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**MONTANA FIRST JUDICIAL DISTRICT COURT,**
**COUNTY OF LEWIS & CLARK**

ALL FAMILIES HEALTHCARE; BLUE MOUNTAIN CLINIC; AND HELEN WEEMS, MSN APRN-FNP, on behalf of themselves, their employees, and their patients,

Plaintiffs,

vs.

STATE OF MONTANA; MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; and CHARLIE BRERETON, in his official capacity as Director of the Department of Public Health and Human Services,

Defendants.

Cause No.: DDV-2023-592
Hon. Christopher Abbott

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION**

## INTRODUCTION

Plaintiffs All Families Healthcare, Blue Mountain Clinic, and Helen Weems, APRN-FNP, offer reproductive health care, including abortion care, in Montana and seek a temporary restraining order and preliminary injunction to once again bar enforcement of Montana House Bill 937 and the final rules implementing the Act (together "the Scheme").[1]

Last year, Plaintiffs filed this challenge to HB 937, which prohibits any person from operating or advertising an abortion clinic unless licensed by Defendant Department of Public Health and Human Services ("DPHHS"). On the eve of HB 937 taking effect on October 1, 2023, and in the absence of even proposed rules implementing the law, this Court entered a temporary restraining order, barring the State from enforcing the licensure requirement. TRO and Order to Show Cause, Dkt. No. 48, Sept. 27, 2023. That order expires on November 19, 2024. *See* Order Extending TRO and Vacating Prelim. Inj. Hr'g, Dkt. No. 54, Oct. 18, 2023 (TRO expires 60 days following the effective date of final rules, which were adopted September 20, 2024, with an immediate effective date). All Families and Blue Mountain do not and cannot meet certain requirements in the Scheme, and certain parts of the Scheme would eliminate access to telehealth abortion. The clinics applied for licenses and requested waivers from some requirements on October 1, 2024. As the expiration of the TRO approaches, impending enforcement of the Scheme would end or significantly curtail access to abortion and violate the Montana Constitution.

The Scheme is just the latest of the State's many efforts to violate Montanans' fundamental rights to privacy, due process, and equal protection by singling out abortion for unique, additional,

[1] *See* H.B. 937, 2023 Mont. Laws 492 (attached as Exhibit A to Proposed First Amended Complaint); Notice of Public Hearing on Proposed Adoption, MAR Notice No. 37-1052 (July 26, 2024), https://dphhs.mt.gov/assets/rules/37-1052pro-arm.pdf ("Proposed Rules") (attached as Ex. B to Proposed First Amended Complaint); Notice of Adoption, Mont. Admin. Reg. No. 18, 2242-68 (Sept. 20, 2024), https://dphhs.mt.gov/assets/rules/37-1052adp-arm.pdf ("Final Rules") (attached as Ex. C to Proposed First Amended Complaint). The Final Rules reflect only changes made to the Proposed Rules; accordingly, the Proposed Rules reflect most of the text of the Rules as adopted.

and medically unnecessary restrictions, despite ***no*** threat to patient health and safety.

Binding Montana precedent squarely controls this case and has repeatedly halted other measures that restrict Montanans' right to abortion. *See, e.g.*, *Weems v. State*, 2023 MT 82, 412 Mont. 132, 529 P.3d 798 ("*Weems II*") (holding unconstitutional law restricting provision of abortion to only physicians and physician assistants); *Armstrong v. State*, 1999 MT 261, 296 Mont. 361, 989 P.2d 364 (holding unconstitutional law restricting provision of abortion to physicians only). This newest set of restrictions follows the same playbook as the numerous other abortion laws Montana courts have enjoined in recent years.[2] It is mirrors targeted restrictions on abortion provider ("TRAP") laws states passed a decade ago that courts have likewise held unconstitutional. *E.g.*, *Hodes & Nauser v. Stanek*, 318 Kan. 995, 551 P.3d 62 (2024) (holding 2011 Kansas abortion facility licensing statutes and regulations violated state constitutional right to abortion).

Like those restrictions, the Scheme violates the Montana Constitution's guarantee of privacy: it infringes on Montanans' right to abortion and averts no bona fide medical risk. The Scheme additionally violates patients' rights to equal protection and Plaintiffs' own equal protection rights, and is unconstitutionally vague because it grants considerable discretion to DPHHS and risks arbitrary and discriminatory enforcement.

Invasion of Plaintiffs' and patients' rights alone constitutes irreparable harm. Moreover,

[2] *Planned Parenthood of Mont. v. State*, 2022 MT 157, 409 Mont. 378, 515 P.3d 301 ("*PPMT I*") (affirming preliminary injunction against multiple laws, including omnibus restriction that banned telehealth for abortion); Order Granting Pls.' Mots. For Prelim. Inj., Planned Parenthood of Mont. v. State, No. ADV-2023-299 (1st Jud. Dist. Jul. 11, 2023) ("*PPMT II*") (preliminary injunction against DPHHS rules and statutes that restrict Medicaid coverage of abortion) (attached as Exhibit A), *appeal filed* No. 23-287 (May 24, 2023); Order Granting Pls.' Mots. For Prelim. Inj., Planned Parenthood of Mont. v. State, No. ADV-2023-231 (1st Jud. Dist. Jul. 11, 2023) ("*PPMT III*") (preliminary injunction against telehealth abortion ban and ban on a common method of second-trimester abortion) (attached as Exhibit B), *appeal field* No. 23-288 (May 24, 203); *Planned Parenthood of Mont. v. State*, No. DDV-2013-407, 2023 WL 4317682 (1st Jud. Dist. Feb. 21, 2023) ("*PPMT IV*") (summary judgment and permanent injunction against parental consent law for abortion), *aff'd*, 2024 MT 178, 554 P.3d 153 ("*PPMT V*"); *Planned Parenthood of Mont. v. State*, No. DV-21-999 (13th Jud. Dist. Feb. 29, 2024) ("*PPMT VI*") (summary judgment and permanent injunction against laws challenged in *PPMT I*), *appeal filed* No. 24-0147 (Mar. 8, 2024).

absent injunctive relief, the Scheme imperils Montanans' access to abortion and other health services. By contrast, the State suffers no injury from an injunction. Plaintiffs will remain subject to generally applicable State, federal, and professional oversight and regulation.

To prevent irreparable harm and preserve the status quo, Plaintiffs request this Court enter a temporary restraining order and/or preliminary injunction, enjoining enforcement of the Scheme.

## BACKGROUND

### I. Abortion in Montana.

Abortion is common and safe health care. Abortion is safer than carrying a pregnancy to term: the risk of death associated with childbirth is approximately 13 times higher than that associated with abortion. Banks Aff. ¶ 23. In addition to the health harms of being denied a wanted abortion, people denied a wanted abortion and their children are more likely to experience long-term economic insecurity. Weems Aff. ¶ 61.

Additionally, as the Montana Supreme Court last year: "[t]he overwhelming evidence" establishes that "abortion care is one of the safest procedures in this country and the world;" "[c]omplication rates from abortion are similar to or lower than other outpatient procedures;" and "[w]hen complications do occur, they are usually minor and easily treatable—normally at home or in an outpatient setting." *Weems II*, ¶ 48; *see also* Banks Aff. ¶ 24 (reiterating same points, including that abortion and vasectomies have similarly low complication rates).

Mainstream medical authorities conclude there is no valid reason to regulate abortion differently than identical or comparable care, including miscarriage care and other gynecological care. Banks Aff. ¶ 30; *see also Weems II*, ¶ 12 ("According to expert witnesses—including the State's expert witnesses—medication and aspiration abortions are very similar and use techniques and protocols identical to that used for managing a miscarriage."); *see also id.* ¶ 48.

All Families is the only clinic providing abortion care in Northwest Montana and has provided abortion care from the same physical location since it opened in 2018. Weems Aff. ¶ 2. Blue Mountain is a medical clinic that fully integrates family medicine, mental health counseling, and reproductive and sexual health care into its medical practice. Banks Aff. ¶ 35. Blue Mountain has provided abortion care since it opened in 1977, as the first and only abortion clinic in the State; it has provided abortion care from its current location since 1995. Banks Aff. ¶ 4.

All Families and Blue Mountain offer medication abortion. Weems Aff. ¶ 9; Banks Aff. ¶ 41. The medications cause a miscarriage, and the same medications are used to treat spontaneous miscarriage (including by Plaintiffs). Weems Aff. ¶¶ 39, 44; Banks Aff. ¶ 15. Patients do not pass their pregnancy in the clinic, but at home or another location they choose. Banks Aff. ¶ 61.

Both clinics offer medication abortion in person and via direct-to-patient telehealth. Banks Aff. ¶ 41; Weems Aff. ¶ 10. Medication abortion makes up most of the abortion care All Families provides and is largely provided via telehealth. Weems Aff. ¶¶ 10, 12. Telehealth offers flexibility and discretion, particularly for those who cannot take time off work, find childcare, or whose privacy would be jeopardized by an in-person visit. It is also ideal for the many patients who live in the remote, rural regions of Montana, which can be hours from the nearest clinic. *Id.* ¶ 12.

Both clinics also offer procedural abortion, which is the same procedure performed to manage spontaneous miscarriage. Weems Aff. ¶ 47; Banks Aff. ¶ 41. Procedural abortion requires comparable skill and/or technique to other gynecological procedures, including procedures that Plaintiffs perform, such as insertion and removal of intrauterine devices ("IUDs," a long-acting, reversible birth control), loop electrosurgical excision procedures ("LEEPs," a procedure to diagnose and treat abnormal cervical tissue), and endometrial biopsies. Banks Aff. ¶ 29.

Plaintiffs' patients seek abortion care for many reasons: some lack the financial means to

raise a child; others are not ready to become a parent; many have physical and emotional health issues that would be exacerbated by continuing a pregnancy; and some have become pregnant as a result of incest or rape. Banks Aff. ¶ 42. The availability of abortion care enables patients not to forego educational and economic opportunities due to unplanned childbirth; to provide care to existing family members; to avoid raising children with an absent, unwilling, or abusive partner; and to prevent health harms caused by pregnancy and childbirth. *Id.* ¶ 43.

## II. Regulation of Health Care, Including Abortion Care, in Montana.

Montana licenses health care providers and some, but not all, facilities where patients access care. Montana health care providers, including Plaintiffs, are subject to generally applicable State, federal, and professional regulation. Like other providers, Plaintiffs are subject to licensure, regulation, and oversight by State professional boards (such as the Board of Medical Examiners and Board of Nursing). §§ 37-3, 37-8, 37-20, 37-27, MCA. The Montana Department of Labor and Industry and the professional licensing boards have licensing and regulatory requirements and are charged with investigating complaints about licensees and disciplining them.

Plaintiffs are also subject to regulation, including inspection, by the Board of Pharmacy because they dispense medications. *See* Weems Aff. ¶ 15 (registered with the Board of Pharmacy as a medical practitioner dispenser); Banks Aff. ¶ 36 (Blue Mountain licensed as a limited-service pharmacy); Admin. R. M. 24.174.1802, 1803 (medical practitioner dispensers are subject to inspection); Admin. R. M. 24.174.830(7) (licensed pharmacy inspection). Plaintiffs are further subject to DPHHS oversight and regulation through the Clinical Laboratory Improvement Amendments ("CLIA") and State abortion-reporting laws. Weems Aff. ¶ 15; Banks Aff. ¶ 36.

Montana has a separate set of licensure requirements that applies to some facilities where health care is provided. *See* §§ 50-5-103(1), 50-5-204(3), MCA. "Health care facilities" licensed

by DPHHS include hospitals, outpatient centers for surgical services, and long-term care facilities, among others. § 50-5-101(20)(a), MCA. "Health care facility" ***does not*** include "offices of private physicians, dentists, or other physical or mental health care workers regulated under Title 37 [of the Montana Code]." § 50-5-101(20)(b), MCA. Providers' offices thus are not required to be licensed as "health care facilities."

Additionally, some health clinics, including those that operate as birth centers, may become licensed as facilities but are not required to. As DPHHS explained in prior rulemakings, clinicians licensed under Title 37 may continue to practice without additionally licensing the *facilities* in which they practice. DPHHS assured nurse practitioners that facility licensure, which would have mandated a physician medical director, was available, but ***not*** required for nurse-practitioner-run clinics. *See* 37-526 Mont. Admin. Reg. 7 (Apr. 14, 2011) (Comment #1). According to DPHHS facility licensure was optional, allowing facilities the option to charge a facility fee to insurance:

> **[I]f a practitioner is already licensed to practice medicine they may open a private practice or clinic without having to license as a health care facility**. Any licensed practitioner can sign up and bill Medicare/Medicaid for professional services rendered. . . . **If a licensed healthcare practitioner additionally wants to bill for a facility fee** (such as for a birthing center) a health care facility license must be acquired; hence the rule for licensing 'outpatient facilities for primary care.' The health care facility standards are only applicable to those healthcare professionals who would seek and qualify for a healthcare facility license, in addition to their professional credentials.

37-526 Mont. Admin. Reg. 7 (Apr. 14, 2011) (Response #1) (emphasis added).

