ETHICS AND PUBLIC POLICY CENTER

March 18, 2025

Via Federal eRulemaking Portal

Derek S. Maltz
Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: DOJ Drug Enforcement Administration Proposed Rule, "Special Registrations for Telemedicine and Limited State Telemedicine Registrations," RIN: 1117-AB40, 90 Fed. Reg. 6541

Dear Acting Administrator Maltz:

We are scholars at the Ethics and Public Policy Center (EPPC). Eric Kniffin is a member of EPPC's Administrative State Accountability Project (ASAP) and a former attorney in the U.S. Department of Justice's (DOJ) Civil Rights Division. Rachel Morrison is the director of EPPC's ASAP and a former attorney with the Equal Employment Opportunity Commission. We write to offer public comment regarding the Department of DOJ Drug Enforcement Administration's (DEA) proposed rule, "Special Registrations for Telemedicine and Limited State Telemedicine Registrations" (Proposed Rule).[1]

We do not take a position on any particular aspect of the Proposed Rule and its proposed regulations on access to controlled substance medications via telemedicine. Rather, we write to encourage DEA to ensure, as it regulates telemedicine and medicine more broadly, that it clearly affirms the rights of states to regulate the practice of medicine.

The Tenth Amendment reserves to the states and the people "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States." Federalism plays an essential role in protecting the rule of law and the liberty of the people by ensuring that the most important governmental decisions are made by more accountable local officials. While the federal government has a legitimate role in regulating medicine, federal laws and regulations should leave states free to pass their own laws and regulations on matters like telemedicine so that they can adapt practices to their unique needs and circumstances.

[1] 90 Fed. Reg. 6541 (Jan. 17, 2025), https://www.federalregister.gov/documents/2025/01/17/2025-01099/special-registrations-for-telemedicine-and-limited-state-telemedicine-registrations.

A. DEA policies should reflect the Trump Administration's efforts to protect the right of states to regulate the practice of medicine.

In recent years, the United States Supreme Court has heard many cases that concern states' rights to regulate the practice of medicine. For example, *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), affirms that the U.S. Constitution does not prohibits states from regulating medical procedures that intentionally kill innocent unborn human life. The end of the Court's opinion affirms that the Constitution leaves states free to pursue their own "legitimate interests," including "respect for preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the preservation of discrimination on the basis of race, sex, or disability." *Id*. at 301. President Trump affirmed during his campaign that his Administration would respect states' rights in this regard. He said that "the states will determine by vote or legislation" what that their abortion policy would be. "And whatever they decided must be the law of the land—in this case, the law of the state."[2]

After the Supreme Court decided *Dobbs*, the Biden-Harris Administration, understanding that neither Congress nor most states agreed with its extreme pro-abortion policies, attempted to use the administrative state (including DOJ) to override states' rights to regulate abortion procedures.[3] One of the examples we have cited is DOJ's claim that EMTALA requires physicians to perform or complete abortions, even when such practices are illegal under state law.[4] The Biden-Harris Administration sued the State of Idaho over this issue and the case went all the way to the Supreme Court, which dismissed the case as improvidently granted.[5] Thankfully, earlier this month the Trump Administration agreed to drop the case and the court has issued a dismissal, allowing Idaho to regulate abortion.[6]

States' right to regulate the practice of medicine is also at issue in *United States v. Skrmetti* (U.S. No. 23-477), which is now pending before the Supreme Court. At oral argument in December, the previous administration argued that the Fourteenth Amendment's Equal Protection Clause prohibits Tennessee (and, by extension, the 26 other states that have passed similar laws) from protecting children from so-called "gender transition" procedures. But on February 7, the DOJ told the Supreme Court that, "[f]ollowing the change in Administration," the United States' position has changed: "The Department has now determined that [the challenged Tennessee law] does not deny equal protection on account of sex or any other characteristic."[7]

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[2] *See* Rachel N. Morrison & Eric Kniffin, *Leaving Abortion to the States Requires Federal Action*, WSJ, Apr. 23, 2024, https://www.wsj.com/articles/leaving-abortion-to-the-states-requires-federal-action-regulation-a97f704e.
[3] *See* Br. of EPPC as Amicus Curiae in *Tennessee v. HHS*, No. 24-5220 (6th Cir., Oct. 16, 2024) (summarizing Biden Administration executive actions that attempted to override state pro-life laws), https://eppc.org/publication/eppc-scholars-file-amicus-brief-supporting-tennessees-title-x-funding/.
[4] *Id*. at 5-6.
[5] *Moyle v. United States*, 603 U.S. 324 (2024).
[6] Order, *United States v. Idaho*, No. 23-35440 (9th Cir. March 13, 2025), https://storage.courtlistener.com/recap/gov.uscourts.idd.50547/gov.uscourts.idd.50547.183.0.pdf.
[7] Letter from Deputy Solicitor General Curtis E. Gannon to the Supreme Court of the United States (Feb. 7, 2025), https://www.supremecourt.gov/DocketPDF/23/23-477/342223/20250207133625781_Letter%2023-477.pdf.

