutilated under the guise of ‘care.’”²

This Subpoena is not a legitimate exercise of federal law enforcement authority. It is an improper attempt to regulate the practice of medicine in an area traditionally reserved to the states, to override Rhode Island’s choice to protect this necessary medical treatment, and to discriminate against people in protected classes that Rhode Island (and federal) laws explicitly protect. The fact that DOJ is so brazen about its true purpose does not make it any less improper. The Subpoena therefore constitutes an abuse of the narrowly circumscribed authority provided to the government under 18 U.S.C. § 3486 to investigate federal health care offenses, and represents a grave, improper, and unjustified intrusion on patient privacy.

¹ See *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, The White House (Jan. 20, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/> (last visited May 1, 2026).

² Josh Gerstein, *DOJ tried to subpoena an online trans health care provider. A judge quashed it*, Politico (Oct. 29, 2025), <https://www.politico.com/news/2025/10/29/doj-subpoena-gender-affirming-care-ruling-00627891> (last visited May 1, 2026).

The Court is not writing on a blank slate. There have now been seven decisions from other federal courts quashing or limiting identical subpoenas issued to other providers of medical care for gender dysphoria. *See In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229 (D. Mass. 2025); *QueerDoc, PLLC v. U.S. Dep't of Just.*, 807 F. Supp. 3d 1295 (W.D. Wash. 2025); *In re Subpoena No. 25-1431-014*, 810 F. Supp. 3d 555, 607 (E.D. Pa. 2025); *In re Subpoena Duces Tecum No. 25-1431-016*, No. 2:25-MC-00041-JHC, 2025 WL 3562151, at *16 (W.D. Wash. Sept. 3, 2025); *In re 2025 UPMC Subpoena*, No. 2:25-MC-01069-CB, 2025 WL 3724705, at *3 (W.D. Pa. Dec. 24, 2025), *judgment entered*, No. 2:25-MC-01069-CB, 2026 WL 570419 (W.D. Pa. Mar. 2, 2026); *In re Dep't of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063-SKC-CYC, 2026 WL 33398, at *2 (D. Colo. Jan. 5, 2026); *In re Children's Nat'l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792, at *9 (D. Md. Jan. 21, 2026). This Court should join that consensus and conclude that the Subpoena was issued in bad faith and with an improper purpose. If the Subpoena is not quashed, it threatens irreparable harm to the privacy rights of Rhode Island's children, their mental and physical health, and the physician-patient relationship upon which their care depends.

BACKGROUND

I. Medical Care for Gender Dysphoria Is Medically Necessary and Legally Protected Healthcare in Rhode Island.

Medical care for gender dysphoria represents evidence-based best practice for treatment of gender dysphoria, including in minors. All major medical organizations recognize gender dysphoria—which occurs when there is a conflict between the sex a person is assigned at birth and the gender with which they identify—as a medical

condition that can cause significant distress, and that appropriate medical care can effectively treat gender dysphoria.³ A “Systematic Medical Evidence Review of Hormonal Transgender Treatment Report,” conducted in response to the Utah legislature’s efforts to ban medical care for gender dysphoria for transgender minors, concluded that

the consensus of the evidence supports that [medical care for gender dysphoria] treatments are effective in terms of mental health, psychosocial outcomes, and the induction of body changes consistent with the affirmed gender in pediatric GD patients. The evidence also supports that the treatments are safe in terms of changes to bone density, cardiovascular risk factors, metabolic changes, and cancer.⁴

There is no “one-size-fits-all” approach to medical care for gender dysphoria: it is adapted to the needs of each patient, and treatments can include puberty suppression or hormone therapy.⁵ Medical care for gender dysphoria is thus a vital lifeline

³ See, e.g., *Clarification on Evidence-Based Gender-Affirming Care H-185.927*, American Medical Association (2024), <https://tinyurl.com/38mcbdjK> (last visited May 1, 2026) (“medical and surgical treatments for gender dysphoria and gender incongruence, as determined by shared decision making between the patient and physician, are medically necessary as outlined by generally-accepted standards of medical and surgical practice.”); *What is Gender Dysphoria*, American Psychiatric Association, <https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria> (last visited May 1, 2026) (outlining treatment options).

⁴ *Gender-Affirming Medical Treatments for Pediatric Patients with Gender Dysphoria*, University of Utah College of Pharmacy, Drug Regimen Review Center (Aug. 6, 2024), at 90, <https://le.utah.gov/AgencyRP/reportingDetail.jsp?rid=636> (last visited May 1, 2026).

⁵ Eli Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, International Journal of Transgender Health, World Professional Association for Transgender Health (WPATH) (2022), at S7, <https://tinyurl.com/459r3jth> (last visited May 1, 2026). In very rare cases, treatment includes gender-affirming surgery, *id.*, although RI Hospital does not perform surgeries as treatment for gender dysphoria for minors.

for many gender-diverse individuals, who may otherwise experience severe distress, anxiety, depression, and suicidal ideation without treatment.⁶

Reflecting this well-established medical consensus, Rhode Island law provides explicit guarantees of a patient’s ability to receive medical care for gender dysphoria, including R.I. Gen. Laws § 23-101, known as the Healthcare Provider Shield Law. That law specifically defines “Legally protected healthcare activity” in Rhode Island to include “gender-affirming healthcare services.” R.I. Gen. Laws § 23-101-2. The Rhode Island General Assembly passed the Healthcare Provider Shield law after finding, among other things, that “Access to transgender healthcare services . . . is a legal right in this state [and] [i]nterference with legally protected healthcare activity, or the aiding and assisting of legally protected healthcare activity, as defined by this act, whether or not under the color of law, is against the public policy of this state.”⁷

The Healthcare Provider Shield Law was enacted specifically to protect Rhode Island patients and providers from exactly the type of interference the federal government is now attempting—investigations and enforcement actions from other jurisdictions seeking to punish the provision of lawful healthcare. The law creates a cause of action for “[a]ny person in this state upon whom a subpoena seeking information concerning legally protected healthcare activity . . . [to] move to modify or quash such subpoena on any grounds provided by court rule, statute, or on the

⁶ Patrick Boyle, What Is Gender-Affirming Care? Your Questions Answered, Association of American Medical Colleges (AAMC) (April 12, 2022), <https://tinyurl.com/5n6nj8ej> (last visited May 1, 2026).

⁷ General Assembly 2024 -- S 2262 SUBSTITUTE A, <https://webserver.rilegislature.gov/BillText24/SenateText24/S2262A.pdf> (last visited May 1, 2026).

grounds that the subpoena is inconsistent with the public policy as set out in this act” and prohibits Rhode Island courts from enforcing out-of-state subpoenas, judgments, or other legal process related to legally protected healthcare activity. R.I. Gen. Laws § 23-101-5. And in 2015, the Rhode Island Executive Office of Health and Human Services issued guidance expressly stating that Rhode Island Medicaid covers medical care for gender dysphoria, including specifically for patients age 17 and younger.⁸ There is no doubt, therefore, that medical care for gender dysphoria is available and protected by law in Rhode Island, and consistent with the medically appropriate standards of care.

Moreover, Rhode Island state law provides comprehensive legal protections for transgender people. State law prohibits discrimination against a person on the basis of gender identity or expression in employment, housing, credit, and public accommodations. R.I. Gen. Laws § 28-5-3; § 28-5-7; § 34-37-4; § 34-37-4.3; § 11-24-2. A place of “public accommodation” is any place that is open to the public, including clinics and hospitals. R.I. Gen. Laws § 11-24-3. As a result, medical facilities in Rhode Island are not permitted to refuse, withhold, or deny a person services because of a person’s perceived or actual gender identity or expression, including discriminatory denial of privacy protections.

⁸ See *Rhode Island Gender Dysphoria/Gender Nonconformity Coverage Guidelines*, Rhode Island Executive Office of Health and Human Services (Oct. 28, 2015), https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf (last visited May 1, 2026).

