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DOJ Targets Gender?Affirming Care under FDCA and FCA: Scrutinizes Off?Label Drug Use and False Diagnosis Codes

Health Care Law Brief on **July 16, 2025**

Last month, the United States Department of Justice ("DOJ") issued its "Civil Division Enforcement Priorities" memorandum, memorializing a shift from its predecessor administration's policy on gender-affirming healthcare ("DOJ Memo"). The DOJ Memo portends a significant rise in government investigations and False Claim Act ("FCA") liability for suppliers and providers that may be linked to gender affirming care.

The DOJ Memo instructs the DOJ's Civil Division to "use all available resources" to investigate physicians, pharmaceutical companies, hospitals, and "other appropriate entities" for potential violations of the Food, Drug, and Cosmetic Act ("FDCA") in connection with the sale or distribution of drugs used in gender-affirming care. Furthermore, it directs the DOJ to "aggressively pursue" violations of the FCA against health care providers who allegedly fraudulently bill Federal health care programs, including by specific reference Medicaid, for gender-affirming care.

When viewed in context of the relevant Executive Orders issued earlier this year, the DOJ Memo appears to be an expected, incremental step outlining enforcement of the current administration's priorities. Executive Order14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 30, 2025) ("EO 14168"), which established a government policy of recognizing two sexes: male and female, specifically prohibits the use of federal funds to promote "gender ideology." Based on EO 14168, the DOJ Memo directs the DOJ to investigate providers under the FCA who submit Medicaid claims with "false diagnosis codes" in an attempt to circumvent state and federal bans on certain gender-affirming care.

The FDCA directive, in particular, is closely tied to Executive Order 14187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8771 (Feb. 3, 2025), which aims to prevent entities from misleading the public about the effects of gender-affirming health care. The DOJ Memo instructs the DOJ to specifically target entities that manufacture or distribute drugs used in gender transitions, even if those drugs are not labeled for such use. Under the Trump administration's interpretation of the FDCA, promoting the off-label use of drugs to "facilitate a child's so-called 'gender transition'" may expose pharmaceutical companies or pharmacies to investigation.[1] Thus, the pharmaceutical industry should be aware of investigative risks that could emanate from products that could be used in gender-affirming care, such as androgen blockers labeled to treat prostate cancer.[2]

In addition, on July 2, 2025, as a follow-up to the DOJ Memo, the DOJ and United States Department of Health and Human Services announced the continuation of a joint "working group" aimed at enforcing the FCA within the health care industry. The announcement emphasizes that the enforcement priorities outlined in the DOJ Memo are central to the working group's objective. As such, the working group will also be involved in investigating FCA violations related to gender-affirming care. Additionally, the working group encourages *qui tam* filings, inviting private whistleblowers to report providers of gender-affirming care who submit such claims to the government, e.g., Medicaid claims with false diagnosis codes.

The DOJ has swiftly initiated investigations into potential violations of the FCA. For example, on July 9, 2025, it announced that 20 subpoenas had been sent to "doctors and clinics involved in performing transgender medical procedures on children." While the recipients were not disclosed, providers should take note of how quickly the DOJ is taking such action.

Additionally, enforcement of the DOJ Memo may not be limited to civil actions. EO 14187 directed the DOJ to consider using 18 U.S.C. 116 to criminally prosecute providers for providing gender-affirming health care items and services. Originally enacted in 1996, that statute was amended in 2021 after a federal judge struck down the original version for exceeding the limits of the Commerce Clause under the United States Constitution. The statute includes an exemption for procedures deemed "necessary to the health" of the patient. However, it remains unclear how courts would interpret this exemption in cases involving gender-affirming care post-DOJ Memo.

Overall, the DOJ Memo underscores the heightened legal risks that gender-affirming care now poses for participants in the health care industry that receive Federal funding. Specifically, pharmaceutical companies face uncertainty regarding the off-label use of drugs in gender-affirming care under the FDCA. Health care providers should also proceed with caution when treating Medicaid patients as submitting diagnosis codes associated with or adjacent to gender-affirming care could be construed as fraudulent under the FCA.

Proskauer's Health Care Group has extensive experience in matters involving the FCA and FDCA, and is well-positioned to assist participants in the health care industry with navigating the complex, ever-changing regulatory landscape.

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Special thanks to summer associate Nathaniel Perkoski for his contribution to this post.

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[1] *See* Memorandum from Attorney General, *Preventing the Mutilation of American Children*, at 4 (April 22, 2025) ("Even if otherwise truthful, the promotion of off-label uses of hormones, including through informal campaigns like those conducted by sales reps or under the guise of sponsored continuing medical education courses, run afoul of the FDA's prohibitions on misbranding and mislabeling.").

[2] *See* Columbia Doctors, *Estrogen and Anti-Androgen Hormone Therapy for Gender Affirmation Information* (July 10, 2025), https://www.columbiadoctors.org/health-library/article/estrogen-anti-androgen-hormone-tl

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