We encourage DEA to ensure that its efforts to oversee the practice of telemedicine uphold the Trump Administration's strong track record of letting states exercise their inherent police powers over the practice of medicine, including their ability to determine how best to protect the health of unborn children, pregnant women, and minors struggling to accept their sexed bodies.

B. As related to telemedicine, DEA should uphold states' rights to regulate the distribution of abortion drugs.

One area where telemedicine and abortion policy overlap is the subject of abortion drugs. Just as states have restricted the distribution of powerful pain-killers to protect the health of their citizens from the ongoing opioid crisis,[8] many states have prohibited the sale and use of the abortion drug mifepristone to advance the public interest in protecting unborn life and women's health.[9] Although mifepristone is not currently a controlled substance under federal law, and thus not subject to the Proposed Rule, mifepristone is deadly for unborn children and dangerous for many of the women who use it. We are concerned that if abortion is categorized as a controlled substance or if similar telemedicine regulations are adopted for other classes of drugs, abortion drugs could become readily available via telemedicine, which would open the door to increased risks for women's health and coercion.

Recent medical research from the United Kingdom confirms that mifepristone is a dangerous drug and there are important public health reasons for ensuring that women have the benefit of an in-person visit before receiving a prescription for a chemical abortion. As British researcher and physician Calum Miller has explained,

> During the COVID-19 pandemic, a small minority of countries permitted abortion providers to send abortion pills—usually mifepristone and misoprostol—by post to women after a remote consultation by video or telephone (hereafter, "telemedicine" refers to either)—that is, without any in-person contact throughout the process. This was an unprecedented move since full telemedicine had not been studied in legal, experimental conditions prior to this… In the United Kingdom… ambulance calls and responses relating to medical abortion also increased dramatically between 2018 and 2021, following the introduction of [chemical abortion] at home and then full telemedicine.[10]

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[8] Prescribing Policies: States Confront Opioid Overdose Epidemic," National Conference of State Legislatures, Aug. 2017, https://www.legis.iowa.gov/docs/publications/SD/864399.pdf.

[9] *See* Steve Gorman, "Louisiana becomes first US state to classify abortion pills as controlled substances," Reuters (May 24, 2024) https://www.reuters.com/world/us/louisiana-governor-signs-bill-classifying-abortion-pills-controlled-substances-2024-05-24/.

[10] Calum Miller, "Telemedicine Abortion: Why It Is Not Safe for Women," in Nicholas Colgrove, ed., *Agency, Pregnancy and Persons: Essays in Defense of Human Life* at 288, 296 (2023) available at https://www.routledge.com/Agency-Pregnancy-and-Persons-Essays-in-Defense-of-Human-Life/Colgrove-Blackshaw-Rodger/p/book/9781032020419?srsltid=AfmBOoocGJIcn49Q0xp-TlkbErklNmTFPOvzkzO0WgVvDAZD3jnnJsLc. Even the most zealous advocates for mifepristone did not countenance that: "Prescribing RU 486 will maintain the same doctor-patient relationship that accompanies the use of an antibiotic or any drug." Lawrence Lader, *A Private Matter*, 17 (Prometheus Books 1995).

Further, British researchers, "using [their] rights under the Freedom of Information Act[,] . . . asked each of the ten [National Health Service] Ambulance Trusts in England to provide data related to the number of emergency ambulance responses made when the caller indicated complications arising from the use of abortion pills, a combination treatment of mifepristone and misoprostol. Data was requested for three time periods: A—during 2018, when all medical abortions were provided in a clinic; B—during 2019, when women were able to self-administer misoprostol (the second part of the combined treatment) at home, after having received the mifepristone (the first part of the combined treatment) at an abortion clinic; C—from April 2020, when women were able to self-administer both mifepristone and misoprostol at home."[11] These researchers found "that emergency ambulance responses for complications arising after a medical abortion are three times higher for women using pills-by-post at home, compared to those who have their medical abortion in a clinic."[12] "In a related freedom of information investigation, [they] found that complications arising from the failure of medical abortion treatment result in 590 women presenting at the emergency department of their local NHS hospital in England every month. The treatment failure rate is 5.9%, 1-in-17."[13]

In 2000, when the Food and Drug Administration's (FDA) first approved mifepristone for use as an abortifacient in the United States, a woman seeking a chemical abortion was required to visit the doctor three times and comply with other limitations and protections known as Risk Evaluation and Mitigation Strategies (REMS). These REMS were required because the FDA approved mifepristone under Subpart H, which allows for expedited approval of treatments with a meaningful benefit over existing treatments for serious or life-threatening conditions. The FDA granted approval of mifepristone for use as an abortifacient even though abortion does not treat a medical condition and pregnancy is not a serious or life-threatening condition.