II. RI Hospital's Provision of Medical Care for Gender Dysphoria to Patients in DCYF Care or Custody.

RI Hospital provides medical care for gender dysphoria, including care to some minor patients who are in DCYF care or custody. Declaration of the Child Advocate, Katelyn Medeiros (Medeiros Decl.) ¶ 5, attached hereto as Exhibit 1. This medical care is individualized to each patient and their family, and may include mental health counseling, social support, and in appropriate cases, medication such as puberty blockers or hormone therapy.⁹

III. The Administration's Campaign To Eliminate Medical Care for Gender Dysphoria.

The Subpoena issued to RI Hospital, and more than 20 identical subpoenas DOJ served on health care providers that provide medical care for gender dysphoria to patients around the country,¹⁰ are not isolated law enforcement actions; rather, they are components of a coordinated federal campaign by the Trump Administration to target transgender individuals and eliminate access to gender-affirming medical care nationwide, even where such care is lawful and protected under state law. Without seeking any legislation from Congress to carry out this attempt to federalize the regulation of medical care, the Administration began a concerted effort to change how

⁹ *Gender and Sexual Health Services*, Brown University Health, <https://www.brown-health.org/centers-services/gender-and-sexual-health-services> (last visited May 1, 2026).

¹⁰ See, e.g., *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children*, DOJ Office of Public Affairs, <https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical> (last visited May 1, 2026).

doctors treat patients with gender dysphoria, as part of a campaign to deny the very existence of transgender Americans and those with gender identities it disfavors.

On January 28, 2025, President Trump issued Executive Order 14187, titled “Protecting Children from Chemical and Surgical Mutilation.”¹¹ The Order villainized medical professionals who provide lifesaving treatment for allegedly “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.”¹² The Order went on to declare that “[t]his dangerous trend will be a stain on our Nation’s history, and it must end.”¹³ The Order equated “gender affirming care” with “chemical and surgical mutilation” and directed the Attorney General to prioritize investigations related to such care.¹⁴

The Administration has also characterized lifesaving medical care for gender dysphoria as “child abuse” and equated it with “sexual mutilation.”¹⁵ In April 2025, the White House issued a proclamation for National Child Abuse Prevention Month claiming that “the sinister threat of gender ideology” is “one of the most prevalent

¹¹ *Protecting Children from Chemical and Surgical Mutilation*, The White House (Jan. 28, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/protecting-children-from-chemical-and-surgical-mutilation/> (last visited May 1, 2026).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *National Child Abuse Prevention Month, 2025*, The White House (April 3, 2025), <https://www.whitehouse.gov/presidential-actions/2025/04/national-child-abuse-prevention-month-2025/> (last visited May 1, 2026).

forms of child abuse facing our country today,” specifically calling out “hormone therapy [and] puberty blockers.”¹⁶ The Administration “pledge[d] to stop the atrocity of child abuse in all its forms” and “affirm[ed] that every perpetrator who inflicts violence on our children will be punished to the fullest extent of the law”—explicitly characterizing this lifesaving medical care as abuse and violence.¹⁷

Following the Trump Administration’s marching orders, on April 22, 2025, then-Attorney General Pam Bondi issued a memorandum to DOJ leadership titled “Preventing the Mutilation of American Children.”¹⁸ The memorandum stated that “the Department will act decisively to protect our children and hold accountable those who mutilate them under the guise of care.”¹⁹ The memo directed DOJ to investigate healthcare providers offering medical care for gender dysphoria, using the pretext of alleged Federal Food, Drug, and Cosmetic Act (FDCA) and False Claims Act (FCA) violations. Then-Attorney General Bondi concluded the memo by making the real purpose of these investigations crystal clear, denigrating the dedicated medical professionals who provide this lifesaving care by comparing them to drug cartels and terrorists:

Protecting America’s children must be our top priority, whether from drug cartels, terrorists, or even our own medical community. Every day, we hear more harrowing stories about children who will suffer for the

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Memorandum from Attorney General, Preventing the Mutilation of American Children*, Office of the Attorney General, at 3-4 (April 22, 2025) (hereinafter “Preventing the Mutilation of American Children Memo”), <https://tinyurl.com/2b9kaja7> (last visited May 1, 2026).

¹⁹ *Id.*

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.*²⁰

In other words, the unambiguous purpose of these investigations is to attack and suppress an “unconscionable ideology” the Administration disfavors, part of its coordinated effort to deny the very existence of all who do not fit its preferred ideology of an imagined “immutable biological reality” of binary sex.

On June 11, 2025, the Assistant Attorney General for the Civil Division issued a memorandum stating that the Division would use “all available resources to prioritize investigations of doctors, hospitals, pharmaceutical companies, and other appropriate entities” providing medical care for gender dysphoria under the guise of FDCA and FCA investigations.²¹ The memorandum explicitly referenced the Attorney General’s directive to “hold accountable those who mutilate [children] under the guise of care.”²²

On July 9, 2025, DOJ publicly announced that it had “sent more than 20 subpoenas to doctors and clinics involved in performing transgender medical procedures on children.”²³ The Attorney General personally stated: “Medical professionals and

²⁰ *Id.*, emphasis added.

²¹ *Memorandum from Assistant Attorney General Brett A. Shumate, Civil Division Enforcement Priorities*, Office of the Assistant Attorney General, at 2-3 (June 11, 2025) (hereinafter “Civil Division Memo”), <https://tinyurl.com/mr3bym4f> (last visited May 1, 2026).

²² *Id.*

²³ *Department of Justice Subpoenas Doctors and Clinics Involved in Performing Transgender Medical Procedures on Children*, DOJ Office of Public Affairs, <https://www.justice.gov/opa/pr/department-justice-subpoenas-doctors-and-clinics-involved-performing-transgender-medical> (last visited May 1, 2026).

organizations that mutilated children in the service of a warped ideology will be held accountable by this Department of Justice.”²⁴ DOJ’s purpose in issuing the subpoenas is plain from its repeated public statements: to intimidate and coerce providers into abandoning lawful medical care.

The Trump Administration’s campaign has already accomplished its explicit goal of chilling access to medical care for gender dysphoria. Clinics that serve transgender individuals are even shutting down entirely.²⁵ The White House celebrated that 18 hospitals had curtailed their medical care for gender dysphoria programs as a result of the Administration’s efforts.²⁶ At a Federal Trade Commission conference in July 2025, a DOJ supervisor of these investigations responded to a comment that “there’s a very good chance [medical care for gender dysphoria] will stop even in blue states” by stating: “Working on it.”²⁷

The message is unmistakable: the Trump Administration is attempting to use the DOJ’s law enforcement power to eliminate medical care for gender dysphoria,

²⁴ *Id.*

²⁵ See Sonja Sharp, *Children’s Hospital Los Angeles Halts Transgender Care Under Pressure from Trump*, Los Angeles Times (June 12, 2025), <https://ti.nyurl.com/276vhe7y> (last visited May 1, 2026).

²⁶ See *President Trump Promised to End Child Sexual Mutilation — and He Delivered*, The White House (July 25, 2025), <https://www.whitehouse.gov/articles/2025/07/president-trump-promised-to-end-child-sexual-mutilation-and-he-delivered/> (last visited May 1, 2026).

²⁷ See *Transcript of The Dangers of “Gender-Affirming Care” for Minors*, Federal Trade Commission (July 9, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-The-Dangers-of-Gender-Affirming-Care-for-Minors-Transcript.pdf (last visited May 1, 2026).

regardless of state law, medical consensus, or the constitutional rights of patients, as part of its broader campaign against transgender people.