Accordingly, today, licensed clinicians may practice in office and clinic settings ***without*** DPHHS licensure. Although the facilities themselves are not licensed, health care provided by their practitioners remains subject to federal, State, and professional regulation. For decades, this is how the State has regulated Plaintiffs and other clinics that provide abortion care. Weems Aff. ¶ 18; Banks Aff. ¶ 36; Mayo Aff. ¶ 3. It is also how the State regulates other outpatient clinics or

offices—which can include everything from primary care and gynecology clinics to dental and dermatology offices to birth centers.[3] *See* Banks Aff. ¶ 10; Mayo Aff. ¶¶ 8, 10.

## III. HB 937, the Final Rules, and Plaintiffs' Applications for Waivers.

Representative Lola Sheldon-Galloway introduced HB 937 on March 27, 2023. Proponents of the bill cited no health and safety incidents concerning any Montana clinicians who provide abortion care or at any Montana facility that offers abortion care.

HB 937 makes it unlawful to operate or advertise an "abortion clinic" in the State without a valid license issued by DPHHS pursuant to HB 937. HB 937 § 1, 2. The penalty for operating an abortion clinic without a license, or for violating any licensure regulation, is up to $1,000 per day. §§ 50-5-111, 50-5-112(1), MCA. "Abortion clinic" means a facility that performs any "surgical abortion procedures" or prescribes, administers, or dispenses an "abortion-inducing drug" to five or more patients per year. HB 937 § 1(a), b(iv). "Abortion clinic" does not include a facility that provides an "abortion-inducing drug" for a purpose other than abortion. *Id.* § 1(2)(c).

HB 937 does not alter existing law, which provides that "health care facility" "**does not** include offices of private physicians, dentists, or other physical or mental health care workers regulated under Title 37." § 50-5-101(20)(b), MCA (emphasis added). Accordingly, Montana law continues to permit clinicians' offices to be unlicensed—unless those clinicians' offices, like Plaintiffs, provide abortion care.

DPHHS issued proposed rules on July 26, 2024, and on September 20, 2024, adopted final Rules, which largely mirror the proposed rules, including their immediate effective date. The Rules repeatedly reference standards for outpatient centers for surgical services, *see, e.g.*, Proposed Rules, at 1175-76, which the medical consensus agrees are inappropriate to mandate for abortion.

[3] DPHHS makes optional licensure available for freestanding clinics that operate as birth centers. *See* 37-526 Mont. Admin. Reg. 7 (Apr. 14, 2011) (licensure path for birth centers created so licensed centers can bill facility fees).

Banks Aff. ¶ 20.

The Scheme has no more relevance to abortion than other care provided in similar settings in this state—most notably miscarriage care, which is identical to abortion but subject to none of these mandates. Mayo Aff. ¶ 7; Weems Aff. ¶ 65; Banks Aff. ¶¶ 9-11. For example:

- The Rule II(4) initial and annual $450 licensure fee is exponentially more than the licensure fees for any other health care facility. *Compare with* § 50-5-202, MCA ($20 licensure fee for facilities with 20 beds or fewer, and $1 per bed for facilities with 21 or more beds). Rule II also mandates annual licensure for abortion clinics, but other facilities may be licensed for up to three years. *See* Admin. R. M. 37.106.310 (all health care facilities).

- Rule III's physical plant requirements, including specific "patient room" and corridor dimensions, bear no specific relationship to abortion. DPHHS does not define "patient room," but describes it as where patients are "assessed or treated," and thus includes rooms where patients are counseled or provided pills for medication abortion. *See* Final Rules, Response #65, at 2260. Plaintiffs do not meet each requirement, Weems Aff. ¶ 23; Banks Aff. ¶ 48, and like other mandates, these do not apply to clinics providing identical care or care that is more invasive or risky than abortion. *See supra* BACKGROUND § II.

- Rule VII requires abortion clinics document for every patient a physical exam and testing for Rh factor—tests and exams that are medically unnecessary for many. Mandating in-person tests and exams also ends access to abortion via telehealth. Weems Aff. ¶ 33; Banks Aff. ¶ 54.

- Rule IX's mandate for a written transfer agreement with a hospital is unnecessary to facilitate transfer of patients and has no relevance for patients who are advised to the hospital if needed once they return home (which may be far from the clinic). Plaintiffs already have transfer protocols, which exist for patients seeking both abortion and non-abortion care. Blue Mountain has put these protocols into practice more frequently for patients not seeking abortion care. Weems Aff. ¶ 41; Banks Aff. ¶¶ 64, 65.

- Rule X restricts administration of anesthesia to physicians or certified registered nurse anesthetists ("CRNAs") and does not define anesthesia, so it is unclear whether it applies to only to local anesthesia, minimal or moderate sedation, and/or general anesthesia, or all forms. Absent a definition, the Rule denies patients seeking abortion care basic pain management available to others: It bars All Families' patients from receiving local anesthesia administered by Ms. Weems and bars the minimal and moderate sedation Blue Mountain offers, which a registered nurse administers as prescribed by a physician. Weems Aff. ¶ 47; Banks Aff. ¶ 71. No such similar rule applies to identical or comparable care.

Additionally, Rules I and III reference waivers, and on October 1, 2024, Plaintiffs submitted applications to DPHHS for abortion clinic licenses and requested waivers from certain

requirements, including those described above. Weems Aff. ¶ 58; Banks Aff. ¶ 79. Rule III permits DPHHS to waive physical plant requirements for existing clinics if it determines that compliance would be "extremely difficult or impossible" and that "the level of safety to patients and staff is not diminished." Proposed Rule III, at 1769 (adopted as proposed). Rule I permits waivers of "certain" requirements "if not necessary in light of the scope of, and any gestational limits on," the abortion care the clinic provides. Proposed Rule I, at 1767 (adopted as proposed). Rule I states further that "general requirements and provisions and requirements pertaining to the abortion services provided by the abortion clinic may not be waived." Final Rules, at 2242.

DPHHS states that "[t]he issuance and identification of any waivers in the license would occur after review of the application, in discussion with the provider, and be individualized," Final Rules, Response #66, at 2260, but otherwise does not explain what applicants must do to seek waivers or give guidance on how DPHHS will decide whether to grant waivers.

**LEGAL STANDARD**

"A preliminary injunction order or temporary restraining order may be granted when the applicant establishes that: (a) the applicant is likely to succeed on the merits; (b) the applicant is likely to suffer irreparable harm in the absence of preliminary relief; (c) the balance of equities tips in the applicant's favor; and (d) the order is in the public interest." § 27-19-201, MCA. The Legislature intended this standard to "mirror the federal preliminary injunction standard." § 27-19-201(4), MCA.

The federal standard in the Ninth Circuit—and thereby the Montana standard—follows a "sliding scale" approach where "a stronger showing of one element may offset a weaker showing of another." *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). When the "balance of hardships tips sharply" in the plaintiff's favor, there is a likelihood of irreparable

injury, and the injunction is in the public interest, the plaintiff need only show "serious questions going to the merits." *Id.* at 1135. "Serious questions" are "questions that cannot be resolved one way or the other at a hearing on the injunction" because they require "'more deliberative investigation.'" *Republic of the Philippines v. Marcos*, 862 F.2d 1355, 1362 (9th Cir. 1988) (citation omitted).

Plaintiffs satisfy each element of the sliding scale standard for a temporary restraining order and preliminary injunction. And because Plaintiffs are in fact likely to succeed on the merits, they certainly satisfy the lower serious-question standard.

## ARGUMENT

### I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

Under *Armstrong*, *Weems II*, and *PPMT I*, the Scheme violates Plaintiffs' patients' rights to privacy and equal protection under the Montana Constitution. *See also supra* n.2 (citing cases enjoining Montana abortion restrictions). The Scheme infringes on Montanans' fundamental right to abortion and is subject to strict scrutiny, which it cannot withstand. Further, under Article II, Section 17 of the Montana Constitution, the Scheme is void for vagueness because it fails to give fair notice of key aspects of its requirements and risks arbitrary and discriminatory enforcement.

#### A. <u>The Scheme violates Plaintiffs' patients' fundamental right to privacy.</u>

Article II, section 10 of the Montana Constitution guarantees each individual the right to abortion, including "from a health care provider of her choosing." *Armstrong*, ¶ 2; *see also id.* ¶ 34 ("Montana adheres to one of the most stringent protections of its citizens' right to privacy in the United States."). The State constitution safeguards an individual's right to decide whether to continue or terminate a pre-viability pregnancy "in the context of her individual values, her beliefs as to the sanctity of life, and her personal situation." *Id.* ¶ 49. "Few matters," the Court stressed,

"more directly implicate personal autonomy and individual privacy than medical judgments affecting one's bodily integrity and health," and the course of one's life. *Id.* ¶¶ 45, 53, 72.

In a challenge to an abortion law, the State must show that the law is necessary and narrowly tailored to "preserve the safety, health and welfare of a particular class of patients or the general public from a medically-acknowledged, *bona fide* health risk." *Id.* ¶¶ 34, 59. A narrowly tailored law is "the least onerous path that can be taken to achieve the state objective." *Weems II*, ¶ 44 (quoting *Wadsworth v. State* (1996), 275 Mont. 287, 302, 911 P.2d 1165, 1174). "Subject to this narrow qualification, however, the legislature has neither a legitimate presence nor voice in the patient/health care provider relationship superior to the patient's right of personal autonomy which protects that relationship from infringement by the state." *Armstrong*, ¶ 59.

The Scheme unquestionably infringes the fundamental right to abortion. Like other restrictions on the right, it singles out abortion for unique and additional regulation. *See, e.g.*, *Armstrong*, ¶¶ 58-59, 63-64 (law "prohibit[ed] [physician assistants] from performing abortions, yet made no attempt to prohibit [them] from performing other more risky medical procedures such as uncomplicated deliveries of babies, inserting IUDs, and prescribing and administering most drugs"); *Weems II*, ¶¶ 30, 49 (law barred advanced practice nurse practitioners from offering abortion despite the fact they "already competently" "provide a broad range of health care within their scope of practice that is identical to, or significantly more complex, than" abortion care).

DPHHS's statements that abortion has been largely unregulated in Montana and that the Rules bring abortion clinics in line with other health care, *see, e.g.*, Final Rules, Response #59, at 2258-59, is patently untrue. The Scheme would not apply to Plaintiffs' clinics or their patients if Plaintiffs ceased providing abortion care but continued to offer the same medications and procedures for miscarriage. And, under current law abortion and miscarriage care are not

unregulated: both are subject to generally applicable regulation by federal, State, and professional authorities. *See supra* BACKGROUND § II. The challenged Scheme alters the status quo only for abortion, and that targeted restriction of abortion infringes patients' right to privacy. [4]

Moreover, the Scheme threatens to end or significantly curtail Montanans' access to abortion. Plaintiffs do not meet each of the Scheme's requirements, including arbitrary dimensions for patient rooms and hallways; for a physician medical director; restrictive staffing requirements for anesthesia; or a written hospital transfer agreement. The Scheme additionally subjects people seeking abortion care to medically unnecessary tests and exams—invasions of their bodily autonomy—and, because they must be done in person, end access to abortion by telehealth. Although Plaintiffs have sought waivers from certain requirements, DPHHS has not yet responded. When the TRO expires, Plaintiffs will be forced to cease offering abortion care, and Montanans will be unable to access abortion from chosen providers. *See supra* BACKGROUND § III.

The Scheme is wholly unnecessary to avert a medically-acknowledged *bona fide* health risk. *See Armstrong*, ¶ 62. Just two months ago, the Montana Supreme Court reiterated that "abortion care is safe and presents relatively minimal health risk" and "dispose[d] of any of the State's claimed compelling state interests which might be premised upon abortion care presenting a medically acknowledged, *bona fide* health risk." *PPMT V*, ¶ 31. The Scheme is based on the same faulty premise.

Multiple aspects of the Scheme circumvent existing preliminary or permanent injunctions. The requirement for a physician medical director conflicts with the permanent injunction in

[4] This is true regardless of responses to Plaintiffs' licensure application and waiver requests. The question is not whether Plaintiffs can conform to the Scheme. Rather, the question is whether the State can *compel* compliance with the Scheme, which the State cannot do "except in the face of a medically-acknowledged *bona fide* health risk." *See, e.g.*, *Armstrong*, ¶ 62; *see id*. (absent that, the State "has no interest, much less a compelling one, to justify its interference with an individual's fundamental privacy right" to obtain abortion care).

*Armstrong* and *Weems II*, which held unconstitutional laws that restrict the provision of abortion by advanced practice clinicians including physician assistants and nurse practitioners. The mandate for medically unnecessary testing and a physical exam, and the elimination of access to telehealth abortion, conflicts with three separate injunctions. *PPMT I*, ¶¶ 12, 14, 51 (affirming preliminary injunction of telehealth ban and in-person exam requirement); *PPMT II*, at 3, 10-11 (preliminarily enjoining Medicaid coverage restrictions that impose in-person exam requirement, and rejecting argument that restriction did not eliminate telehealth because exam need not be done at abortion clinic); *PPMT III*, at 9, 12 (preliminarily enjoining ultrasound requirement, which would eliminate telehealth access to abortion by imposing in-person requirement, and rejecting same argument that ultrasound need not occur at abortion clinic).

There is no valid reason why the State's current, generally applicable laws are inadequate to protect Montanans' health, especially as abortion is one of the safest health services available in the United States. Banks Aff. ¶ 9; *see Weems II*, ¶ 46 (relying on "the overwhelming evidence presented to the District Court that abortion care is one of the safest forms of medical care in this country and the world"). Mainstream medical authorities conclude that abortion is safely provided in outpatient settings, like Plaintiffs' clinics, and have condemned laws like those challenged here which single out abortion under the pretext of health and safety. Banks Aff. ¶ 30.

