

DOJ Orders Investigations into Gender-Affirming Care for Minors

Insights

05.08.25

On April 22, 2025, Attorney General Pam Bondi by issued a memorandum (the "Memo") directing the Department of Justice ("DOJ") to investigate providers of gender-affirming care to minors. Drafted in response to Executive Order 14187, issued by President Trump ("Executive Order"), the Memo directs prosecutors to conduct civil and criminal investigations and pursue charges based on a novel interpretation of a law banning "female genital mutilation," the Food Drug & Cosmetics Act (the "FDCA"), and the False Claims Act (the "FCA"). Taken together, the Executive Order and the Memo represent a sharp departure from the prior administration's guidance regarding gender-affirming care, raising the prospect of future investigations or litigation for providers.

The Memo

In the Memo, AG Bondi expresses concern over the long-term effects of gender-affirming care for children and the role of medical professionals in promoting such treatments. While AG Bondi does not focus on all potential treatments for gender dysphoria, (e.g., psychotherapy, counseling) she does describe the provision of gender affirming care as "fraud" and "exploitation" perpetrated by the medical community at the expense of the children receiving care and their families.[1]

To address these concerns, AG Bondi directs DOJ attorneys and federal agencies to:

- Investigate violations of the FDCA: the FDCA includes a criminal provision for "misbranding." While physicians can prescribe an FDA-approved medication for any medically-necessary purpose, on or off-label, a pharmaceutical company cannot market a drug beyond its approved indications. In the Memo, AG Bondi encourages the DOJ to investigate claims about the on or off-label use of puberty blockers and sex hormones, such as Lupron, used in gender-affirming care.
- Pursue investigations under the FCA: AG Bondi also encourages
 prosecutors to investigate claims for non-covered services that were
 coded inappropriately (such as coding treatment for gender dysphoria as
 early-onset puberty when that was not an appropriate diagnosis), while
 encouraging qui tam whistleblowers to report alleged violations.
- Investigate and prosecute suspected cases of female genital mutilation ("FGM"): AG Bondi encourages investigations under a federal criminal statute prohibiting FGM, which is defined as "any procedure

PROFESSIONAL



DAVID S. SCHUMACHER Partner Boston



ALICIA MACKLIN
Partner
Los Angeles



HEATHER M. ROMERO Associate Boston



ANDREW HAYES
Associate
Boston
Washington, D.C.



MARTHA P. CRAMER Associate Washington, D.C.



performed for non-medical reasons that involves partial or total removal of, or other injury to, the external female genitalia" but excludes a "surgical operation" that is "necessary to the health of the person on whom it is being performed, and is performed by a person licensed in the place of its performance as a medical practitioner." [2] We are unaware of prosecutions under this statute regarding gender-affirming care. In the Memo, AG Bondi also calls for legislative efforts to revise this statute to "enhance protections" for minors.

- Cease reliance on the World Professional Association for Transgender Health ("WPATH") guidelines .
- **Establish a federal and state coalition** to build cases against violations of federal or state laws banning FGM and related practices, such as Alabama's Vulnerable Child Compassion and Protection Act.
- **Promote new legislation** creating a private right of action for children and parents against medical professionals for chemical and surgical "mutilation," including "a long statute of limitations and retroactive liability." [3]

Administration Efforts to Restrict Gender-Affirming Care

The Memo is part of a broader coordinated strategy across the federal government in response to the Executive Order, entitled "Protecting Children from Chemical and Surgical Mutilation," which was issued on January 28, 2025. [4] In the Executive Order, President Trump defines "chemical and surgical mutilation" as synonymous with certain forms of "gender affirming-care," including the use of puberty blockers and sex hormones, and surgical procedures. [5]

The Executive Order also states that "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." [6] President Trump further instructs DOJ, the Department of Health and Human Services ("HHS") and other agencies to utilize regulatory and enforcement authority to restrict access to gender-affirming care for minors. Finally, in the Executive Order, President Trump directed HHS to restrict gender-affirming care through Medicare or Medicaid conditions of participation or conditions for coverage. [7]

On April 28, 2025, the White House issued a public <u>Fact Sheet</u> entitled "Report to the President on Protecting Children from Surgical and Chemical Mutiliation" ("Report"). The Report described actions taken in the three months since the Executive Order, including enforcement actions directed by State Attorneys General and the Food & Drug Administration (the "FDA"). Recent actions include:

- Review of Standards: On April 30, 2025, HHS released a "Review of Evidence and Best Practices" for gender-affirming care, as part of an effort to end reliance prior guidelines that the Administration deems "junk science." [8] Of note, the American Academy of Pediatrics and other organizations have expressed significant concerns about this report, including that it "misrepresents the current medical consensus and fails to reflect the realities of pediatric care." [9]
- **Grant Funding Elimination**: The National Institutes for Health is pursuing "accountability and transparency in all taxpayer-funded studies," such as by identifying instances where data has been "withheld from the public for political reasons." HHS intends to eliminate grant funding related to gender-affirming care for minors.
- **Increased Provider Scrutiny**: The Centers for Medicare and Medicaid Services ("CMS") notified providers of future efforts to align official policy toward the Executive Order, including through survey, certification, and enforcement programs.
- **Non-Essential Benefit Reclassification**: CMS issued a proposed rule prohibiting insurers in the Affordable Care Act ("ACA") Marketplaces from providing coverage for gender affirming care as an essential health benefit starting in 2026.
- **Guidance to State Medicaid Programs**: CMS sent a Dear Medicaid Directors letter, stating that there is a "lack of reliable evidence" showing the "long-term benefits" of gender-affirming care for minors. In the letter, CMS warns that the Administration views gender-affirming care as incongruous with their "responsibility to ensure that Medicaid payments are consistent with quality of care and that covered services are provided in a manner consistent with the best interest of recipients."[10]



The Executive Order has been challenged in court in two pending cases for interfering with federal research or education grants. In both cases, federal judges partially enjoined the Executive Order. [11] However, the injunctions do not address certain directives to HHS in the Executive Order, including modification of Medicare or Medicaid conditions of participation or conditions for coverage, clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs, mandatory drug use reviews, or issuance of quality, safety, and oversight memoranda. [12]

Trends to Consider

Though the Memo is facially concerned with gender-affirming care for minors, the directives may also impact adult care. For example, the off-label hormone treatments targeted by the Memo may be used into adulthood. Additionally, the WPATH guidelines that DOJ will no longer rely on and that are addressed in HHS' Review of Evidence and Best Practices are used as a standard of care for all ages.

Beyond federal enforcement, 27 states have enacted laws that limit minors' access to gender-affirming care. These states are also likely to join the coalition contemplated by the Memo, and providers in these states should be particularly alert to emerging enforcement trends. At the same time, numerous states have expressed that clinicians should continue providing gender affirming care for minors and warned that refusal to provide such care could run afoul of protective laws that prohibit discrimination based on gender identity and that seek to protect access to care. Providers must be cognizant of the tension between federal efforts and state laws, as well.

Takeaways for Providers

Providers should take the enforcement threats embodied in the Memo and Executive Order seriously and consult with legal counsel and compliance departments about any potential impact on their practice. In particular:

- **Providers Can Mitigate Risk Through Robust Compliance.** Providers of certain types of gender-affirming care can expect increased scrutiny from the DOJ. Proactively conducting internal audits, ensuring accurate clinical documentation, and returning any verified overpayments can help mitigate the impact of federal investigations under the FCA. Such measures should assess compliance with both federal and state law.
- Off-Label Use of Puberty Blockers is Not Illegal Per Se. The use of medications off-label is a common and accepted practice in the medical community. Off-label use of pharmaceuticals and medical devices is not inherently controversial and is often based on substantial clinical evidence and professional guidelines. Determining when off-label use is appropriate is within a practitioner's medical judgment.
- Federal Regulation of Medical Practice is Limited. The Supreme Court has repeatedly held that the regulation of medical practice is traditionally reserved for states under the 10th Amendment. [13] Practitioners should therefore educate themselves on state-level restrictions on gender-affirming care and seek counsel on the subject.

 Practitioners working across state lines, either via telemedicine or by travelling across a physical border, should ensure they understand legal requirements for and restrictions on care provided in the state where a patient is located. Providers should also keep in mind that DOJ may still pursue investigations or enforcement actions despite a provider's compliance with state-specific standards.
- [1] Memo, pp. 1-2.
- [2] 18 U.S.C. § 116. Violation of this law is a felony, carrying a maximum prison sentence of 10 years.
- [3] Memo, p. 5.
- [4] Executive Order, Sec. 8.
- [5] Executive Order, Sec. 2.
- [6] Executive Order, Sec. 1.



- [7] Executive Order, Sec. 5.
- [8] Executive Order Sec. 2; https://opa.hhs.gov/gender-dysphoria-report
- [9] https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-hhs-report-treatment-for-pediatric-gender-dysphoria/
- [10] CMS Letter, p. 1, https://www.cms.gov/files/document/letter-stm.pdf.
- [11] See PFLAG, Inc. v. Donald J. Trump, 1:25-cv-00337 (D. Maryland); Washington, et al. v. Trump, et al., 25-807 (9th Cir.).
- [12] Executive Order at Sec. 5.
- [13] Reno v. Condon, 528 U.S. 141 (2000); Printz v. United States, 521 U.S. 898 (1997); New York v. United States, 505 U.S. 1 (1992).

RELATED CAPABILITIES

Government Investigations

False Claims Act

Medicare and Medicaid Audits, Appeals, and Reimbursement Litigation

Compliance

Hospitals and Health Systems