IV. The Administration's Broader Attacks on Transgender People.

This Subpoena is only one part of the Trump Administration's coordinated effort to deny the existence of gender identity, strip rights from transgender people, and eliminate access to medical care for gender dysphoria entirely. This targeted campaign began on Inauguration Day, when the Administration issued Executive Order 14168 titled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," stating "[i]t is the policy of the United States to recognize two sexes, male and female. These sexes are not changeable and are grounded in fundamental and incontrovertible reality."²⁸

The President subsequently issued related Executive Orders including banning transgender people from participating in the military²⁹ and withholding federal funds from schools "promoting gender ideology."³⁰ The Administration also repealed a number of prior executive orders that extended a variety of protections to

²⁸ *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, The White House (Jan. 20, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/> (last visited May 1, 2026).

²⁹ *Prioritizing Military Excellence and Readiness*, The White House (Jan. 27, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/prioritizing-military-excellence-and-readiness/> (last visited May 1, 2026).

³⁰ *Ending Radical Indoctrination in K-12 Schooling*, The White House (Jan. 29, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-indoctrination-in-k-12-schooling/> (last visited May 1, 2026).

transgender people.³¹ The language of these Executive Orders denigrates and attacks the integrity of transgender people, including by stating they are not capable of living an “honorable, truthful, and disciplined lifestyle.”³² And the Administration has attempted to enforce its preferred ideology by disqualifying grant applicants from federal funding unless they agree that they “[do] not and will not deny the sex binary in humans or promote the notion that sex is a chosen or mutable characteristic.”³³ These actions, taken together, make clear that the Administration is intent on targeting transgender people in many facets of their lives, including their healthcare, to the point of denying their very existence.

V. The Subpoena Seeks Access to Highly Sensitive Medical Records of Minor Patients.

In the context of the Trump Administration’s multi-pronged effort to attack transgender people and end medical care for gender dysphoria, on July 9, 2025, DOJ served RI Hospital with an administrative subpoena purportedly issued pursuant to 18 U.S.C. § 3486. *See In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0, ECF No. 1 (N.D. Tex. Apr. 30, 2026). On April 30, 2026, the government filed a

³¹ *Initial Rescissions of Harmful Executive Orders and Actions*, The White House (Jan. 20, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/initial-rescissions-of-harmful-executive-orders-and-actions/> (last visited May 1, 2026).

³² *Prioritizing Military Excellence and Readiness*, The White House (Jan. 27, 2025), <https://www.whitehouse.gov/presidential-actions/2025/01/prioritizing-military-excellence-and-readiness/> (last visited May 1, 2026).

³³ *Continuum of Care Builds Notice of Funding Opportunity Number FR-6902-N-25A*, United States Department of Housing and Urban Development (Sept. 5, 2025), <https://simpler.grants.gov/opportunity/23e87946-467a-486f-b6c5-db8c6b3c2317> (last visited May 1, 2026).

Petition for Enforcement of the Administrative Subpoena in the United States District Court for the Northern District of Texas. *Id.* A copy of the Subpoena, which the government filed with its motion to compel in the Northern District of Texas, is attached hereto as Exhibit 2. The Subpoena is identical or substantially similar to those issued to other children’s hospitals nationwide.³⁴ The subpoena seeks an extraordinarily broad range of sensitive information for a “Relevant Time Period” spanning from January 1, 2020 through the present—more than five years of records.

Most troubling are the following requests:

Request 11: “Documents sufficient to identify each patient (by name, date of birth, social security number, address, and parent/guardian information) who was prescribed puberty blockers or hormone therapy.”

Request 12: “For each such patient identified in [Request 11], documents relating to the clinical indications, diagnoses, or assessments that formed the basis for prescribing puberty blockers or hormone therapy.”

Request 13: “All documents relating to informed consent, patient intake, and parent or guardian authorization for minor patients identified in [Request 11], including any disclosures about off-label use (i.e., uses not approved by the United States Food and Drug Administration) and potential risks.”³⁵

These requests demand the identities and complete medical histories of every minor patient who received medical care for gender dysphoria at RI Hospital over more than five years. The medical records responsive to these requests contain the most intimate details imaginable: children’s mental health struggles, experiences

³⁴ See *In Re: Subpoena No. 25-1431-014*, 2:25-mc-00039 (E.D. Pa. July 8, 2025), ECF No. 1; *In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324 (D. Mass. July 8, 2025), ECF No. 5-1; *QueerDoc, PLLC v. U.S. Dep’t of Just.*, No. 2:25-MC-00042-JNW (W.D. Wash. Oct. 27, 2025).

³⁵ See Exhibit 2.

with bullying or discrimination, family dynamics, sexual development, gender identity, trauma histories, suicidal ideation, and deeply personal conversations with physicians and therapists. For children in DCYF care, these records may also contain information about abuse or neglect, foster care placements, court involvement, and other highly sensitive circumstances. The records would identify not only the children themselves but also their parents, guardians, foster families, siblings, friends, teachers, social workers, and others mentioned in clinical notes.

In other words, for a population of children that already lacks trust in the legal and medical systems, DOJ now seeks unfettered access to everything from their Social Security numbers and addresses to the intimate details about their state of mind, their sexual orientation and gender identity, and the course of treatment they chose with their physician and custodians. And DOJ has stated that it will not just scrutinize that information but that it may share that information with others.³⁶

VI. The Subpoena's Impact on Children in Rhode Island.

Children whose medical records are sought by this subpoena—including those in DCYF care or custody—are among the most vulnerable individuals in Rhode Island. Many have experienced significant trauma. Many struggle with mental health challenges. Many have been victims of abuse, neglect, discrimination, or bullying. For

³⁶ *Memorandum For Select Component Heads: Preventing the Mutilation of American Children*, Office of the Attorney General (Apr. 22, 2025), <https://www.justice.gov/ag/media/1402396/dl> (“I will partner with state attorneys general to identify leads, share intelligence, and build cases.”) (Last visited May 1, 2026).

many of these children, medical care for gender dysphoria has been, quite literally, lifesaving.

The prospect that their most intimate medical information will be turned over to federal prosecutors who have publicly characterized their necessary medical treatment as “mutilation” and “child abuse” is devastating. Children in DCYF care already face significant challenges in trusting adults and authority figures. Learning that the federal government seeks their private medical records, with the stated goal of “bringing an end” to the care they need, will compound their trauma and sense of vulnerability.

Moreover, many children who received medical care for gender dysphoria have not publicly disclosed their transgender status. Being “outed” to a hostile government by this “investigation” could subject them to harassment, discrimination, bullying, or even violence. Transgender individuals, particularly youth, face dramatically elevated rates of victimization.³⁷ The risk of harm is particularly acute given the Administration’s inflammatory rhetoric equating this medical care with abuse and mutilation.

³⁷ See Michelle M. Johns, et al., *Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students*, *Morbidity and Mortality Weekly Report*, US Department of Health and Human Services/Centers for Disease Control and Prevention (Jan. 25, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6803a3-H.pdf> (last visited May 1, 2026).

These harms also extend beyond those whose records are directly sought. If children and families fear that seeking medical care will result in federal investigation, they will be less likely to seek necessary treatment or to be candid with their healthcare providers. This chilling effect undermines the physician-patient relationship and threatens public health.

VII. The Child Advocate.

The Office of the Child Advocate (“OCA”) was established by the Rhode Island General Assembly to serve as an independent voice for children in the care or custody of DCYF. R.I. Gen. Laws § 42-73-1 *et seq.* The Child Advocate is appointed by the Governor and confirmed by the Senate to serve as the state’s watchdog for children’s rights and welfare. *Id.*

By statute, the Child Advocate has broad authority to “take all possible action including, but not limited to ... formal legal action, to secure and ensure the legal, civil, and special rights of children” who are in DCYF protective care, custody, or receiving treatment services. R.I. Gen. Laws § 42-73-7. This mandate expressly includes protecting children’s legal rights through litigation when necessary. The General Assembly entrusted the Child Advocate with this authority precisely to ensure that vulnerable children have a powerful advocate who can take legal action to protect their interests. The Child Advocate therefore has a statutory duty to protect these children’s rights, including their constitutional right to privacy in their medical records and their right to access lawful medical treatment without federal government interference or intimidation.