The Scheme is not tailored to advance any alleged health and safety interest and is both under- and over-inclusive. It is under-inclusive because it does not apply to identical care provided for purposes other than to induce an abortion—*i.e.*, miscarriage—similar care, or care that generally carries more risk than abortion. Indeed, HB 937 explicitly ***exempts*** from the definition of "abortion clinic," and thus from facility licensure, clinics that provide the *same* medications used to induce an abortion when used for another purpose. HB 937 § 1(2)(c). And, the Scheme

also does not apply to every facility where patients access care for continued pregnancy and childbirth, although it carries greater risk than abortion, Banks Aff. ¶ 23; *see supra* BACKGROUND § III.

The Scheme is also over-inclusive because it applies indiscriminately to abortion care without regard for the patient's circumstances, the type of abortion (procedural or medication), the point in pregnancy when abortion care is provided, or the type of sedation or anesthesia offered. For example, the Scheme mandates facility licensure for clinics that provide abortion care even though many patients obtain that care via medication, which involves taking pills outside the clinic setting. Weems Aff. ¶ 26; Banks Aff. ¶ 49. Some patients never even set foot in Plaintiffs' clinics because they access medication abortion via telehealth. Weems Aff. ¶¶ 10, 12; Banks Aff. ¶ 38. Yet, absent facility licensure, Plaintiffs must cease providing *all* abortion care. And, although DPHHS indicates it may waive certain requirements for clinics that only offer medication abortion, Final Rules, Response #66, at 2260, that does nothing for patients who access medication abortion from a clinic that also offers procedural abortion.

Courts have struck down similar efforts to target abortion for additional regulation, on top of generally applicable laws. Earlier this year, the Kansas Supreme Court held unconstitutional a similar statutory and regulatory scheme mandating a host of abortion-specific regulations for facilities that provide abortion. *Hodes & Nauser v. Stanek*, 318 Kan. 995, 551 P.3d 62 (2024). Like the Scheme, the Kansas laws plucked abortion out of an otherwise generally appliable set of requirements for clinicians' offices. 318 Kan. at 998, 551 P.3d at 67-68. And, like the Montana Scheme, the Kansas laws were subject to and fail strict scrutiny. 318 Kan. at 1030, 551 P.3d at 85.

The U.S. Supreme Court also held unconstitutional a similar Texas scheme, under a less rigorous standard of constitutional review than the strict scrutiny the Montana Constitution

demands. *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582 (2016) (abortion-specific facility scheme unconstitutional under federal undue burden standard), *abrogated by Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022). As in Texas, the Scheme here would "not provide better care or . . . more frequent positive outcomes" but, rather, would be "harmful to, [and] not supportive of, women's health." *Id.* at 619, 623 (internal quotation marks and alterations omitted).

As these prior courts have held, schemes like the one challenged here are a solution in search of a problem. Abortion is legal in Montana and protected as a fundamental right under the Montana Constitution. Nonetheless, abortion has been subject to numerous efforts to restrict it, and Montana courts have blocked every one of these recent efforts. *See supra* n.2 (citing cases) and accompanying text. The Scheme here is no different and likewise fails strict scrutiny.

### B. The Scheme violates abortion providers' and their patients' equal protection rights.

The Scheme is also unconstitutional because it violates Montana's equal protection guarantee. Montana Const. art. II, § 4. In an equal protection challenge, Montana courts first "identify the classes involved and determine whether they are similarly situated." *Henry v. State Comp. Ins. Fund*, 1999 MT 126, ¶ 27, 294 Mont. 449, 982 P.2d 456. "A law or policy that contains an apparently neutral classification may violate equal protection if in reality it constitutes a device designed to impose different burdens on different classes of persons." *Snetsinger v. Mont. Univ. Sys.*, 2004 MT 390, ¶ 16, 325 Mont. 148, 104 P.3d 445 (internal quotation marks and alterations omitted). Second, courts determine the appropriate level of scrutiny to apply. *Id.* ¶ 17. If a suspect class or fundamental right is affected, courts use strict scrutiny, meaning that "the legislation [at issue] must be justified by a compelling state interest and must be narrowly tailored to effectuate only that compelling interest." *Armstrong*, ¶ 34.

The Scheme distinguishes between similarly situated patients with respect to their

fundamental right to personal and procreative autonomy: Montanans who decide to terminate their pregnancy and those who access other pregnancy care, such as *identical* miscarriage care or care for continued pregnancy and childbirth. Montanans who continue their pregnancies may continue to access care from their chosen provider without interference imposed by the challenged Scheme while those seeking an abortion will be blocked from their chosen providers by the Scheme. *See PPMT V*, ¶ 28 (parental consent law creates two classes of pregnant minors and discriminates against minors who choose abortion).

The Scheme impacts the fundamental right to privacy (among other rights contained in Mont. Const. art. II) and therefore strict scrutiny applies. The State cannot meet its heavy burden under strict scrutiny to show that this discrimination is narrowly tailored to serve a compelling interest. For the reasons discussed *supra*, there is no health-protective—or any other valid—rationale for the State to discriminate against people who seek abortion care by imposing unique requirements that only apply to abortion, when patients who seek identical miscarriage care, or other reproductive health care, access such care without the same government interference.

The Scheme additionally infringes on *Plaintiffs'* own equal protection rights. Where a classification does not affect a fundamental right or suspect class, rational basis review applies. *In re S.L.M.* (1997), 287 Mont. 23, 32, 951 P.2d 1365, 1371. Rational basis requires courts make "[a] careful inquiry . . . into . . . 'the rationality of the connection between legislative means and purpose [and] the exercise of alternative means for effectuating the purpose.'" *In re C.H.* (1984), 210 Mont. 184, 198, 683 P.2d 931, 938 (citation omitted).

The Scheme distinguishes between Plaintiffs, who provide abortion care in clinics under pre-existing regulation under Title 37 of the Montana Code, and providers who provide identical or more complex care in clinics and offices under that same regulation. The providers are similarly

situated with respect to the care they provide and the regulation to which they are subject under current law. But only providers of abortion are subject to the Scheme. The Scheme also treats abortion clinics differently than other licensed health care facilities, imposing more bureaucratic and onerous requirements. Several of the requirements—including for licensure itself, high licensure fee, mandates specific exams and tests, and threat to telehealth—are more prescriptive and restrictive than for other facilities. *See supra* BACKGROUND § III.

There is no rational connection between the Scheme's differential treatment and any valid State interest. As discussed *supra*, the Scheme has no impact on Plaintiffs' provision of miscarriage care, which is identical to abortion care. And DPHHS does not mandate licensure for facilities involved in care that carries more risk than abortion, including for continued pregnancy and during childbirth. Mandating Plaintiffs obtain facility licensure as a condition of providing abortion care simply because it is abortion care lacks any rational basis.

### C. The Scheme is unconstitutionally vague.

The Scheme is unconstitutionally vague because it forces Plaintiffs to speculate as to what is required, making it difficult or impossible for them to try to comply, and because it fails to set standards DPHHS will follow, thereby risking discriminatory and arbitrary enforcement.

To preserve due process, laws must "give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden." *State v. Woods* (1986), 221 Mont. 17, 22, 716 P.2d 624, 627. "A noncriminal statute or regulation is unconstitutionally vague if a person of common intelligence must necessarily guess at its meaning." *Mont. Media, Inc. v. Flathead Cnty.*, 2003 MT 23, ¶ 58, 314 Mont. 121, 63 P.3d 1129. Laws may not "trap the innocent by not providing fair warning." *State v. Stanko*, 1998 MT 321, ¶ 58, 292 Mont. 192, 974 P.2d 1132 (citation omitted). Further, "laws must provide explicit standards for those who apply them." *Id.*, ¶ 23. Vague laws

fail to provide minimal guidelines to govern those who enforce them and to prevent their arbitrary or discriminatory application. .*See State v. Christensen*, 2020 MT 237, ¶¶ 1332, 401 Mont. 247, 472 P.3d 622. The Scheme fails to satisfy these standards.

The Scheme forces Plaintiffs to guess at its meaning because it does not sufficiently identify the conduct that is required or prohibited. The Rules contain numerous vague and uncertain terms, which DPHHS refused to define. *See, e.g., supra* BACKGROUND § III (discussing, for example, patient rooms and anesthesia); Banks Aff ¶ 61 (pathological exam); Weems Aff. ¶¶ 56-75 (waivers and timing) Additionally, the Rules lack standards to safeguard against discriminatory enforcement. For example, although the Rules reference waivers, DPHHS provides no information as to what applicants must do to seek or support requests for waivers. Nor do the Rules provide guidance as to how DPHHS will determine whether an applicant is entitled to a waiver. DPHHS states that waivers will "be individualized," Final Rules, Response #66, at 2260, which invites arbitrary enforcement. The absence of such standards is even more troubling in light of the Rules' unclear provisions.

## II. THE REMAINING FACTORS WEIGH IN FAVOR OF IMMEDIATE RELIEF.

### A. HB 937 and the Rules will cause irreparable injury.

Absent a temporary restraining order and preliminary injunction preventing the Scheme from being enforced, Plaintiffs and their patients suffer irreparable harm. Violations of Montanans' constitutional rights to privacy, equal protection, and due process alone constitute irreparable harm and justify preliminary relief. *See, e.g., PPMT I,* ¶ 6 ("loss of a constitutional right constitutes an irreparable injury" (citation omitted)).

Beyond the constitutional harm, the Scheme threatens to end or significantly limit abortion access. Without licenses subject to the requested waivers, All Families and Blue Mountain will be

forced to cease providing abortion care. Weems Aff. ¶ 8; Banks Aff. ¶ 12. Even temporary disruption of services means appointments need to be rescheduled or patients referred elsewhere. *See* Weems Aff. ¶ 8. Delays limit patients' options, and risk pushing patients beyond the point where they are eligible for medication abortion. *See* Weems Aff. ¶ 60. Obstacles to abortion force patients to remain pregnant, and experience the symptoms, risks, and costs that come along with pregnancy, childbirth, and/or parenthood. *Id.* ¶ 61. Unnecessary and unwarranted medical risk, arbitrarily imposed on patients seeking abortion care, is an archetypal irreparable harm.

Abortion is also a critical part of Plaintiffs' practices. Weems Aff. ¶¶ 10, 12; Banks Aff. ¶¶ 40, 41. Imposing unique and extra regulation on Plaintiffs simply because they provide abortion care interferes with their relationship with their patients and injures their practices. *See Chalk v. U.S. Dist. Ct.*, 840 F.2d 701, 709-10 (9th Cir. 1988) (irreparable harm based on interference with teacher's profession); *Am. Med. Ass'n v. Weinberger*, 522 F.2d 921, 925-26 (7th Cir. 1975) (irreparable harm where regulations undermined patient confidence in health care providers).

DPHHS's insistence on imposing the Rules immediately despite no threat to patient health and safety exacerbates these harms. Plaintiffs are unsure from one day to the next whether they will be able to provide abortion care, or have to upend their practices or end abortion care entirely. Weems Aff. ¶¶ 65-69; Banks Aff. ¶¶ 81-83. The shifting ground strains providers, staff, and patients. Weems Aff. ¶ 67; Banks Aff. ¶¶ 82, 84. As the November 19 expiration of the current TRO approaches, patients cannot be sure their appointments will proceed as scheduled. Weems Aff. ¶ 70; Banks Aff. ¶ 82. And only patients seeking abortion—or other gender-based care—are subject to such government-created confusion and uncertainty.

**B. <u>The balance of the equities and public interest weigh in favor of Plaintiffs.</u>**

The remaining factors—the balance of the equities and the public interest— "merge into

one inquiry when the government opposes a preliminary injunction." *Porrettu v. Dzurenda*, 11 F.4th 1037, 1050 (9th Cir. 2021).

Plaintiffs and their patients face immediate irreparable harm absent preliminary relief, and the State is not harmed by an injunction that preserves the status quo. Plaintiffs are already subject to government regulation and oversight, and the State has no need to enforce this new abortion-specific Scheme. *See supra* BACKGROUND § III.

The State also has no legitimate interest in enforcing unconstitutional laws. *See Doe v. Kelly*, 878 F.3d 710, 718 (9th Cir. 2017) ("[T]he government suffers no harm from an injunction that merely ends unconstitutional practices and/or ensures that constitutional standards are implemented." (citation and internal quotation marks omitted)). The status quo protects Plaintiffs' and their patients' ability to make evidence-based health decisions free from unwarranted government intervention, consistent with the values of privacy and bodily autonomy secured by the Montana Constitution's Declaration of Fundamental Rights. *Armstrong*, ¶ 56 ("[T]he right to control fundamental medical decisions is an aspect of the right of self-determination and personal autonomy that is deeply rooted in this Nation's history and tradition." (internal quotation marks and citation omitted)). The State, by contrast, loses nothing by way of immediate relief preserving the status quo: the Montana Constitution requires the State not to violate individuals' constitutional rights, and abortion providers remain subject to State regulation as they have been for years.

## CONCLUSION

Plaintiffs ask this Court to grant the application for a temporary restraining order and preliminary injunction prohibiting the Defendants and their agents, employees, appointees, and successors from enforcing, threatening to enforce, or otherwise applying HB 937 and the Rules.