In 2016, however, the FDA—without justification—began to loosen the restrictions required by Subpart H. The FDA dropped the required in-person medical visits from three to one.[14] In 2021, the FDA dropped the remaining in-person visit requirement, meaning that a woman can now obtain mifepristone through the mail with no in-person examination, sonogram, or laboratory analysis.[15] In 2023, the FDA allowed mail-order mifepristone distribution, meaning a pregnant woman may have no contact with a doctor during the process of obtaining a chemical abortion.

Prescribing chemical abortion drugs via telemedicine exposes women to several risks. One of the most significant of these risks is a ruptured ectopic pregnancy. Chemical abortion is extremely dangerous in cases of ectopic pregnancy. Ultrasounds, which require an in-person assessment, are critical for identifying gestational age and in ruling out ectopic pregnancies. The current REMS requires that the prescriber have the "[a]bility to diagnose ectopic pregnancies,"

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[11] Kevin Duffy, "Emergency Ambulance Responses Three Times Higher for Pills-by-Post" at 1 Percuity (Nov. 16, 2021) https://percuity.blog/2021/11/16/emergency-ambulance-responses-three-times-higher-for-pills-by-post/.
[12] *Id.*
[13] *Id*.
[14] Information on Mifeprex Changes and Ongoing Monitoring Efforts, Government Accountability Office at 7 (Mar. 2018) https://www.gao.gov/assets/gao-18-292.pdf.
[15] Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, U.S. Food and Drug Administration (Mar. 2023) https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-andproviders/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

but this offers women no protection as the FDA does not require the mother to see the prescriber in person.[16]

Without ensuring that women have the in-person visit necessary to accurately assess gestational age, fetal life, and pregnancy location, a woman is unable to provide informed consent for the specific benefits, risks, and alternatives relevant to her situation. The risks of complications following a chemical abortion increase with gestational age and without an early ultrasound, it is impossible to accurately determine gestational age. It is expected that "1-in-17 women using the abortion pills at home, will subsequently need hospital treatment for complications arising from the medical abortion treatment failure, presenting with retained products of conception and/or hemorrhage."[17]

Telemedicine has other important limitations that may undermine states' interest in protecting maternal health. A telemedicine visit may not allow for a thorough discussion of the patient's medical history or assessment of her needs, potentially missing important details that could also impact the procedure's safety and the ability of the woman to provide informed consent. Telemedicine also makes it more difficult for a provider to assess whether a woman is not being coerced into performing an abortion against her will.

For all these reasons, the DEA should also ensure that its final rule does not infringe on states' right to make their own judgment as to whether, and if so under what conditions, pregnant women may obtain mifepristone through telemedicine.

C. DEA should ensure its regulations do not permit for the "chemical … mutilation" of children through telemedicine.

On January 28, 2025, President Trump issued an executive order, titled "Protecting Children from Chemical and Surgical Mutilation," aimed at addressing the growing number of children harmed by "the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions."[18]

The EO defines "chemical and surgical mutilation" as including "the use of sex hormones, such as …testosterone, to align an individual's physical appearance with an identity that differs from his or her sex." Testosterone, a steroid, is a controlled substance and thus subject to the Proposed Rule.[19]

The executive order established 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."[20] We urge DEA to ensure that its proposed rule on telemedicine of

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[16] Risk Evaluation and Mitigation Strategy (REMS) Singla Shared System for Mifepristone 200MG, Food and Drug Administration at 1, https://www.fda.gov/media/164651/download?attachment.
[17] FOI Investigation into Medical Abortion Treatment Failure at 4 Percuity (Oct. 2021) https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf.
[18] 90 Fed. Reg. 8771 (Jan. 28, 2025), https://www.federalregister.gov/documents/2025/02/03/2025-02194/protecting-children-from-chemical-and-surgical-mutilation.
[19] The Anabolic Steroids Control Act of 1990 placed testosterone in Schedule III of the Controlled Substances Act.
[20] *Id.*

controlled substances aligns with the policy of the EO and does not support the access to testosterone for transition purposes via telemedicine.

Conclusion

For the reasons stated above, we urge DEA to carefully examine the Proposed Rule in light of the President's commitment to respecting states' right to regulate the practice of medicine. A one-size-fits-all approach to telemedicine could prevent states from thoughtfully protecting the rights and interests of their own citizens and would deprive them of the authority reserved to them by the Constitution. This is an important area of state authority, particularly when it comes to protecting unborn human life and children from gender ideology.

As DEA takes public comments into account, we ask that you to ensure that any final version of this rule respects the authority of states to protect unborn human life, protect mothers from the distribution of dangerous abortion drugs via telemedicine, and protect children from accessing testosterone for transition purposes via telemedicine.

Sincerely,

Eric Kniffin, J.D.
Fellow
Administrative State Accountability Project
Ethics & Public Policy Center

Rachel N. Morrison, J.D.
Fellow and Director
Administrative State Accountability Project
Ethics & Public Policy Center