LEGAL STANDARD

A motion to quash a subpoena issued under 18 U.S.C. § 3486 is subject to the standard generally applicable to a motion to quash an administrative subpoena. *See Doe v. United States*, 253 F.3d 256, 268 (6th Cir. 2001). An administrative subpoena is enforceable only if “(1) the subpoena is issued for a congressionally authorized purpose, the information sought is (2) relevant to the authorized purpose and (3) adequately described, and (4) proper procedures have been employed in issuing the subpoena.” *U.S. Dep’t of Just. v. Ricco Jonas*, 24 F.4th 718, 726 (1st Cir. 2022); *United States v. Powell*, 379 U.S. 48, 57-58 (1964). “The requirement that subpoenas be used only for a legitimate and authorized governmental purpose prohibits the government from ‘engaging in arbitrary fishing expeditions’ and from ‘selecting targets of investigation out of malice or an intent to harass.’” *In re Subpoena Duces Tecum*, 228 F.3d 341, 349 (4th Cir. 2000) (cleaned up) (quoting *United States v. R. Enters., Inc.*, 498 U.S. 292, 299 (1991)). “Persons from whom [an agency] seeks relevant information are not required to submit to [the agency’s] demand, if in any respect it is unreasonable or overreaches the authority Congress has given.” *Okla. Press Pub. Co. v. Walling*, 327 U.S. 186, 217 (1946); *see also Doe*, 253 F.3d at 265 (holding that an administrative subpoena must “satisf[y] the terms of its authorizing statute”). Section 3486 administrative subpoenas, like the Subpoena at issue here, may only be used in investigations concerning the limited universe of federal criminal offenses identified in the statute. *See* 18 U.S.C. § 3486(a)(1)(A).

Additionally, even where a subpoena satisfies these baseline requirements, courts must consider whether a subpoena was issued for a proper purpose. *Ricco Jonas*, 24 F.4th at 726. A subpoena issued for an improper purpose, such as harassment, or issued in bad faith, cannot be enforced. *See United States v. Powell*, 379 U.S. 48 (1964); *In Re: Administrative Subpoena No. 25-1431-019*, 800 F. Supp. 3d 229, 236-37 (D. Mass. September 9, 2025) (quashing an identical subpoena to Boston Children’s Hospital because it “was issued for an improper purpose, motivated only by bad faith.”). The First Circuit has concluded that courts “have adequate justification to deny enforcement of [a] subpoena” when there is evidence that a subpoena’s issuance was motivated by bad faith. *United States v. Comley*, 890 F.2d 539, 542 (1st Cir. 1989) (citing *United States v. Westinghouse Elec. Corp.*, 788 F.2d 164, 166–67 (3d Cir. 1986) (“[I]f a subpoena is issued for an improper purpose, such as harassment, its enforcement constitutes an abuse of the court’s process.”)).

ARGUMENT

I. The Child Advocate Has Standing To Challenge the Subpoena.

The Child Advocate has standing to move to quash the subpoena on behalf of children in DCYF custody or care whose medical records are sought. A party has standing to move to quash a subpoena issued to a non-party if “the information sought by the subpoena implicates a personal right or privilege of the party.” *Ponder v. Ocwen Loan Servicing, LLC*, No. CV 19-MC-91215-ADB, 2019 WL 2249675, at *2 (D. Mass. May 24, 2019) (collecting cases). “The personal right or privilege claimed need not be weighty: parties need only have some personal right or privilege in the information sought to have standing to challenge a subpoena to a third party.” *S.E.C. v.*

Navellier & Assocs., Inc., No. 17-cv-11633, 2019 WL 688164, at *2 (D. Mass. Feb. 19, 2019) (quoting *Degradis v. Children’s Hosp. Bos.*, 203 F. Supp. 3d 193, 198 (D. Mass. 2016)). And, generally, “the subject of an administrative subpoena has an opportunity to challenge the subpoena before yielding the information.” *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 3 (1st Cir. 1996).

The Child Advocate “monitors each child in the care of DCYF to protect their legal rights and ensure their safety, including their physical, mental, medical, educational, and behavioral needs while in out-of-home placements. [] [The Child Advocate] has the right to intervene in any case where a child’s safety, education, and physical and mental welfare are not being met, and if a resolution cannot be reached, [the Child Advocate] can initiate litigation on the child’s behalf.” *Off. of the Child Advocate on Behalf of Jane Doe v. Providence Pub. Sch. Dep’t*, No. 25-CV-649-JJM-AEM, 2026 WL 1068031, at *4 (D.R.I. Apr. 20, 2026). Here, the Child Advocate seeks to protect the constitutional privacy rights of identifiable children in the state of Rhode Island’s care whose medical records are sought by the subpoena. These children face concrete injury—invasion of their privacy, disclosure of their most intimate medical information, potential “outing” of their gender identity, and exposure to harassment or discrimination—that is directly traceable to the subpoena and redressable by quashing it.

Moreover, the Child Advocate has statutory authority under Rhode Island law to bring this motion. R.I. Gen. Laws § 42-73-7 expressly empowers the Child Advocate

to “take all possible action including, but not limited to ... formal legal action, to secure and ensure the legal, civil, and special rights of children” in DCYF care or custody. Denying the Child Advocate standing to challenge a subpoena that threatens these children’s constitutional privacy rights would frustrate the Rhode Island General Assembly’s intent in creating the Office of the Child Advocate.

Moreover, this Court is unquestionably the proper venue in which the Child Advocate should bring this motion to quash. The Child Advocate, and the children in DCYF custody or care on whose behalf she brings this motion, are all located in Rhode Island. RI Hospital, to whom the subpoena was issued, is located in Rhode Island and carries on business only in Rhode Island. The records DOJ seeks to obtain are all located in Rhode Island. And DOJ served the subpoena on RI Hospital in Rhode Island, with instructions to produce records in Washington, D.C. *See, e.g.*, 18 U.S.C. § 3486(a)(3) (“The production of records relating to a Federal health care offense shall not be required under this section at any place more than 500 miles distant from the place where the subpoena for the production of such records is served.”). The Child Advocate was not a party to, and had no notice of, the Texas proceeding, and has had no opportunity to be heard on the Subpoena in any court.

II. The Subpoena Was Issued for an Improper Purpose and in Bad Faith.

The subpoena must be quashed because it was issued for an improper purpose: to eliminate medical care for gender dysphoria at a federal level, rather than to investigate any legitimate federal crime. A subpoena issued “for an improper purpose, such as to harass” or “to put pressure” on recipients is not enforceable. *Powell*, 379 U.S. at 58. Similarly, subpoenas issued in bad faith or motivated by animus cannot

be enforced. *Comley*, 890 F.2d at 542; *see also Sec. & Exch. Comm'n v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 129 (3d Cir. 1981).

A. The Subpoena's Purpose Is To End Gender-Affirming Medical Care, Not Investigate Crime.

As discussed in more detail above, the Administration has openly and repeatedly stated that its purpose in conducting the investigations that produced the Subpoena is to “end” medical care for gender dysphoria. These statements are directly relevant to the Court’s inquiry in evaluating whether the Subpoena was issued for a congressionally authorized purpose or instead an improper one. The subpoena was issued at the actual direction of the Attorney General. *See Exhibit 2*. DOJ’s own counsel admitted in related litigation that DOJ believes “it is a rational governmental objective or purpose to eliminate the medicalized gender-affirming care of minors and that’s exactly what this investigation is about.” *See Tr. of Mot. Hr’g 25:14-17, In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324 (D. Mass. Sep. 1, 2025), ECF No. 30.