Respectfully submitted this 7th day of October 2024

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## CERTIFICATE OF SERVICE

I, Alex Rate, hereby certify on this date I filed a true and accurate copy of the foregoing document with the electronic filing system for Montana courts and electronic service was sent to:

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Dated October 7, 2024

# Exhibit A

**MONTANA FIRST JUDICIAL DISTRICT COURT,**
**COUNTY OF LEWIS AND CLARK**

| | |
|---|---|
| PLANNED PARENTHOOD OF MONTANA; ALL FAMILIES HEALTHCARE; BLUE MOUNTAIN CLINIC; SAMUEL DICKMAN, M.D.; and HELEN WEEMS, APRN-FNP, on behalf of themselves and their patients,<br><br>Plaintiffs,<br><br>vs.<br><br>STATE OF MONTANA; MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; and CHARLIE BRERETON, in his official capacity as Director of the Department of Public Health and Human Services,<br><br>Defendants. | Cause No. ADV-2023-299<br><br>Hon. Mike Menahan<br><br>**[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION** |

Before the Court are motions for preliminary injunctions filed by Plaintiffs Planned Parenthood of Montana ("PPMT"), All Families Healthcare, Blue Mountain Clinic, Dr. Samuel Dickman, and Helen Weems, in which they seek to enjoin Defendants the State of Montana, the Montana Department of Public Health and Human Services ("DPHHS"), and DPHHS Director Charlie Brereton (collectively, "the State") from enforcing the DPHHS rule proposed at Montana

Administrative Register Notice 37-1024 amending Mont. Admin. R. 37.82.102 and 37.86.104 ("the Rule"), 2023 House Bill 544 ("HB 544"), and 2023 House Bill 862 ("HB 862"). Raph Graybill, Tanis Holm, Peter Im, and Dylan Cowit represent Plaintiffs PPMT and Dr. Dickman. Akilah Deernose, Alex Rate, Erin Erickson, Hillary Schneller, Jen Rasay, and Adria Bonillas represent Plaintiffs All Families Healthcare, Blue Mountain Clinic, and Ms. Weems. Montana Attorney General Austin Knudsen, Thane Johnson, Alwyn Lansing, Michael Russell, Levi Roadman, and Emily Jones represent Defendants.

**FACTS**

Plaintiffs challenge the constitutionality of the Rule, HB 544, and HB 862, all of which restrict Medicaid coverage of abortions in Montana. In support of their motions, Plaintiffs submitted the affidavits of Dr. Dickman, the Chief Medical Officer of PPMT; Martha Fuller, President and Chief Executive Officer of PPMT; Ms. Weems, a nurse practitioner and the sole clinician at All Families Healthcare; and Nicole Smith, the Executive Director of Blue Mountain Clinic. In support of its response to Plaintiffs' motions, the State submitted the affidavit of Michael Randol, the Medicaid and Health Services Director at DPHHS. On May 23, 2023, this Court held an evidentiary hearing on Plaintiffs' motions, at which it heard testimony from Dr. Dickman, Ms. Weems, Ms. Smith, Mr. Randol, and the State's expert witness Dr. George Mulcaire-Jones. On the same day, the Court held an evidentiary hearing on PPMT and Dr. Dickman's request for a preliminary injunction enjoining 2023 House Bills 575 and 721 in Case No. ADV-2023-231. Pursuant to the parties' stipulation, in both cases, the Court may rely on testimony taken in either hearing. Dkt. 41 at 2. The parties stipulated to the qualifications of the expert witnesses for purposes of the hearing. *Id.*

The Rule and HB 544 are similar in substance. They restrict Medicaid coverage of abortions in three ways. First, they require that abortions covered by Medicaid be provided by a physician, not by an advanced practice clinician ("APC") such as a physician's assistant or an advanced practice registered nurse ("APRN"). Second, they require that Medicaid patients seeking abortions first obtain prior authorization from DPHHS. As part of the prior authorization process, patients must undergo an in-person physical examination and cannot obtain an abortion without one. Third, the Rule and HB 544 create new, narrow definitions of "medically necessary service" that apply only to abortions. HB 862, the other restriction Plaintiffs challenge, bans Medicaid coverage of abortions except in cases of rape or incest or if the abortion is necessary to save the pregnant person's life.

Based on affidavits and live testimony, the Court finds that when Medicaid does not cover an abortion sought by a Medicaid patient, the patient's ability to access the abortion is severely impeded. At the hearing, Dr. Dickman and Ms. Weems both testified about the effect of the availability of Medicaid coverage on abortion access. The Court finds their testimony credible in light of their experience as abortion providers and in particular their experience providing abortions to Medicaid patients. Dr. Dickman also testified that he had conducted research that found that when Medicaid does not cover abortions, a significant percentage of low-income patients seeking abortions are forced to delay paying for essentials such as bills and groceries. Dkt. 5 ("Dickman Aff.") ¶¶ 57–59. The State's witnesses did not offer evidence regarding the effect on abortion access when Medicaid does not cover abortions.

The Court turns to the evidence regarding the individual requirements of the Rule and HB 544. With respect to the physician-only requirement, Plaintiffs' affidavits offer evidence that few physicians provide abortions in Montana and that Plaintiffs rely heavily on APCs for abortion care,

such that the physician-only requirement will dramatically reduce the availability of abortions for Medicaid patients. Dkt. 6 ("Fuller Aff.") ¶¶ 14, 19; Dkt. 8 ("Weems Aff.") ¶ 20; Dkt. 7 ("Smith Aff.") ¶ 21. Further, Plaintiffs offered evidence that APCs provide abortions as safely and effectively as physicians. Dickman Aff. ¶¶ 20, 21; Weems Aff. ¶ 17. The Court credits this testimony, along with Ms. Weems's testimony that because she is the sole clinician at All Families Healthcare, the physician-only requirement could force her to close her clinic. Weems Aff. ¶¶ 9, 27. The State failed to rebut Plaintiffs' evidence about the effect of the physician-only requirement on their operations.

As to the prior authorization requirement of the Rule and HB 544, the Court finds that the requirement would force Medicaid patients to make an additional in-person trip to a health care provider to receive a physical examination and that it would impose a waiting period on Medicaid patients; this would especially burden those who have limited access to transportation, inflexible work schedules, caretaking responsibilities, or are victims of intimate partner violence. Dickman Aff. ¶ 29; Weems Aff. ¶¶ 24–25; Smith Aff. ¶¶ 29–30, 39–40, 46. Dr. Mulcaire-Jones testified that it would be possible for a Medicaid patient to obtain the in-person examination at a health care provider other than Plaintiffs, elsewhere in Montana. Be that as it may, the requirement would still force Medicaid patients to make an unnecessary in-person trip to *a* provider and delay their care for a period of time that the Rule and HB 544 do not limit.

The Court also finds that the prior authorization requirement would eliminate Plaintiffs' provision of medication abortion to Medicaid patients via direct-to-patient telehealth. Direct-to-patient medication abortion allows patients to connect with a health care provider from their own home or a location of their choosing for a virtual appointment through a secure video platform, typically without requiring the patient to undergo an ultrasound. Dickman Aff. ¶ 28; Weems Aff.

¶ 13. Providers perform a screening process to determine whether a patient is eligible for a direct-to-patient medication abortion, including confirming that it is not medically necessary for the patient to receive an ultrasound prior to the abortion. If the patient is eligible, the abortion medication is then mailed to the patient. Dickman Aff. ¶ 28. In this case, Plaintiffs offered evidence that direct-to-patient medication abortion is a safe and effective method of abortion that improves access for rural patients and patients who have difficulty accessing transportation. Fuller Aff. ¶¶ 10, 24–25; Dickman Aff. ¶¶ 31, 35; Weems Aff. ¶¶ 29–30; Smith Aff. ¶¶ 28–30.

At the hearing on HB 575 and HB 721, both parties also offered testimony about the safety of direct-to-patient medication abortion, including whether it is medically necessary to perform an ultrasound prior to a medication abortion. Dr. Dickman and Plaintiffs' expert witness Dr. Steven Ralston testified that direct-to-patient medication abortion is safe and effective and that the standard of care does not require providing an ultrasound prior to a medication abortion in all cases. Dr. Mulcaire-Jones testified that providing an ultrasound is necessary in all cases and that direct-to-patient medication abortion is not safe and does not conform with the standard of care. With respect to abortion safety and the standard of care for providing abortions, the Court credits the testimony of Drs. Dickman and Ralston over the testimony of Dr. Mulcaire-Jones. Drs. Dickman and Ralston are both abortion providers, and Dr. Ralston testified about the research demonstrating the safety and efficacy of direct-to-patient medication abortions and the major medical organizations that support it, including the American College of Obstetricians and Gynecologists, the Society for Family Planning, the Royal College of Obstetricians and Gynaecologists, the National Abortion Federation, and the World Health Organization. In contrast, Dr. Mulcaire-Jones testified that he has never provided or observed an abortion, and he did not cite any scientific research that direct-to-patient medication abortion is unsafe.

Accordingly, the Court finds that direct-to-patient medication abortion is safe and conforms with the standard of care, which does not require an ultrasound prior to all medication abortions.

Finally, the Court turns to the issue of medical necessity. The Court finds that there is no health-based justification for the narrow definitions of medical necessity in the Rule and HB 544, which change the definition of "medically necessary" only for abortion. Dickman Aff. ¶ 57. The Court also finds that Dr. Dickman and Ms. Weems exercise their clinical judgment to make an individualized determination of medical necessity with respect to each of their abortion patients who are Medicaid recipients.

At the hearing, the State introduced as an exhibit the MA-037 form, the state-created form on which abortion providers document medical necessity. The form includes a space for the provider to write a brief explanation regarding medical necessity and instructs the provider to "[a]ttach additional documentation as needed." The Court finds that, on its face, the form does not require providers to submit additional documentation or to submit sufficient documentation for DPHHS to confirm the provider's finding of medical necessity. The Court credits the testimony of Dr. Dickman and Ms. Weems that they complete the MA-037 forms truthfully and accurately.

According to Mr. Randol, based on an audit of the forms, DPHHS concluded that the abortion providers did not provide sufficient explanations or documentation for it to independently verify the findings of medical necessity, but as the Court has found, DPHHS did not require such documentation to begin with. The State argued at the hearing that the Rule and HB 544 are designed to prevent Medicaid fraud. The Court finds that the State has introduced no evidence that abortion providers in Montana do not make individualized determinations of medical necessity for each Medicaid patient, that they are untruthful in completing the MA-037 forms on which they document medical necessity, or that they engage in Medicaid fraud.

With respect to the evidence regarding HB 862, which would ban Medicaid coverage of abortions except in cases of rape or incest or if the abortion is necessary to save the pregnant person's life, the Court finds that Medicaid covers very few abortions in these two categories. During the ten-year period from July 2011 to June 2021, DPHHS reports that only six abortions in Montana were reported as falling in these two categories. Dkt. 24 ("Randol Aff.") ¶ 15.

**PRINCIPLES OF LAW**

Pursuant to 2023 Senate Bill 191, as of March 2, 2023, "[a] preliminary injunction order or temporary restraining order may be granted when the applicant establishes that: (a) the applicant is likely to succeed on the merits; (b) the applicant is likely to suffer irreparable harm in the absence of preliminary relief; (c) the balance of equities tips in the applicant's favor; *and* (d) the order is in the public interest." *See* SB 191, 2023 Leg. Reg. Sess. (Mont. 2023) (amending § 27-19-201, MCA) (emphasis added). The Montana Legislature intended for this standard to "mirror the federal preliminary injunction standard" and "closely follow United States supreme court case law." SB 191, § 1. This new standard is conjunctive, not disjunctive, meaning the moving party must establish all four factors to obtain relief. *See All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131–35 (9th Cir. 2011) (addressing interaction of four factors).

Under the federal preliminary injunction standard, "[a] preliminary injunction is not a preliminary adjudication on the merits, but a device for preserving the status quo and preventing the irreparable loss of rights before judgment." *Textile Unlimited, Inc. v. A..BMH & Co.*, 240 F.3d 781, 786 (9th Cir. 2001) (citing *Sierra On–Line, Inc. v. Phoenix Software, Inc.*, 739 F.2d 1415, 1422 (9th Cir. 1984)).

## ANALYSIS

Upon consideration of the parties' arguments, the Court determines that Plaintiffs have standing to challenge the Rule, HB 544, and HB 862 and that they have met their burden to show that the laws should be preliminarily enjoined.

### I. Standing

At the outset, the Court must address the State's argument that Plaintiffs do not have standing to bring their claims. Plaintiffs bring the claims at issue at this stage on behalf of their patients. The Montana Supreme Court has repeatedly held that health care providers "have standing to assert on behalf of their women patients the individual privacy rights under Montana's Constitution of such women to obtain a pre-viability abortion from a health care provider of their choosing." *Armstrong v. State*, 1999 MT 261, ¶ 13, 296 Mont. 361, 989 P.2d 364; *see also Weems v. State*, 2019 MT 98, ¶ 12, 395 Mont. 250, 440 P.3d 4 ("*Weems I*") ("[W]hen 'governmental regulation directed at health care providers impacts the constitutional rights of women patients,' the providers have standing to challenge the alleged infringement of such rights.") (quoting *Armstrong*, ¶¶ 8–13). Although the Rule, HB 544, and HB 862 operate through restrictions placed on abortion providers, they impact the constitutionally protected rights of Plaintiffs' Medicaid patients by making it much more difficult, if not impossible, for them to access abortion. Applying Montana's well-settled precedent, the Court concludes that Plaintiffs have standing to bring claims asserting their patients' constitutional rights.

Defendants ask this Court to disregard Montana Supreme Court precedent "in light of [the] shifting legal landscape" around abortion cases. The Court is not persuaded there have been any relevant changes in federal standing law, and in any event the Court cannot—and will not—disregard directly applicable precedent on standing from the Montana Supreme Court. *Cf. State*

*v. Whitehorn*, 2002 MT 54, ¶ 14, 309 Mont. 63, 50 P.3d 121 ("Under the principles of binding authority, the District Court could not overrule our holding …, only this Court could do so."). *Armstrong* and *Weems I* confer third-party standing on abortion providers to challenge laws that "impact the constitutional rights of women patients" or which are "directed at health care providers." Plaintiffs therefore plainly have standing.

The State also argues that Plaintiffs lack standing because they have not demonstrated a "close relationship" to their Medicaid patients. Under *Armstrong*, abortion providers by definition have a close relationship with their patients. *Armstrong*, ¶ 9; *see also Singleton v. Wulff*, 428 U.S. 106, 117 (1976) ("The closeness of the relationship [between a patient and an abortion provider] is patent . . . . A woman cannot safely secure an abortion without the aid of a physician, and an impecunious woman cannot easily secure an abortion without the physician's being paid by the State."). Moreover, the Court finds, based on the testimony of Dr. Dickman and Ms. Weems regarding their conversations with their patients and the affidavits of Ms. Weems and Ms. Smith, that Plaintiffs all have relationships with their patients of sufficient closeness to establish standing. *See* Weems Aff. ¶ 21; Smith Aff. ¶ 26.

## II. Privacy Claims

Article II, section 10 of the Montana Constitution "protects a woman's right of procreative autonomy—i.e., here the right to seek and to obtain a specific lawful medical procedure, a pre-viability abortion, from a health care provider of her choice." *Armstrong*, ¶ 14.

This Court must first address the State's argument that the restrictions on Medicaid coverage of abortions in the Rule, HB 544, and HB 862 do not implicate the right to privacy at all because they deal only with whether Medicaid will provide funding for particular abortions. In *Jeannette R. v. Ellery*, No. BDV-94-811, 1995 WL 17959705 (1st Jud. Dist., May 22, 1995)

("*Jeannette R.*"), this Court recognized that the State violates Medicaid patients' right to privacy when it "inject[s] coercive financial incentives favoring childbirth into a decision that is constitutionally guaranteed to be free from governmental intrusion." *See* Order on Mots. for Summ. J., *Jeannette R.* at 18 (quoting *Moe v. Sec'y of Admin. & Fin.*, 417 N.E.2d 387, 402 (Mass. 1981)). When the State chooses not to fund medically necessary abortions, the right at issue "is not an assurance of governmental funding of abortion," but rather "the right to privacy, which is the right to be left alone [and] protects the individual from undue governmental interference." *Id.* at 19. *Jeannette R.* held that the State must cover all medically necessary abortions. *Id.* at 23. The evidence in this case provides no basis to depart from that holding; in fact, the record further supports the conclusion that prohibiting Medicaid from covering abortions infringes on Medicaid recipients' ability to access abortion. The Court concludes that, like the administrative rule at issue in *Jeannette R.*, the Rule, HB 544, and HB 862 infringe on Plaintiffs' patients' right to privacy.

After this Court decided *Jeannette R.*, the Montana Supreme Court held in *Armstrong* that "except in the face of a medically-acknowledged, *bona fide* health risk, clearly and convincingly demonstrated, the legislature has no interest, much less a compelling one, to justify its interference with an individual's fundamental privacy right to obtain a particular lawful medical procedure from a health care provider that has been determined by the medical community to be competent to provide that service and who has been licensed to do so." *Armstrong*, ¶ 62. Under *Jeannette R.* and *Armstrong*, Medicaid must pay for medically necessary abortions, and it must leave to a patient and their provider decisions regarding whether an abortion is medically necessary—a decision that is within a medical provider's clinical judgment. Any interference with this relationship is subject to strict scrutiny. *Id.* ¶ 34.

The Court analyzes in turn the requirements of the Rule, HB 544, and HB 862 under strict scrutiny, beginning with the physician-only provisions of the Rule and HB 544. The State contends that these provisions do not prohibit APCs from providing abortions to Montanans on Medicaid, arguing instead that they only bar reimbursement. But just as the rule prohibiting Medicaid from covering medically necessary abortions in *Jeannette R.* infringed on the right to abortion of Medicaid-eligible Montanans, barring Medicaid from covering abortions provided by APCs infringes on the right to abortion of Medicaid-eligible Montanans who seek abortion care from such providers. Applying the strict scrutiny analysis, this Court concludes that there is no medically acknowledged bona fide health reason for restricting Medicaid coverage of abortions to physicians only. *Armstrong* held that there was no bona fide health reason to require that "abortions be performed only by a physician to the exclusion of a trained, experienced and medically competent physician assistant." *Armstrong*, ¶ 66. Further, just last month, the Montana Supreme Court held that "there is no medically acknowledged, bona fide health risk for the State to restrict the availability of abortion care by preventing [advanced practice registered nurses ("APRNs")] from performing abortions." *Weems v. State*, 2023 MT 82, ¶ 1, ___ Mont. ___, ___ P.3d ___, 2023 WL 3400808 ("*Weems II*"). The physician-only requirements of the Rule and HB 544 do not satisfy strict scrutiny.

Turning to the prior authorization requirements in the Rule and HB 544, the Court concludes that Plaintiffs have established that these requirements infringe on their patients' right to abortion because they require Medicaid patients to make an extra in-person visit to a health care provider, impose a waiting period, and ban Plaintiffs' provision of medication abortion to Medicaid patients via direct-to-patient telehealth. The State has not demonstrated that the prior authorization requirements address a medically acknowledged, bona fide health risk. For that

reason alone, this Court concludes that these provisions fail strict scrutiny as articulated in *Armstrong*. This conclusion is bolstered by *Planned Parenthood of Montana v. State by & through Knudsen*, 2022 MT 157, ¶ 51, 409 Mont. 378, 515 P.3d 301("*PPMT v. State*"), in which the Montana Supreme Court affirmed a preliminary injunction of a statute that also required an extra visit, imposed a waiting period, and banned direct-to-patient medication abortion.

The State argues that the prior authorization requirements serve the compelling governmental interest in preventing Medicaid fraud. But the Montana Supreme Court has never recognized this as a compelling interest that can justify an abortion restriction. Further, the State has introduced no evidence that abortion providers engage in Medicaid fraud when they make medical necessity determinations. Regardless, the Court concludes that the Rule and HB 544 are not narrowly tailored to address any interest in preventing Medicaid fraud. Far from paperwork requirements ensuring that providers are not committing fraud, they impede Medicaid patients' access to abortions by requiring patients to make an additional visit to a health care provider, imposing a waiting period, and eliminating the option of medication abortion via direct-to-patient telehealth for Montanans on Medicaid.

The State's invocation of a risk of a federal audit is also unavailing. The hypothetical possibility of an audit is not a medically acknowledged bona fide health risk, nor is it otherwise a compelling state interest that would justify infringing on a constitutional right. Moreover, federal law prohibits Montana Medicaid from seeking federal funds for abortions unless there is a risk of death to the pregnant person or the pregnancy results from rape or incest. It has nothing to say about whether Montana Medicaid may otherwise cover medically necessary abortions. The State introduced no evidence that there was insufficient documentation for the six abortions between July 2011 and June 2021 that fell into the two federally funded categories.

The Court turns to the final provision of the Rule and HB 544, the narrowed definitions of medical necessity. The definition of medical necessity in Mont. Admin. R. 37.82.102(18)(a) has remained substantially unchanged since it was promulgated in 1980, *see* MAR Notice No. 46-2-222 at 631–32 (Feb. 28, 1980), including when this Court decided *Jeannette R.* in 1995. The State cannot circumvent *Jeannette R.*'s requirement that it cover medically necessary abortions by restricting the category of abortions classified as medically necessary. The State has offered no medically acknowledged, bona fide health risk that the new definitions address, nor has it offered any reason to implement a definition of medical necessity unique to abortion. Nor does the State offer any reason why its narrow, more restrictive definitions of medical necessity are authorized under *Jeannette R.* or could somehow be read to effectuate that decision. Rather, the definitions serve to limit access to abortions otherwise required to be covered by *Jeannette R.*, and this Court has before it no reason to disturb the analysis and holding of that case. At their core, these definitions attempt to supplant the clinical judgment of Plaintiffs as to what constitutes "medical necessity"—an essential component of the provider-patient relationship that *Armstrong* and its progeny protect from government disruption and interference. As a result, the provisions of the Rule and HB 544 that narrow the definition of medical necessity fail strict scrutiny.

Finally, the Court addresses HB 862, which bars Medicaid coverage for abortions except in cases where the patient is at risk of death or the pregnancy results from rape or incest. *Jeannette R.* declared unconstitutional a regulation that did the same thing. The State has not established any medically acknowledged bona fide health risk that HB 862 addresses—indeed, it bans virtually all medically necessary abortions under Medicaid, save for these extremely narrow exceptions. Under the principles articulated in *Jeannette R.* and *Armstrong*, HB 862 fails strict scrutiny.

For all of these reasons, this Court concludes that at this preliminary stage, Plaintiffs have shown they are likely to succeed on their claims that the Rule, HB 544, and HB 862 violate the right to privacy under the Montana Constitution.

**III. Equal Protection Claims**

Article II, Section 4 of the Montana Constitution states that "[n]o person shall be denied the equal protection of the laws." Mont. Const. Art. II, § 4. This clause "embod[ies] a fundamental principle of fairness: that the law must treat similarly-situated individuals in a similar manner." *McDermott v. Mont. Dep't of Corrs.*, 2001 MT 134, ¶ 30, 305 Mont. 462, 29 P.3d 992 (2001). Plaintiffs argue that the Rule, HB 544, and HB 862 each violate the equal protection clause by discriminating against pregnant Medicaid patients who decide to terminate their pregnancies and that the Rule and HB 544 also violate the guarantee by discriminating against pregnant Medicaid patients seeking an abortion from an APC.

Under the equal protection clause, if a classification "affects a suspect class or threatens a fundamental right," the Court must apply strict scrutiny. *Id.* ¶ 31. To survive strict scrutiny, the law or policy must be "narrowly tailored to serve a compelling State interest." *Id.* Because the Rule, HB 544, and HB 862 each infringe on Montanans' fundamental right to access pre-viability abortions, *see supra*, this Court must apply strict scrutiny. The Rule and statutes can survive strict scrutiny only if they are narrowly tailored to address a medically acknowledged, bona fide health risk, the lone compelling interest that the Supreme Court has recognized can justify a restriction on pre-viability abortions. *See Armstrong*, ¶ 59.

First, Plaintiffs have established that they are likely to succeed on the merits of their claim that the Rule, HB 544, and HB 862 each violate equal protection by discriminating against pregnant Medicaid patients who decide to terminate their pregnancies. The Rule and statutes enact

restrictions that will prevent pregnant Medicaid patients who decide to terminate their pregnancies from accessing those medically necessary abortions, *see supra*, without imposing similar restrictions on medically necessary care for Medicaid patients who choose to continue their pregnancies. As this Court explained in *Jeannette R.*, "[t]he state has taken the class of indigent pregnant Medicaid eligible women and divided them. One class, who needs medically necessary treatment (an abortion) are not entitled to help from the state. However, another class (those women for whom child birth is a medically necessary treatment) are entitled to state financial help." *Jeannette R.* at 22. Plaintiffs have established that this classification is not narrowly tailored to address a medically acknowledged, bona fide health risk—preventing Medicaid patients from obtaining medically necessary care does not address any such risk.

Second, Plaintiffs have established that they are likely to succeed on the merits of their claim that the Rule and HB 544 each violate equal protection by discriminating against pregnant Medicaid patients seeking an abortion from an APC. The Rule and HB 544 treat two similarly situated classes differently: Medicaid would cover abortions for pregnant Medicaid patients who seek an abortion from a physician but not for pregnant Medicaid patients who seek an abortion from an APC. Plaintiffs have established that this classification is not narrowly tailored to address a medically acknowledged, bona fide health risk. Plaintiffs have established that APCs can safely and effectively provide abortions; *see also Weems II*, ¶ 51 ("The State has failed to meet its burden of demonstrating that APRN-FNPs and APRN-CNMs providing abortion care present a medically acknowledged, bona fide health risk. The State has failed to present any evidence that demonstrates abortions performed by APRNs include more risk than those provided by physicians or PAs. The State has failed to identify any reason why APRNs should be restricted from providing abortions, and thus failed to articulate a medically acknowledged, bona fide health risk."). The Court

concludes that Plaintiffs have shown they are likely to succeed on their claims that the Rule, HB 544, and HB 862 violate the equal protection clause of the Montana Constitution.

## IV. Remaining Preliminary Injunction Factors

Turning to irreparable harm, the Montana Supreme Court has held that "the loss of a constitutional right constitutes irreparable harm," *PPMT v. State*, ¶ 60, which Plaintiffs have demonstrated here. The same is true under federal preliminary injunction law. *See Edmo v. Corizon, Inc.*, 935 F.3d 757, 798 (9th Cir. 2019). As described above, the statutes and the Rule infringe on the fundamental constitutional rights of Plaintiffs' Medicaid patients.