As a district court in the Western District of Washington concluded, quashing an identical subpoena, “[n]o clearer evidence of improper purpose could exist than the Government’s own repeated declarations that it seeks to end the very practice it claims to be merely investigating.” *QueerDoc*, 807 F. Supp. 3d at 1303. Incredibly, in a public response issued to questions about that court’s order quashing an identical subpoena, DOJ doubled down and eliminated any remaining doubt about its true purpose: “As Attorney General Bondi has made clear, this Department of Justice will

use every legal and law enforcement tool available to protect innocent children from being mutilated under the guise of ‘care.’”³⁸

That is not a legitimate law enforcement purpose. The regulation of medical practice is “primarily, and historically, a matter of local concern.” *Hillsborough Cnty. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 719 (1985). While Congress may “set uniform national standards in these areas,” it has done so only rarely. *See Gonzales v. Oregon*, 546 U.S. 243, 271 (2006). When the federal government seeks to disrupt areas of traditional state authority, courts require a clear statement that Congress intended such a shift. *See West Virginia v. EPA*, 597 U.S. 697, 722-24 (2022) (citing *Oregon* as example of “major questions doctrine”). There is no congressional statement here, much less a clear one, that would allow the Administration to regulate the practice of medicine federally.

Indeed, just last year the Supreme Court reaffirmed that “[w]e afford States ‘wide discretion to pass legislation in areas where there is medical and scientific uncertainty,’” including specifically in the area of medical care for gender dysphoria. *United States v. Skrametti*, 605 U.S. 495, 524 (2025) (quoting *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007)). Rhode Island has not merely declined to ban medical care for gender dysphoria—it has affirmatively protected it from exactly the type of interference DOJ is now attempting. The Rhode Island Healthcare Provider Shield Law specifically protects patients and providers from investigations and enforcement actions

³⁸ Josh Gerstein, *DOJ tried to subpoena an online trans health care provider. A judge quashed it*, Politico (Oct. 29, 2025), <https://www.politico.com/news/2025/10/29/doj-subpoena-gender-affirming-care-ruling-00627891> (last visited May 1, 2026).

by other jurisdictions seeking to punish the provision of lawful healthcare. R.I. Gen. Laws § 23-101. The Subpoena represents precisely the type of interference the Rhode Island General Assembly sought to prevent. The Healthcare Provider Shield Law demonstrates Rhode Island's clear and emphatic public policy: medical care for gender dysphoria is not merely lawful, it is a protected right, and interference with that right, "whether or not under the color of law," violates state law.

When a state has exercised its traditional authority over the practice of medicine by not only permitting but affirmatively protecting certain medical care, the federal government's attempt to override that policy choice through a pretextual criminal investigation is particularly improper. DOJ seeks to accomplish through a pretextual criminal investigation what it lacks authority to achieve through legislation: a nationwide ban on medical care for gender dysphoria that overrides state law and policy. An attempt to intimidate physicians into stopping medical care that is protected under state law is an impermissible goal for the federal government. *See Gonzales*, 546 U.S. at 273-75 (Attorney General could not revoke physicians' licenses under federal Controlled Substances Act for prescribing drugs in compliance with Oregon's Death With Dignity Act); *Hillsborough Cnty.*, 471 U.S. at 719. There is a straight path between the government's explicit directives to end medical care for gender dysphoria and the DOJ's bad faith subpoena. *See In re Children's Nat'l Hosp.*, No. 1:25-CV-03780-JRR, 2026 WL 160792, at *6 (D. Md. Jan. 21, 2026) (quashing an identical subpoena on the grounds that it "lacks a proper investigative purpose.")

Pursuing an unlawful end—and trying to dress that aim up with pretextual justifications—is the very definition of bad faith.

B. DOJ’s Purported Legal Bases for the Subpoena Are Pretextual.

In support of its efforts to enforce the Subpoena in Texas, and identical subpoenas in other cases, DOJ has claimed the subpoenas are proper because it is investigating potential violations of the FDCA or the FCA. *See, e.g.*, Declaration of Lisa K. Hsiao, filed in *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0 (N.D. Tex. Apr. 30, 2026), attached hereto as Exhibit 3; *In Re: Administrative Subpoena 25-1431-032*, No. 4-26MC-006-0, ECF No. 1 (N.D. Tex. Apr. 30, 2026); *In re Admin. Subpoena No. 25-1431-019*, ECF No. 36 (D. Mass. Oct. 7, 2025). But these theories are both legally deficient and factually unsupported, especially in the context of DOJ’s own repeated and public statements about its true purpose in issuing the subpoenas.

1. The FDCA Does Not Prohibit Off-Label Prescribing.

Physicians may prescribe an approved drug for an unapproved use without violating the FDCA. The FDCA “does not regulate the practice of medicine,” and off-label prescribing “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001). Indeed, the FDCA expressly states that it does not empower the primary agency charged with enforcing the FDCA—namely, the FDA—to interfere with the authority of a medical provider to “prescribe or administer any legally marketed device to any patient for any condition or disease within a legitimate health care practitioner-patient relationship.” 21 U.S.C. § 396.

The FDA’s own guidance likewise consistently upholds doctors’ right to engage in off-label prescription and administration for legitimate medical purposes. For example, one guidance document states: “[O]nce a drug or medical device has been approved or cleared by FDA, generally, health care professionals can lawfully use or prescribe that product for uses or treatment indications that are not included in the product’s approved labeling. . . . [T]he FDA recognizes that these off-label uses may even constitute a medically recognized standard of care.”³⁹ Similarly, DOJ’s own Office of Legal Counsel also affirms that off-label prescribing and administration is not a violation of the FDCA: “[W]hile the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses.”⁴⁰

Courts have consistently recognized the rule that off-label prescribing and use of drugs is permissible. *See Buckman Co.*, 531 U.S. at 350; *United States v. Fackeau*,

³⁹ Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices, U.S. Food & Drug Admin. (Dec. 2011) (draft guidance for comment purposes only), <https://www.fda.gov/media/82660/download> (last visited May 1, 2026); *see also Understanding Unapproved Use of Approved Drugs “Off Label”*, U.S. Food & Drug Admin. (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> (last visited May 1, 2026) (“[O]nce the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.”)

⁴⁰ Steven A. Engel, *Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. 81, 85 (2019), <https://www.justice.gov/olc/opinion/file/1162686/dl?inline> (last visited May 1, 2026).

89 F.4th 1, 13 (1st Cir. 2023), cert. denied, 145 S. Ct. 137 (2024) (“[T]he FDCA expressly protects the ‘authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease.’” (quoting 21 U.S.C. § 396)). Indeed, it is well established that “medical professionals may lawfully prescribe and administer a device for an off-label use as long as that device has received [FDA] clearance for any intended use.” *Facteau*, 89 F.4th at 15; *see also Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) (“[N]either Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers. A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA.”); *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 317 (D. Mass. 2011) (“[T]he FDA ... cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary.”)

DOJ itself recently made these same representations to the Third Circuit, arguing that “off-label prescription of a drug can sometimes be both medically accepted and reasonable and necessary for a given patient” and that the FDCA’s “misbranding provisions govern how drugs may be marketed; they do not govern whether federal healthcare programs will reimburse for the drugs, as prescribed for particular patients.” *Penelow v. Janssen Prods. LP*, No. 25-1818, ECF No. 56 at 36 (3d Cir. Aug. 27, 2025). If the FDCA does not prohibit the conduct DOJ now seeks to investigate criminally, then the investigation cannot be justified under the FDCA.

2. DOJ Cannot Convert RI Hospital's Clinical Treatment Decisions into Commercial Distribution of Misbranded Drugs.

In an effort to avoid the settled rule that the FDCA does not prohibit off-label prescribing, in its motion to compel compliance with the Subpoena, filed in Texas, the government claims that RI Hospital is a distributor or seller of misbranded drugs under 21 U.S.C. §§ 331, 352. That theory fails.