Further, Plaintiffs have established that if the Rule, HB 544, and HB 862 were to take effect, they would have devastating health consequences for Plaintiffs' Medicaid patients. Because of the low number of physicians providing abortions in Montana, the physician-only requirement in the Rule and HB 544 would significantly reduce the availability of abortions and impede abortion access for Montanans on Medicaid. The prior authorization requirements in the Rule and HB 544 would require an additional visit to a health care provider, impose a waiting period, and eliminate direct-to-patient medication abortion, irreparably harming rural Medicaid patients, Medicaid patients with disabilities, Medicaid patients with limited access to transportation, and Medicaid patients suffering from intimate partner violence. Finally, the Rule and HB 544's restriction of the definition of medical necessity would limit the abortions Medicaid would cover, meaning that Montanans on Medicaid whose abortions would be covered under the definition of medical necessity applicable to almost all other medical care—and whose health care providers have deemed their abortions to be medically necessary—would be forced either to draw on their limited financial resources to pay for an abortion or to forgo medically necessary care. HB 862 would go farther, making it impossible for almost all Medicaid patients to obtain coverage

for their abortions. The Court concludes that the Rule, HB 544, and HB 862 would each cause Montanans on Medicaid to delay their abortions, needlessly subjecting them to increased medical risk, or to carry a pregnancy to term against their will. The Rule, HB 544, and HB 862 would each cause Plaintiffs' patients irreparable harm.

As to the remaining preliminary injunction factors, the balance of the equities and the public interest, these "merge into one inquiry when the government opposes a preliminary injunction." *Porretti v. Dzurenda*, 11 F.4th 1037, 1050 (9th Cir. 2021). The State has no legitimate interest in enforcing unconstitutional regulations and laws. *See Doe v. Kelly*, 878 F.3d 710, 718 (9th Cir. 2017). The equities and the public interest weigh in favor of protecting Plaintiffs' patients' constitutional rights by preserving the status quo, under which Plaintiffs make clinical determinations of medical necessity with respect to their Medicaid patients free from unwarranted government intervention, consistent with the values of privacy, bodily autonomy, and individual dignity secured by the Montana Constitution's Declaration of Fundamental Rights. *See Armstrong*, ¶ 56. Granting a preliminary injunction will ensure that Montanans on Medicaid continue to have access to constitutionally protected abortions and safe, effective medical care.

**CONCLUSION**

Because the Court issues a preliminary injunction, it need not reach the issue of Plaintiffs' request in the alternative for a writ of prohibition.

Upon consideration of the evidence and the parties' arguments, the Court finds the following:

1. Plaintiffs have established that they are likely to succeed on the merits of their claims that the Rule, HB 544, and HB 862 violate the Montana Constitution's guarantees of the right to privacy and the right to equal protection;

2. Plaintiffs and their patients will suffer irreparable harm if enforcement of the Rule, HB 544, and HB 862 is not preliminarily enjoined;
3. The balance of the equities weighs in favor of granting preliminary relief; and
4. Granting a preliminary injunction would serve the public interest.

**ORDER**

**IT IS HEREBY ORDERED** that Plaintiffs' Motions for Preliminary Injunctions are **GRANTED** and Defendants are **ENJOINED** from enforcing the Department of Public Health and Human Services rule proposed at Montana Administrative Register Notice 37-1024 amending Mont. Admin. R. 37.82.102 and 37.86.104, 2023 House Bill 544, and 2023 House Bill 862 with respect to any abortions provided while this order is in effect, pending a final disposition of this litigation.

Pursuant to Montana Code Annotated § 27-19-306(1)(b)(ii), no bond is required.

DATED this ___ day of June, 2023.

_____
MIKE MENAHAN
District Court Judge

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Electronically Signed By:
Hon. Judge Mike Menahan
Tue, Jul 11 2023 03:14:47 PM

# Exhibit B

**MONTANA FIRST JUDICIAL DISTRICT COURT,**
**LEWIS AND CLARK COUNTY**

| | |
|---|---|
| PLANNED PARENTHOOD OF MONTANA and SAMUEL DICKMAN, M.D., on behalf of themselves and their patients,<br><br>Plaintiffs,<br><br>vs.<br><br>STATE OF MONTANA, by and through AUSTIN KNUDSEN, in his official capacity as Attorney General, the MONTANA DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES, and CHARLIE BRERETON, in his official capacity as Director of the Department of Public Health & Human Services,<br><br>Defendants. | Cause No. ADV-2023-231<br><br>**[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION** |

Before the Court are Plaintiffs Planned Parenthood of Montana (PPMT) and Dr. Samuel Dickman's Motion for Preliminary Injunction on House Bill 575 (HB 575) and Motion for Preliminary Injunction on House Bill 721 (HB 721). Raph Graybill, Michelle Nicole Diamond, Sean C. Chang, Melissa Cohen, Diana O. Salgado, and Dylan Cowit represent Plaintiffs. Attorney General Austin Knudsen, Thane Johnson, Michael Russell, Alwyn Lansing, and Emily Jones represent Defendants State of Montana (State), the Montana Department of Public Health & Human Services (DPHHS), and Charlie Brereton, in his official capacity as Director of DPHHS.

## FACTS

Plaintiffs brought this lawsuit on behalf of themselves and their patients to challenge the constitutionality of two Montana statutes: HB 575 and HB 721. HB 575 requires that prior to every abortion, a determination of viability be "made in writing by the physician or physician assistant performing an abortion and include the review and record of an ultrasound." HB 575 § 1. According to Plaintiffs, HB 575 will prevent them from providing direct-to-patient medication abortions (MABs), which are provided prior to fetal viability, via telehealth, and typically without an ultrasound. Plaintiffs also challenge the constitutionality of HB 721, which prohibits performing dilation and evacuation (D&E) procedural abortions except in a medical emergency. HB 721 § 3. HB 721 would effectively ban pre-viability abortions, beginning after approximately 15 weeks from the first day of the patient's last menstrual period (LMP). A violation of HB 721 is a felony punishable by a fine or imprisonment of up to ten years. *Id.* § 3(2).

On May 3, 2023, Governor Greg Gianforte signed HB 575 into law. On May 16, 2023, the Governor signed HB 721 into law. Both laws have immediate effective dates. This Court granted Plaintiffs' motions for temporary restraining orders against HB 575 and HB 721 on May 4 and May 18, respectively.

PPMT is the largest provider of reproductive health care services in Montana, operating five health centers throughout the State. Verified Amend. Compl. ¶¶ 14-15. Dr. Dickman is PPMT's Chief Medical Officer. *Id.* ¶ 17. Plaintiffs offer MABs up to 11 weeks LMP and procedural abortions up to 21 weeks and 6 days LMP, among other services. *Id.* ¶¶ 17-18.

There is no dispute that all MABs provided by Plaintiffs are pre-viability abortions. *Id.* ¶ 32. Plaintiffs provide two forms of MAB using telehealth: site-to-site and direct-to-patient. *Id.*

¶ 34. For site-to-site MABs, a patient visits a PPMT health center and connects through a secure video telehealth platform with an abortion provider at another PPMT health center. *Id.* ¶ 35 n.7. For direct-to-patient MABs, patients connect with a PPMT provider through a secure video telehealth platform from the patient's home or a location of their choice; are screened for eligibility to participate in the direct-to-patient program; and, if the patients are eligible, have their MAB medications mailed to a Montana address. *Id.* ¶ 36. Relying on peer-reviewed medical literature regarding the safety and efficacy of providing MABs through direct-to-patient telehealth, PPMT has provided direct-to-patient MABs without requiring an ultrasound for years. *Id.* ¶¶ 64-67. Providers can typically determine gestational age for eligible MAB patients using the date of their LMP and screen for health risks (e.g., ectopic pregnancy) when discussing the patients' health history during the telehealth visit. *Id.* ¶¶ 36, 67. Direct-to-patient MABs have allowed Plaintiffs to expand access to abortion in Montana, which is a large and rural state where many patients do not live near an abortion provider. *Id.* ¶ 38. Prolonged travel to an abortion provider can pose particular challenges for patients with mobility limitations; those who cannot afford to take time away from work, school, or family care duties; and those who experience intimate partner violence. *Id.* ¶¶ 10, 39.

Plaintiffs also provide procedural abortions, using the method known as D&E beginning at approximately 15 weeks LMP. *Id.* ¶¶ 17-18, 42. A D&E involves a medical provider removing the contents of the uterus using suction and instruments such as forceps. *Id.* ¶ 42. D&E abortions are the most common method of abortion after approximately 15 weeks LMP, and in Montana, they are the only abortion method available in an outpatient setting at that stage in pregnancy. *Id*. Complication rates from procedural abortions are low, with the American College of Obstetrics and Gynecology (ACOG) explaining that the D&E method is "evidence-

based and medically preferred because it results in the fewest complications for women compared to alternative procedures." *Id.* ¶ 44.

**PRINCIPLES OF LAW**

Pursuant to 2023 Senate Bill 191, as of March 2, 2023, "[a] preliminary injunction order or temporary restraining order may be granted when the applicant establishes that: (a) the applicant is likely to succeed on the merits; (b) the applicant is likely to suffer irreparable harm in the absence of preliminary relief; (c) the balance of equities tips in the applicant's favor; and (d) the order is in the public interest." *See* SB 191, 2023 Leg. Reg. Sess. (Mont. 2023) (amending § 27-19-201, MCA). The Montana Legislature intended for this standard to "mirror the federal preliminary injunction standard" and "closely follow United States supreme court case law." SB 191, § 1. This new standard is conjunctive, not disjunctive, meaning the moving party must establish all four factors to obtain relief. *Id.*; *see also All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131–35 (9th Cir. 2011) (addressing interaction of four factors in federal standard); SB 191 § 1.

Under the federal preliminary injunction standard, "[a] preliminary injunction is not a preliminary adjudication on the merits, but a device for preserving the status quo and preventing the irreparable loss of rights before judgment." *Textile Unlimited, Inc. v. A..BMH & Co.*, 240 F.3d 781, 786 (9th Cir. 2001) (citing *Sierra On–Line, Inc. v. Phoenix Software, Inc.*, 739 F.2d 1415, 1422 (9th Cir. 1984)); *cf. Driscoll v. Stapleton*, 2020 MT 247, ¶ 14, 401 Mont. 405, 473 P.3d 386 (The purpose of a preliminary injunction is to "to preserve the status quo and minimize the harm to all parties pending final resolution on the merits.").

**ANALYSIS**

Upon consideration of the parties' arguments, the Court determines that Plaintiffs have

standing to challenge HB 575 and HB 721 and that they have met their burden to show that the laws should be preliminarily enjoined.

## I. Standing

As an initial matter, Plaintiffs have standing to challenge the constitutionality of HB 575 and HB 721. The Montana Supreme Court has repeatedly held that health care providers "have standing to assert on behalf of their women patients the individual privacy rights under Montana's Constitution of such women to obtain a pre-viability abortion from a health care provider of their choosing." *Armstrong v. State*, 1999 MT 261, ¶¶ 12-13, 296 Mont. 361, 989 P.2d 364; *see also Weems v. State*, 2019 MT 98, ¶ 12, 395 Mont. 250, 440 P.3d 4 ("*Weems I*") ("[W]hen 'governmental regulation directed at health care providers impacts the constitutional rights of women patients,' the providers have standing to challenge the alleged infringement of such rights.") (quoting *Armstrong*, ¶¶ 8–13). Both of the challenged laws "impact the constitutional rights of women patients" and "are regulations "directed at health care providers." HB 575 requires patients to have an ultrasound prior to an abortion, thereby burdening abortion providers' medical practice and prohibiting patients from accessing direct-to-patient MABs. HB 721 prohibits abortion providers from performing a specific medical procedure, thereby burdening their medical practice and preventing patients from accessing abortions after approximately 15 weeks LMP. Applying Montana's well-settled precedent, the Court concludes that Plaintiffs have standing to challenge the constitutionality of HB 575 and HB 721.

Defendants ask this Court to disregard Montana Supreme Court precedent "in light of [the] shifting legal landscape" around abortion cases. The Court is not persuaded there have been any relevant changes in federal standing law, and in any event the Court cannot—and will not—disregard directly applicable precedent on standing from the Montana Supreme Court. *Cf.*

*State v. Whitehorn*, 2002 MT 54, ¶ 14, 309 Mont. 63, 50 P.3d 121 ("Under the principles of binding authority, the District Court could not overrule our holding …, only this Court could do so."). *Armstrong* and *Weems I* confer third-party standing on abortion providers to challenge laws that "impact the constitutional rights of women patients" or which are "directed at health care providers." Plaintiffs therefore plainly have standing.

## II. Likelihood of Success on the Merits

The Montana Supreme Court has repeatedly held that the right to privacy in Article II, Section 10 of the Montana Constitution "protects a woman's right of procreative autonomy — i.e., here, the right to seek and to obtain … a pre-viability abortion, from a health care provider of her choice." *Armstrong*, ¶ 14; *see also Weems v. State*, 2023 MT 82, ¶ 51 ("*Weems II*").[1] Any law that interferes with a Montanan's right to obtain a pre-viability abortion from a qualified health care provider of their choice therefore implicates the fundamental right to privacy and must be reviewed under strict scrutiny. *Weems II*, ¶ 43; *Armstrong*, ¶ 34. The only interest the Montana Supreme Court has recognized justifying the invasion of the right to obtain a pre-viability abortion is if the government clearly and convincingly demonstrates that the abortion restriction addresses a medically acknowledged, bona fide health risk to Montanans. *See Weems II*, ¶ 37; *Armstrong*, ¶ 62.