The FDCA's misbranding provisions regulate the labeling, marketing, and commercial distribution of medical products; they do not transform a physician's patient-specific therapeutic judgment, informed-consent discussion, or medical chart into manufacturer-style "labeling" for a drug. DOJ's recharacterization of hospital-based medical care as drug "distribution" is a transparent attempt to circumvent the FDCA's express protection of medical practice. When a hospital pharmacy fills a prescription written by a treating physician for an individual patient, that act is part of the delivery of medical care, not independent commercial drug distribution. The cases DOJ cites for the breadth of the FDCA's misbranding provisions—*Kordel v. United States*, 335 U.S. 345 (1948); *United States v. Urbuteit*, 335 U.S. 355 (1948); *47 Bottles, More or Less*, 320 F.2d 564 (3d Cir. 1963)—all involve manufacturers and commercial distributors who marketed drugs to the public for unapproved purposes. None involved a healthcare provider dispensing an FDA-approved drug pursuant to an individualized clinical judgment by a treating physician. There is a fundamental difference between a manufacturer promoting a drug for an unapproved indication through advertising and sales representatives, and a physician prescribing an approved drug

off-label based on that physician's medical judgment about a particular patient's needs. DOJ's theory erases that distinction entirely.

If accepted, DOJ's theory would criminalize virtually all off-label prescribing through the back door. If a hospital's act of dispensing an FDA-approved drug pursuant to a physician's off-label prescription automatically renders the drug "misbranded" because its labeling lacks directions for the off-label use, then *every* hospital that fills an off-label prescription, a routine and pervasive practice across American medicine, would be committing a federal crime. That result is untenable, and it is plainly not what Congress intended when it enacted the FDCA's misbranding provisions.

The regulation DOJ invokes, 21 C.F.R. § 201.128, titled "Meaning of 'intended uses,'" is not an independent criminal prohibition. It defines "intended use" for purposes of specific FDA labeling provisions. By its terms, the regulation refers to the objective intent of "the persons legally responsible for the labeling of an article (or their representatives)." *Id.* The "seller" language DOJ quotes must be read in that context. A manufacturer, packer, distributor, or commercial seller that promotes a product for a new unapproved use may create a new intended use and trigger labeling obligations. But a treating physician who prescribes or administers an FDA-approved prescription drug to an individual patient is not thereby acting as the drug's manufacturer, packer, or commercial labeler. Nor does a hospital medical record, intake form, informed-consent form, or patient-specific clinical discussion become "labeling" merely because it mentions the physician's therapeutic purpose.

RI Hospital and its clinicians are not alleged to have manufactured a drug, changed a package insert, repackaged the drug for commercial resale, distributed the drug to other prescribing physicians, or disseminated product labeling on behalf of a manufacturer. The alleged conduct is the provision of medical care: prescribing or administering FDA-approved drugs in a practitioner-patient relationship, documenting the clinical basis for that care, and obtaining informed consent.

Nor can DOJ avoid this problem by invoking manufacturer off-label-promotion cases. The examples DOJ cites in its motion to compel, filed in Texas, involve manufacturers or commercial entities alleged to have promoted products for unapproved uses, paid incentives, distributed sales materials, or otherwise caused product distribution through marketing schemes. Those cases may support subpoenas for manufacturer communications, contracts, payments, sales aids, speaker arrangements, or other non-patient-specific commercial materials. They do not justify treating RI Hospital's clinical records as drug "labeling," and they do not support compelled disclosure of children's identities, diagnoses, Social Security numbers, parent or guardian information, consent forms, and medical histories.

The same is true of DOJ's suggestion that "scientific exchange information" or communications with pharmaceutical representatives may support an FDCA theory. Even assuming DOJ has a legitimate basis to investigate a manufacturer or distributor, that theory would call for narrowly tailored requests for communications with the manufacturer, financial arrangements, and promotional materials. It would not

justify wholesale production of patient charts. A manufacturer-promotion investigation does not require DOJ to identify every Rhode Island child who received care, read their mental-health assessments, obtain their parent or guardian information, or review individualized informed-consent discussions. The mismatch between DOJ's manufacturer-promotion theory and its demand for patient-level records confirms that the subpoena is not tailored to any lawful FDCA inquiry.

Finally, DOJ's reliance on strict liability and the responsible-corporate-officer doctrine does not cure the missing predicate. Those doctrines do not create an FDCA violation where none exists. They address responsibility for a cognizable violation of the Act; they do not make lawful off-label treatment, clinical counseling, informed consent, or routine hospital dispensing into misbranding.

3. DOJ's Off-Label Justification for the Subpoena Would Violate the First Amendment.

DOJ's novel theories of justification for the Subpoena in this case, which appear to turn in part on the guidance doctors give patients to use medications off-label, would also violate the First Amendment rights of doctors to communicate with their patients. It has long been recognized that "punish[ing] physicians on the basis of the content of doctor-patient communications" is impermissible under the First Amendment. *See, e.g., Conant v. Walters*, 309 F.3d 629, 637 (9th Cir. 2002). If DOJ is permitted to prosecute doctors for off-label prescribing and administration, it will undermine the ability of doctors "to speak frankly and openly to patients," which is "[a]n integral component of the practice of medicine." *Id.* at 636.

Indeed, courts have consistently concluded that efforts to prohibit “off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use ‘paternalistically’ interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions.” *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012) (citing *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)); see also *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011). The First Amendment implications of allowing DOJ to investigate off-label prescriptions as potential criminal activity with the Subpoena, standing alone, would be sufficient to doom DOJ’s novel, expansive theories of FDCA liability.

4. There is no Good-Faith Basis for a False Claims Act Investigation, and the Subpoena Is Not Authorized for that Purpose.

DOJ may also suggest it is investigating potential false claims to federal healthcare programs under the FCA. But this theory lacks any legal or factual foundation. First, DOJ has conceded in other matters involving identical subpoenas that its authority to issue the Subpoena is limited to investigations of alleged FDCA violations, not the FCA. See *In Re: Administrative Subpoena No. 25-1431-019*, 1:25-mc-91324, ECF No. 37 at ¶ 5 (D. Mass. Oct. 7, 2025) (“Pursuant to Attorney General Order Number 3591-2015, dated November 10, 2015, the Attorney General authorized the Assistant Attorney General for the Civil Division to issue and serve administrative subpoenas pursuant to 18 U.S.C. §§ 3486(a)(1)(A) and (a)(1)(B) *to investigate violations of the FDCA* that relate to a health care benefit program.” (emphasis

added)); *see also id.*, ECF No. 36 at 4 (“Causing the distribution of unapproved drugs can be an *FDCA violation*, which can be a federal health care offense. 21 U.S.C. § 331(d); 18 U.S.C. § 24.” (emphasis added)). The alleged FDCA violations have nothing to do with billing issues; they relate to alleged off-label use of medications or distribution of misbranded or unapproved drugs. *In Re: Administrative Subpoena No. 25-1431-019*, ECF No. 37 at ¶¶ 11-18.

Nevertheless, DOJ has also claimed the Subpoena seeks evidence that relates to billing for medical care for gender dysphoria and related records. *See id.* ¶¶ 31, 35. That evidence is not relevant to alleged FDCA violations. Evidence of any billing fraud would be relevant only if there were an underlying FDCA violation, which there is not, and even then, only if the intent to defraud were connected to the FDCA violation. *See United States v. Mitcheltree*, 940 F.2d 1329, 1349 (10th Cir. 1991) (“[T]he specific intent requirement in § 333(a)(2) requires not only proof of misbranding under § 331, but also proof of an intent to mislead or defraud *which is connected to the misbranding violation under § 331.*”) (emphasis added). Instead, that kind of evidence would be relevant to an FCA investigation, which DOJ has admitted cannot be the basis for a subpoena under 18 U.S.C. § 3486. The mismatch between DOJ’s FDCA theories and the purported evidence it seeks only further confirms that this asserted basis for the investigation is pretextual.