At the outset, the Court concludes that HB 575 and 721 implicate the right to privacy enumerated in Article II, Section 10 of the Montana Constitution by banning pre-viability abortions. HB 575 bans direct-to-patient MABs, a form of pre-viability abortion that is provided remotely to eligible patients, by requiring all patients to receive an ultrasound before having an abortion. HB 721 bans D&E procedural abortions, which are performed beginning after

[1] Defendants argue that *Armstrong* was wrongly decided and should be overruled. This Court has no authority to overrule binding precedent. *See Whitehorn*, ¶ 14.

approximately 15 weeks LMP, before fetal viability. As both laws restrict access to pre-viability abortions, they plainly implicate the right to privacy.

Contrary to Defendants' assertions, the right to privacy as recognized in *Armstrong* is not merely a right to a health care provider of a patient's choosing. Instead, as the Montana Supreme Court recently stated, "*Armstrong* unequivocally established that a woman has a fundamental right of privacy *to seek abortion care* from a qualified healthcare provider of her choosing, absent clear demonstration by the State of a 'medically-acknowledged, [bona fide] health risk.'" *Weems II*, ¶ 37 (quoting *Armstrong*, ¶ 62) (emphasis added); *see also Armstrong*, ¶ 14 (Article II, Section 10 "protects a woman's *right of procreative autonomy* — i.e., here, the right to seek and to obtain … *a pre-viability abortion* …." (emphasis added)). Though the State generally possesses "a police power by which it can regulate for the health and safety of its citizens," *Wiser v. State*, 2006 MT 20, ¶ 19, 331 Mont. 28, 129 P.3d 133, any such regulation is still subject to strict scrutiny if it implicates a fundamental right. *See Weems II*, ¶¶ 42-43 (rejecting State's argument that because it only regulates who can provide abortions, § 50-20-109(1)(a), MCA, should be subject to rational basis review).

Because HB 575 and HB 721 implicate the fundamental right to privacy, this Court must evaluate whether HB 575 and HB 721 survive strict scrutiny. To survive strict scrutiny, the State must demonstrate that HB 575 and HB 721 are "justified by a compelling state interest and [are] narrowly tailored to effectuate only that compelling interest." *Weems II*, ¶ 34 (quoting *Armstrong*, ¶ 34). "[W]ithin the framework of *Armstrong*, the State's burden is to show there is a 'medically-acknowledged, [bona fide] health risk, clearly and convincingly demonstrated,' justifying interference with a woman's access to abortion and her choice of a health care provider." *Weems II*, ¶ 45 (quoting *Armstrong*, ¶ 62) (alteration in original).

### A. HB 575

The Court concludes that HB 575 does not further a compelling state interest and is not narrowly tailored to do so. Defendants have presented no evidence that HB 575 is necessary to protect patients from a medically acknowledged, bona fide health risk. *Armstrong*, ¶ 59; *Weems II*, ¶ 47.[2]

Based on the evidence before it, the Court finds that MABs, including direct-to-patient MABs provided without an ultrasound, are safe and effective. Dr. Dickman and Plaintiffs' medical expert, Dr. Steven Ralston, testified that based on their own experience as abortion providers and their review of peer-reviewed literature—including a study conducted in Montana—MABs can be provided safely and effectively without an ultrasound and without increasing the rate of complications resulting from the MAB. The Court credits this testimony. On the other hand, Defendants presented no evidence to contradict the fact that PPMT has been providing MABs safely and effectively without use of ultrasound.[3]

At the hearing, the State proffered two purported rationales for its ultrasound requirement; neither can withstand strict scrutiny. First, Defendants argued that ultrasounds are required to determine gestational age accurately, which in turn advances the State's interest in

[2] In addition, to the extent that HB 575's statement that a determination of viability must be "made in writing by the *physician or physician assistant* performing an abortion" could be interpreted to implicitly prohibit advanced practice registered nurses (APRNs) from providing abortions, HB 575 § 1 (emphasis added), such a prohibition likely directly contravenes the Montana Supreme Court's recent decision in *Weems II*. *See Weems II*, ¶ 1 (holding that "there is no medically acknowledged, bona fide health risk for the State to restrict the availability of abortion care by preventing APRNs from performing abortions").

[3] Plaintiffs note that HB 575 imposes similar requirements to those imposed by HB 171, a statute enacted in 2021 that, among other things, would have similarly banned direct-to-patient MABs by requiring in-person examinations prior to all abortions. In preliminarily enjoining HB 171, the district court in Yellowstone County concluded that "medication abortion by . . . telehealth is just as safe and effective as in person." *Planned Parenthood of Mont. v. State*, No. DV 21-00999, 2021 WL 9038524, at *12 (Mont. Dist. Oct. 07, 2021), *aff'd*, 2022 MT 157. The Montana Supreme Court later affirmed the court's grant of a preliminary injunction against HB 171. *Planned Parenthood of Mont. v. State*, No. DA-21-0521, 2022 MT 157, 515 P.3d 301, 409 Mont. 378. These two decisions corroborate this Court's conclusion that at this stage of the litigation, Plaintiffs have shown that direct-to-patient MABs can be provided safely without the need for an ultrasound.

preventing post-viability abortions. The Court is not persuaded that HB 575's ultrasound requirement furthers that interest. Dr. Dickman confirmed that PPMT does not provide MABs without an ultrasound to patients who cannot accurately recall the date of their LMP. The Court also notes that PPMT provides direct-to-patient MABs up to 11 weeks LMP, nearly 13 weeks—or three months—before the 24-week point of fetal viability presumed by the text of HB 575. Based on the testimony of Dr. Ralston and Dr. Dickman, the Court also finds that in many circumstances, it is medically unnecessary to perform an ultrasound to determine gestational age accurately. The Court credits the testimony of Dr. Ralston and Dr. Dickman, both of whom explained that a provider can accurately determine gestational age using the date of the patient's LMP when a patient has regular menstrual periods and can accurately recall the date of their LMP.

Although Defendants' medical expert, Dr. George Mulcaire-Jones, opined that ultrasounds are the standard of care for direct-to-patient MABs, the Court concludes that Dr. Mulcaire-Jones's opinion carries little weight because he has never provided any type of abortion, including a direct-to-patient MAB. Dr. Ralston and Dr. Dickman, by contrast, have extensive experience providing abortion care, including MABs, and testified that the standard of care does not require the use of an ultrasound for all MABs. And peer-reviewed medical literature, which Plaintiffs cite in their Verified Amended Complaint, only buttresses their testimony that it is not the standard of care to require ultrasounds prior to eligible direct-to-patient MABs. The Court therefore credits their testimony over Dr. Mulcaire-Jones' contrary opinion.

Second, the Court finds that at this initial stage, Defendants have not shown that HB 575's ultrasound requirement is medically necessary to screen for ectopic pregnancies, the

State's second rationale. Plaintiffs' witnesses testified that they are able to screen for ectopic pregnancies without an ultrasound, by asking a series of evidence-based screening questions designed to assess the risk that a patient may have an ectopic pregnancy. The Court credits that testimony. Although Dr. Mulcaire-Jones testified that ultrasounds can help screen for ectopic pregnancies, Defendants presented no evidence suggesting that Plaintiffs' methods for screening for ectopic pregnancies without an ultrasound are inadequate or unsafe in the context of an eligible, direct-to-patient MAB.

**B. HB 721**

The Court concludes that HB 721 does not further a compelling state interest, nor is it narrowly tailored to do so. As with HB 575, Defendants present no evidence that HB 721 addresses a medically acknowledged, bona fide health risk. *Armstrong*, ¶ 59; *Weems II*, ¶ 47. Plaintiffs are thus likely to succeed on the merits of their challenge to HB 721.

The Court finds that D&E abortions are safe and effective, as Dr. Dickman testified. Dr. Ralston likewise testified that at the gestational ages at which PPMT performs D&E abortions (between approximately 15 and 21.6 weeks LMP), D&E abortions are safer than childbirth. Dr. Ralston also testified that the State's proposed alternative of an induction abortion is less safe than a D&E, and that the State's other proposed alternatives of inducing fetal demise with an injection of digoxin or potassium chloride (KCl) prior to a D&E add risk to the patient. Plaintiffs also presented evidence from well-regarded medical organizations to support Dr. Dickman and Dr. Ralston's testimony that D&E abortions are safe and effective. *See* The National Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* 63 (2018); Cassing Hammond & Stephen Chasen, *Dilation and Evacuation*, in MANAGEMENT OF UNINTENDED AND ABNORMAL PREGNANCY: COMPREHENSIVE ABORTION CARE

158 (Maureen Paul et al. eds., 2009); ACOG, Practice Bulletin No. 135: *Second Trimester Abortion*, 121(6) Obstetrics & Gynecology 1394, 1394, 1406 (2013). Defendants presented no contrary evidence. The State cites one study in the text of HB 721, but that study shows only that the mortality rate for abortions performed between 13 to 20 weeks LMP is very low. *See* Linda A. Bartlett, et. al., *Risk Factors for Legal Induced Abortion–Related Mortality in the United States*, 103(4) Obstetrics & Gynecology 729, 733 (2004). Moreover, Defendants' own medical expert acknowledged that the instruments and techniques used for D&E abortions are virtually identical to those he used in his own practice for the surgical management of miscarriages. For those reasons, the Court concludes that Defendants failed to demonstrate that HB 721's ban on D&E abortions protects patients from a bona fide health risk.

Defendants argue that HB 721 is justified by the State's interest in prohibiting what it describes as an "inhumane" procedure that carries increased health risks compared to abortions performed in the first trimester. The Court finds that Defendants have not provided any evidence to support this claim. While the risks associated with abortions incrementally increase with gestational age, the evidence before the Court indicates that D&E procedures are extremely safe.

## III. Irreparable Harm

The Court finds that Plaintiffs and their patients will suffer irreparable harm if HB 575 and HB 721 are not preliminarily enjoined.

It is well-established that the deprivation of constitutional rights—including the right to privacy—is itself irreparable harm. *See Mont. Cannabis Indus. Ass'n v. State*, 2012 MT 201, ¶ 15, 366 Mont. 224, 286 P.3d 1161 ("[T]he loss of a constitutional right constitutes irreparable harm for the purpose of determining whether a preliminary injunction should be issued."); *Weems*, ¶ 25 ("We have recognized harm from constitutional infringement as adequate to justify

a preliminary injunction."). As discussed above, this Court has concluded that these laws likely violate the right to privacy. HB 575 and HB 721 would immediately take effect absent a preliminary injunction. Plaintiffs' patients would therefore be immediately deprived of their fundamental constitutional right to privacy absent a preliminary injunction.

Plaintiffs' patients also face irreparable harm to their health if HB 575 and 721 are not preliminarily enjoined. With respect to HB 575, Dr. Dickman testified that direct-to-patient MABs are an important way of providing access to abortion for patients who do not live close to a provider or who have work or caretaking responsibilities, mobility limitations, or particular privacy concerns, such as patients who are the victims of intimate partner violence. Defendants argue that HB 575 will not cause irreparable harm because patients can obtain an ultrasound from another ultrasound provider and send the results to their abortion provider. However, Plaintiffs presented evidence that for some patients, the ultrasound requirement may cut off access to an abortion altogether. For example, Dr. Dickman testified about one recent patient who lives on a Native American reservation who he believes likely would not have been able to obtain an abortion but for the direct-to-patient MAB program.[4] Defendants also ignore that HB 575's ultrasound requirement forces Montanans to undergo additional stress, expense, and unnecessary travel to a health center capable of performing a first-trimester ultrasound—all of which subject Plaintiffs' patients to health risks by delaying critical abortion care, for no corresponding medical benefit. *See Weems II*, ¶ 50 (delays in abortion care "result in comparatively higher risk, greater expenses, and even ineligibility for medication abortion as pregnancy advances"). Based on the foregoing, this Court concludes that HB 575's prohibition

[4] Defendants point out that in the event a patient experiences complications after a MAB provided via telehealth, PPMT allows patients to follow up with a PPMT provider in person at a PPMT health center. This does not undermine Plaintiffs' argument. An in-person appointment is just one method of follow-up that PPMT offers its patients, and the services available *after* a MAB do not speak to the benefits or necessity of a certain method of providing the MAB itself.

of direct-to-patient MABs will likely cause irreparable harm.

With respect to HB 721, the Court finds that contrary to Defendants' assertions, there are no feasible alternatives to D&Es in Montana. Defendants argue that Plaintiffs can continue to provide abortions after 15 weeks LMP using induction abortions or by performing a D&E after first inducing fetal demise with an injection of digoxin or KCl. However, Dr. Ralston testified that inducing fetal demise prior to a D&E requires special training that few abortion providers possess, and that injections of digoxin or KCl actually *increase* the risk to the pregnant patient. Dr. Dickman also testified that neither fetal demise procedures nor induction abortions are available in outpatient settings in Montana, and thus are not a feasible alternative for patients seeking a second trimester abortion. The Court therefore concludes that absent a preliminary injunction, HB 721's prohibition of D&E abortions will cause irreparable harm to Plaintiffs and their patients.