Even if an FCA investigation of billing practices were a legitimate basis, and it is not, the DOJ’s stated purpose for that investigation is legally and factually deficient. The Civil Division memorandum that prompted these subpoenas specifically

referenced investigating providers who “attempt to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes.”⁴¹ But Rhode Island has no such ban; to the contrary, medical care for gender dysphoria is lawful and protected healthcare, and the state affirmatively protected this care from exactly the type of federal interference DOJ is now attempting. There is thus no reason for any Rhode Island provider to “evade” anything, and no basis for investigating false billing. Medicare and many state Medicaid programs explicitly cover this care.⁴² The Subpoena seeks to override Rhode Island’s express legislative determination that medical care for gender dysphoria is a protected legal right and that interference with such care is against state law and public policy.

C. The Requests Are Not Tailored to Any Legitimate Investigation.

Even if DOJ had a legitimate investigative theory—and it does not—the Subpoena’s requests are not narrowly tailored to any such theory. The Fourth Amendment requires that administrative subpoenas “be sufficiently limited in scope [and] relevant in purpose[.]” *See v. City of Seattle*, 387 U.S. 541, 544 (1967). The Fourth Amendment therefore requires that an administrative subpoena “be disallowed if it is far too sweeping in its terms to be regarded as reasonable. . . . And the requirement that subpoenas be used only for a legitimate and authorized governmental purpose

⁴¹ Memorandum from Assistant Attorney General Brett A. Shumate, Civil Division Enforcement Priorities, at 3 (June 11, 2025)

⁴² *See Rhode Island Gender Dysphoria/Gender Nonconformity Coverage Guidelines*, Rhode Island Executive Office of Health and Human Services (Oct. 28, 2015), https://eohhs.ri.gov/sites/g/files/xkgbur226/files/Portals/0/Uploads/Documents/MA-Providers/MA-Reference-Guides/Physician/gender_dysphoria.pdf (last visited May 1, 2026).

prohibits the government from engaging in arbitrary fishing expeditions and from selecting targets of investigation out of malice or an intent to harass.” *In re Dep’t of Just. Admin. Subpoena No. 25-1431-030*, No. 25-MC-00063-SKC-CYC, 2026 WL 33398, at *8 (D. Colo. Jan. 5, 2026) (cleaned up).

If DOJ were truly investigating off-label promotion by pharmaceutical manufacturers, it would not need the identities, Social Security numbers, and complete medical histories of minor patients. If DOJ were truly investigating billing fraud, anonymized billing records would suffice. Instead, the subpoena seeks the most intimate details of children’s lives, going far beyond anything necessary to investigate the purported violations.

D. The Evidence of Bad Faith and Improper Purpose Is Overwhelming.

DOJ’s effort to block lawful medical treatment by opening an unfounded and politically motivated attack on medical care for gender dysphoria, under the pretext of a law enforcement investigation, is not a congressionally authorized purpose. Nor is issuing a subpoena in search of “wrongdoing, as yet unknown,” that could later be a proper or authorized purpose. *In re Sealed Case (Administrative Subpoena)*, 42 F.3d 1412, 1418 (D.C. Cir. 1994). That is precisely what the Administration seeks to do with these subpoenas: they were issued in an attempt to bring an end to a type of medical treatment that this Administration disfavors, but that is lawful and protected in Rhode Island. DOJ’s bad faith is evident from multiple sources. In summary, as discussed in more detail above:

- The Administration has demonized lifesaving medical care for gender dysphoria as “mutilation,” “maiming,” “sterilization,” and “child abuse.”
- The Administration has asserted that transgender citizens cannot lead an “honorable, truthful, and disciplined lifestyle,” and that their medical treatment is part of a “warped ideology” and “evil and backwards lies” that cause “sexual mutilation.” This inflammatory language reveals animus toward transgender individuals and those who provide them care.
- The Administration has attempted to deny the existence of transgender people, forcing grant applicants to agree that they “[do] not and will not deny the sex binary in humans or promote the notion that sex is a chosen or mutable characteristic.”
- The Attorney General explicitly stated the DOJ’s goal is to “bring these [medical care for gender dysphoria] practices to an end”—a policy objective, not a law enforcement purpose.
- DOJ issued subpoenas to at least 20 children’s hospitals nationwide on or around the same date, without any particularized allegations of wrongdoing at any of them. This dragnet approach is inconsistent with targeted criminal investigation.
- The Attorney General took the unprecedented step of publicly announcing the subpoenas to “send a clear and chilling message” to providers. DOJ policy generally prohibits commenting on ongoing investigations, but here the

announcement served to accomplish the true goal of the subpoenas: to intimidate and harass.

- DOJ’s counsel admitted in litigation that the investigation is about eliminating medical care for gender dysphoria as a “rational governmental objective.”
- The White House has celebrated that hospitals have stopped providing medical care for gender dysphoria as a result of these efforts.
- A DOJ supervisor involved in these investigations stated he is “working on” ensuring care will stop “even in blue states.”
- In response to another district court quashing an identical subpoena, DOJ doubled down and made its true purpose clear: it issued the subpoena “to protect innocent children from being mutilated under the guise of ‘care.’”

This is not a legitimate criminal investigation. It is a campaign of harassment and intimidation designed to achieve a policy goal—the end of medical care for gender dysphoria—that Congress has not authorized and the Executive Branch otherwise lacks authority to pursue. One federal court has already found that an identical subpoena “was issued for an improper purpose, motivated only by bad faith” because “the Administration has been explicit about its disapproval of the transgender community and its aim to end [medical care for gender dysphoria]” and “the true purpose of issuing the subpoena is to interfere with the [state’s] right to protect [medical care for gender dysphoria] within its borders, to harass and intimidate [the hospital] to stop providing such care, and to dissuade patients from seeking such care.” *In re Admin.*

Subpoena No. 25-1431-019, 800 F. Supp. 3d at 239. Another court quashed an identical subpoena because the evidence “demonstrates that DOJ has abandoned good faith investigation in favor of policy enforcement through prosecutorial coercion.” *QueerDoc*, 807 F. Supp. 3d at 1302. As that court made clear, its finding was “not speculation about hidden motives—it is the Administration’s explicit agenda.” *Id.* This Court should reach the same conclusion.

III. The Privacy Interests of Children Far Outweigh Any Legitimate Governmental Need.

Even if the Subpoena were issued for a proper purpose—and it was not—it must be quashed because the children whose records DOJ seeks have constitutional privacy interests that far outweigh any governmental need for the information. Because the Subpoena specifically targets highly sensitive medical records pertaining to care for transgender youth, compliance with the subpoena would subject transgender patients and those with gender dysphoria to invasive and sweeping government scrutiny, in violation of their constitutional rights to privacy.

A. Children Have a Constitutional Right to Privacy in Their Medical Records.

The Constitution provides for “the most comprehensive of rights and the right most valued by civilized men”—“the right to be let alone.” *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting). This includes “the individual interest in avoiding disclosure of personal matters,” *Whalen v. Roe*, 429 U.S. 589, 599 (1977). “[T]here can be no question that . . . medical records, which may contain intimate facts of a personal nature, are well within the ambit of materials entitled to privacy protection.” *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d

Cir. 1980); *see also In re Search Warrant (Sealed)*, 810 F.2d 67, 71 (3d Cir. 1987) (“medical records are clearly within this constitutionally protected sphere”). In the First Circuit, “courts have identified two clusters of personal privacy rights recognized by the Fourteenth Amendment. One bundle of rights relates to ensuring autonomy in making certain kinds of significant personal decisions; the other relates to ensuring confidentiality of personal matters.” *Vega-Rodriguez v. Puerto Rico Telephone Co.*, 110 F.3d 174, 182–83 (1st Cir. 1997); *Borucki v. Ryan*, 827 F.2d 836, 840 (1st Cir. 1987).

“The autonomy branch of the Fourteenth Amendment right to privacy is limited to decisions arising in the personal sphere—matters relating to marriage, procreation, contraception, family relationships, child rearing, and the like.” *Vega-Rodriguez*, 110 F.3d at 183. The confidentiality branch, also referred to as “informational privacy,” *see National Aeronautics and Space Administration v. Nelson*, 562 U.S. 134, 146 (2011), “includes ‘the individual interest in avoiding the disclosure of personal matters ...’” *Daury v. Smith*, 842 F.2d 9, 13 (1st Cir. 1988) (citing *Whalen*, 429 U.S. at 599).

District courts in the First Circuit have had no trouble concluding that “forced disclosure of plaintiffs’ transgender status violates their constitutional right to decisional privacy. Much like matters relating to marriage, procreation, contraception, family relationships, and child rearing, ‘there are few areas which more closely intimate facts of a personal nature’ than one’s transgender status.” *Arroyo Gonzalez v. Rossello Nevares*, 305 F. Supp. 3d 327, 333 (D.P.R. 2018) (quoting *Doe v. Town of*

Plymouth, 825 F. Supp. 1102, 1107 (D. Mass. 1993)). The same court concluded that requiring a person to disclose their transgender status separately violates their “constitutional right to informational privacy. Such forced disclosure of a transgender person’s most private information is not justified by any legitimate government interest.” *Id.*

Moreover, patients, like the children the Child Advocate represents here, have a reasonable expectation of privacy in their medical records such that “unlike prescription drug records, medical records are not subject to pervasive regulatory disclosures under both federal and state law.” *Ricco Jonas*, 24 F.4th at 736. The medical records DOJ seeks to obtain with the Subpoena are not mere prescription drug records; rather, they contain “sensitive medical history and other information, . . . patients’ complaints and symptoms, and the patients’ family members.” *Id.* (cleaned up).

The records sought here are thus precisely the sort the Constitution protects. They contain the most intimate details of children’s mental health, gender identity, sexual development, family relationships, trauma histories, and struggles with their sense of self. The Subpoena would, by definition, force the children whose records DOJ would obtain to disclose their transgender status, and so violates their constitutional right to privacy. In practice, the breadth of the information DOJ seeks also means that any anonymization of these records would be insufficient and ineffective because the volume and detail in those records would inevitably point to a particular child and their family. See *Nw. Mem’l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004) (holding that redaction of medical records would not be sufficient to protect

patients' privacy interests). Moreover, the information sought is so deeply personal that "[e]ven if there were no possibility that a patient's identity might be learned from a redacted medical record, there would be an invasion of privacy." *Id.*

The DOJ has also announced its intention to "partner with state attorneys general to identify leads [and] share intelligence. . . ." ⁴³ Since there is no explicit prohibition on the sharing of information accessed through a subpoena permitted by 18 U.S.C. § 3486, identifying leads and sharing intelligence may mean providing patient information and data to state law enforcement officials. *See* 18 U.S.C. § 3486(e)(1); 5 U.S.C. § 552a(b)(7) (Privacy Act provision permitting disclosure to state law enforcement officials). Such information sharing is terrifying to any parent or guardian who sought medically approved and legal care for their child, particularly now that the Administration is characterizing this care as child abuse and some states are attempting to criminally prosecute parents for obtaining care for their children. ⁴⁴ And even if the government does not publicly disclose the records or share them with hostile state governments, the harm from disclosure to DOJ agents and prosecutors is substantial. These children will know that federal agents, hostile to their medical treatment, have access to their most intimate information.

⁴³ *Memorandum For Select Component Heads: Preventing the Mutilation of American Children*, Office of the Attorney General (Apr. 22, 2025), <https://www.justice.gov/ag/media/1402396/dl> (last visited May 1, 2026).

⁴⁴ Ken Paxton, Attorney General of Texas, *Opinion No. KP-0401, Whether certain medical procedures performed on children constitute child abuse* (Feb. 18, 2022) ("Texas law also imposes a duty on [the Texas Department of Family and Protective Services] to investigate the parents of a child who is subjected to these abusive gender-transitioning procedures"), <https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf> (last visited May 1, 2026).

Compelling disclosure of records that identify individuals based on their transgender status also offends the Equal Protection Clause. *Romer v. Evans*, 517 U.S. 620 (1996), establishes that government actions singling out a class for adverse treatment cannot survive even rational basis review when motivated by animus or moral disapproval. 517 U.S. at 632-35. A subpoena that targets patients because of their transgender identity serves no legitimate investigatory purpose; instead, it functions as an expression of disfavor toward a protected class. The Subpoena should be quashed for this independent reason.

B. Disclosure Would Harm the Physician-Patient Relationship.

Disclosure of the records DOJ seeks in the Subpoena would also severely damage the physician-patient relationship—not just for the children whose records are sought, but for all patients and families considering seeking care. Confidentiality is central to the physician-patient relationship because patients rightly assume that, in general, sensitive personal information they share with their providers will not be disclosed further. The relationship depends on trust. If patients fear that private and sensitive information is subject to collection and review by federal law enforcement, it is reasonable to expect that they will be less likely to pursue necessary medical treatment, or to be candid with their medical providers.

The compelled exposure of these children’s medical records would thus chill their exercise of constitutionally protected rights to seek medical treatment and to associate with providers who deliver that care. The chilling effect therefore extends beyond patients of RI Hospital. When families considering medical care for gender

dysphoria for their children learn that seeking such care may result in a federal investigation, they may delay or forgo necessary medical treatment. Some may even avoid seeking any mental health care for fear it could lead to unwanted scrutiny. This undermines public health and puts vulnerable children at risk.

C. DOJ Has No Legitimate Need for the Information It Seeks.

DOJ cannot articulate any legitimate need to obtain children's identities and comprehensive medical records for every patient who received either puberty blockers or hormone therapy during the last five years. As discussed above, if DOJ were investigating off-label promotion by manufacturers, it would not need patient records at all. If it were investigating billing practices, anonymized records would suffice. There is no compelling explanation for why DOJ needs to know the names, addresses, and Social Security numbers of minor patients, or to read the intimate details of their mental health assessments. In fact, as part of related litigation, DOJ has already failed to identify a particular need for patient and parent information, instead making general assertions that "the acts being investigated here are, at base, statutory violations commonly investigated by the Government in many contexts over many decades" and that "[t]he document requests here are common in such investigations." *In Re: Subpoena No. 25-1431-014*, 2:25-mc-00039, ECF No. 13 at 7 (E.D. Pa. July 8, 2025). That generalized justification for the Subpoena cannot outweigh the core constitutional privacy rights it would invade.

DOJ has statutory authority to investigate criminal health care offenses and may subpoena records in pursuit of legitimate investigations of those offenses. The Subpoena in this case, to the contrary, represents a barely disguised political agenda

in search of a healthcare offense. In sum, “DOJ issued the subpoena first and searched for a justification second.” *QueerDoc*, 807 F. Supp. 3d at 1303. DOJ is seeking to “use its subpoena power to go on a fishing expedition” through “an astonishingly broad array of documents and information that are virtually unlimited in scope.” *In re Admin. Subpoena No. 25-1431-019*, 800 F. Supp. 3d at 238. The Court should not permit it to do so, and should quash the Subpoena.

CONCLUSION

For all these reasons, the Child Advocate respectfully requests that the Court protect the rights of Rhode Island’s children and quash the Subpoena in its entirety. In the alternative, the Child Advocate requests that the Court order Rhode Island Hospital not to comply with the Subpoena, or at a minimum not to provide any information regarding names, dates of birth, Social Security numbers, addresses, parent/guardian information, diagnoses, clinical assessments, consent forms, billing records linked to identified patients, or other personal health information.

Pursuant to LR Cv 7(c), counsel requests oral argument for this motion.

Dated: May 4, 2026

Respectfully submitted,

/s/ Miriam Weizenbaum

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2026, I electronically filed the within Motion to Quash and it is available for viewing and downloading from the Court's CM/ECF System, and that the participants in the case that are registered CM/ECF users will be served electronically by the CM/ECF system.

In addition, I served the within Motion via electronic mail to:

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