## IV. The Balance of Equities and the Public Interest

Finally, the Court concludes that the balance of equities and the public interest also weigh in favor of preserving the status quo. The balance of the equities and the public interest "merge into one inquiry when the government opposes a preliminary injunction." *Porretti v. Dzurenda*, 11 F.4th 1037, 1050 (9th Cir. 2021). The equities weigh strongly in favor of preserving the status quo while this case proceeds. Were these laws to go into effect during the pendency of the litigation, they would restrict Montanans' fundamental constitutional right to seek a pre-viability abortion. Defendants, by contrast, have no legitimate interest in enforcing laws that, as here, likely infringe Montanans' constitutional rights. *Doe v. Kelly*, 878 F.3d 710, 718 (9th Cir. 2017) ("The 'government suffers no harm from an injunction that merely ends unconstitutional practices and/or ensures that constitutional standards are implemented.'") (citation omitted);

*Zepeda v. I.N.S.*, 753 F.2d 719, 727 (9th Cir. 1983) (the government "cannot reasonably assert that it is harmed in any legally cognizable sense by being enjoined from constitutional violations"). And "[i]t is always in the public interest to prevent the violation of a party's constitutional rights." *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (internal quotation marks and citation omitted). Preliminarily enjoining the laws also serves the public interest because it allows Plaintiffs to continue providing—and their patients to continue accessing—constitutionally protected pre-viability abortions in the form of direct-to-patient MABs and D&Es. Accordingly, this Court determines that preservation of the status quo through issuance of a preliminary injunction will serve the public interest.

## V. Conclusion

Upon consideration of the parties' arguments, the Court determines the following:

1. Plaintiffs have established that they are likely to succeed on the merits of their claims that HB 721 and HB 575 violate the Montana Constitution's guarantee of the right to privacy;
2. Plaintiffs and their patients will suffer irreparable harm if enforcement of HB 721 and HB 575 is not preliminarily enjoined;
3. The balance of the equities weighs in favor of granting preliminary relief; and
4. Granting a preliminary injunction would serve the public interest.

## ORDER

**IT IS HEREBY ORDERED** that Plaintiffs' Motions for Preliminary Injunctions on HB 575 and HB 721 are **GRANTED** and Defendants are enjoined from enforcing HB 575 and HB 721 with respect to any abortions provided while this order is in effect, pending a final disposition of this litigation.

Pursuant to Montana Code Annotated § 27-19-306(1)(b)(ii), no bond is required.

DATED this _____ day of June, 2023.

_____
MIKE MENAHAN
District Court Judge

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**MONTANA FIRST JUDICIAL DISTRICT COURT,**
**COUNTY OF LEWIS & CLARK**

| | |
|---|---|
| ALL FAMILIES HEALTHCARE; BLUE MOUNTAIN CLINIC; AND HELEN WEEMS MSN APRN-FNP, on behalf of themselves and their patients<br>Plaintiffs,<br>vs.<br><br>STATE OF MONTANA; MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; and CHARLIE BRERETON, in his official capacity as Director of the Department of Public Health and Human Services<br>Defendants. | Cause No.: DDV-2023-592<br>Hon. Judge Christopher D. Abbott<br><br>**AFFIDAVIT OF HELEN WEEMS, MSN, APRN-FNP, IN SUPPORT OF PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION** |

I, Helen Weems, MSN, APRN-FNP, affirm that:

1. I submit this affidavit in support of Plaintiffs' Application for a Temporary Restraining Order and Preliminary Injunction against the enforcement of HB 937 (the "Act") and the Final Rules related to the licensure of clinics that provide abortion services.

Background and Experience

2. I am a nurse practitioner licensed to practice in Montana, and one of the plaintiffs in this case. I own and am the sole clinician at All Families Healthcare ("All Families"), a sexual and reproductive health clinic in Whitefish, Montana, which I opened in 2018. I am also the only clinician providing abortion care in Northwest Montana. Before All Families opened in 2018, the Northwest region had been without an abortion provider since 2014.

3. I have a master's degree of science in nursing, family practice, from Vanderbilt University in Nashville, Tennessee. I am an advanced practice registered nurse ("APRN") licensed to practice in Montana, and I have been board certified in family practice since 1999. I also have prescriptive authority from the Board of Nursing and am registered with the U.S. Drug Enforcement Authority ("DEA"), which permits me to prescribe schedule II through V controlled substances.

4. For more than 20 years, I have provided health care services as a nurse practitioner, including to low-income patients. I have always provided patient-centered care based on trust and respect for my patients' decisions, regardless of their income level or insurance provider, and use that same approach at All Families.

5. In 2022, All Families served approximately 800 patients, with nearly 1,000 patient visits. All Families provides comprehensive sexual and reproductive health care services, including 2S-LGBTQIA+ care and gender-affirming care; gynecological exams; diagnosis and treatment of sexually transmitted infections; same-day access to the full spectrum of contraceptive

options, including insertion of IUDs and Nexplanon implants; early miscarriage management; and abortion services.

6. I reviewed HB 937, which was passed by the Montana legislature in 2023. I understand the Act provides for "abortion clinic" licensure, requires the Department of Public Health and Human Services ("DPHHS") to issue regulations setting out licensing requirements, and took effect on October 1, 2023. Nearly a year later, on July 26, 2024, DPHHS published Proposed Rules, which I reviewed. I testified at the public hearing on August 16, 2024, in opposition to the Proposed Rules and submitted a written comment in opposition on August 23, 2024. I also reviewed the Final Rules, which were published on September 20, 2024. The Final Rules adopt the Proposed without substantive changes.

7. HB 937 and the Final Rules are unrelated to patient health and safety, and target clinicians that provide abortion care simply because we provide this essential health care, and our patients.

8. HB 937 and the Final Rules threaten to end All Families' abortion practice and force us to close. As a result, HB 937 and the Final Rules will have a grave impact on *all* my patients, not only the patients who turn to All Families for abortion care. At a minimum, HB 937 and the Final Rules risk a lapse in All Families' ability to provide abortion care, which will deny patients access to their chosen provider.

All Families and Our Patients

9. At All Families, I provide medication abortion up to 11 weeks as measured from the first day of the person's last menstrual period ("LMP") and aspiration abortions, also known as procedural abortions, up to 12 weeks and 6 days LMP. In 2023, I provided approximately 380 abortions. As of September 2024, I have provided over 300 abortions this year.

10. Medication abortion makes up the vast majority of abortion care I provide. I provide

medication abortion in person or via telehealth, which lets my patients access care without having to visit All Families in person. For patients accessing abortion via telehealth, I consult with a patient remotely about available options, review prior history, and confirm the patient is eligible for medication abortion. In some cases, patients are not eligible for a medication abortion without first obtaining an ultrasound, which I will refer them for; in most cases, however, the patient and I can date their pregnancy and determine their eligibility for medication abortion based on their LMP, without an ultrasound. Where appropriate, I then write a prescription for medication abortion, and the medications are mailed to the patient in Montana. There are multiple safe and effective medication abortion regimens, including a mifepristone and misoprostol regimen and misoprostol-only regimen.

11. Medication abortion involves no anesthesia. I recommend ibuprofen to my patients for pain management, or may prescribe a narcotic, as well as anti-nausea medication.

12. Of the medication abortion care I provide, more than half is provided via telehealth, and this option has been critical to many of my patients. It provides flexibility and discretion, particularly for those who cannot take time off from work or find childcare, or whose privacy and, sometimes, safety would be jeopardized by making an in-person visit, as may be the case with an abusive partner. It also facilitates medical treatment for my many patients who live in the remote, rural regions of the State, which can be hours from All Families or the nearest other clinic. Some live in the northeastern part of the State, about 9 to 10 hours away, and would otherwise have to travel through treacherous mountain passes and inclement weather to access abortion care. Patients may not have gas money or cars that can reliably and safely make it on these roads.

13. I also provide procedural abortion, which involves dilating the patient's cervix and then evacuating the uterus using suction aspiration. To numb the cervix, I administer a cervical

block, a local anesthetic (lidocaine). For pain management, I prescribe ibuprofen, and occasionally lorazepam to relax the patient.

14. My patients seek abortion services for a variety of reasons: some lack the financial means to raise a child; others are not ready to become a parent; many have physical and emotional health issues that would be exacerbated by continuing a pregnancy; and some have become pregnant as a result of incest or rape. In every circumstance, forcing such patients to continue their pregnancies would cause needless pain and suffering, and can have long-term consequences for patients and their families.

15. All Families meets the applicable standards of care and existing Montana legal requirements for clinicians' offices. I am a licensed nurse practitioner and subject to oversight by the Board of Nursing. I am registered with the Board of Pharmacy as a medical practitioner dispenser, which permits me to dispense prescription medications from All Families, and I am registered with the U.S. DEA. I am also certified by the American Academy of Nurse Practitioners Certification Board. All Families is also subject to regulation by DPHHS to the extent it administers the Clinic Laboratory Improvement Amendments ("CLIA") and enforces Montana's abortion-reporting laws. Additionally, All Families is certified as in compliance with the clinical standards of the National Abortion Federation ("NAF"), the professional association of abortion providers, and is inspected by NAF.

## HB 937 and the Final Rules

### *Arbitrary and Unnecessary Facility Licensure Requirement*

16. For years, Montana provided that health care facility licensure does not apply to offices of private clinicians, like All Families. I understand that is still Montana law—except, as a result of HB 937, for clinicians' offices that provide abortion care, like All Families, which now must obtain specific facility licensure simply because we provide abortion care.

17. Requiring abortion clinics to obtain facility licensure is medically unnecessary, yet another effort to single out abortion care for targeted and extra regulation, and only harms rather than helps patients.

18. To be clear, that is ***not*** because All Families is ***not*** subject to regulation. As explained above, All Families is already subject to federal, State, and professional oversight and regulation—just like other clinicians' offices in the State that do not provide abortion care.

19. If All Families ceased providing abortion care but continued to offer the *same* care (whether by medication or procedure) to manage miscarriage, none of the requirements of HB 937 and the Final Rules would apply.

20. Moreover, most of the abortion care I provide is by medication. HB 937 and the Final Rules set various requirements for our facility to be licensed, although medication abortion generally involves ingesting one pill in the office and another set of pills at home (which, of course, is subject to no "health care facility" regulations). Many of my medication abortion patients never set foot in All Families because they access medication abortion via telehealth. Yet, HB 937 and the Final Rules would require the *facility* to obtain a license and meet these unnecessary requirements. None of that serves any health or safety purpose. Rather, HB 937 and the Final Rules are another mechanism to further confuse, restrict, and control access to abortion in Montana.

21. The Proposed Rules, Final Rules, and commentary from DPHHS repeatedly refer to standards for outpatient centers for surgical services as a reference point for standards for clinics that provide abortion care. The Final Rules also use terminology like "pre-operative," "post-operative," and "admitting diagnosis," suggesting the facilities being described are hospitals or ambulatory surgical centers. A medical consensus confirms that there is no medical reason for mandating abortion care—whether by medication or procedure—be provided in ambulatory

surgical settings, and that abortion is safely performed in outpatient settings, including clinicians' offices.[1]

22. Below are some specific examples of the medically unnecessary requirements.

*Physical Plant Requirements*

23. All Families cannot meet the physical plant requirements in Rule III which mandates all "patient rooms" be 100 square feet, with 4 feet available on one side of the exam table and 3 feet on all other sides, and that corridors be at least 6 feet wide. Proposed Rule III, at 1769 (adopted as proposed).

24. DPHHS does not define "patient room," but states in responses on the Final Rules that "patient rooms" are rooms "in which a patient is assessed or treated." Final Rules, Response 65, at 2260. All Families counsels patients and prescribes, administers, and dispenses medication abortion to patients in a room that does not have an exam table and does not meet the mandated dimensions, but has sufficient space for these purposes. All Families also counsels patients and prescribes, administers, and dispenses medication in that same room for patients who are seeking care other than abortion care. As with the other requirements, there is simply no reason to single out abortion as Rule III does. *See* Proposed Rule III, at 1769 (adopted as proposed).

25. All Families' corridors are not 6 feet wide, as Rule III requires. *See* Proposed Rule III, at 1769 (adopted as proposed). DPHHS does not explain the rationale for this dimension. This width requirement is not necessary, for example, to allow passage by emergency services as All Families' coordinators are wide enough for emergency services, including a stretcher, to pass through.

26. The physical plant requirements are especially nonsensical when it comes to All

[1] National Academies of Sciences, Engineering and Medicine, Quality and Safety of Abortion, at 79.

Families provision of medication abortion, whether in person or via telehealth. It makes no sense for a patient to receive or take pills in a room with an exam table with the mandated dimensions.

27. The requirements are likewise medically unnecessary when it comes to procedural abortion. In general, the dimensions of rooms where health care services are provided are based on the care being provided, including equipment and personnel needed to support the patient during the procedure. There is no medical basis to mandate that abortion procedures be provided in a room of a certain size but not any other gynecological care, including miscarriage care.

28. All Families does not have the means to retrofit our physical plant to meet these requirements. Doing so would require overhauling our small building, which has met our patients' needs for six years; and take substantial time and resources away from patient care—with no corresponding benefit to patients whatsoever.

*Physician Medical Director*

29. Rule V requires a physician medical director to oversee the facility. Proposed Rule V, at 1770 (adopted as proposed). All Families does not have a physician as a clinician or as a medical director; I am the sole clinician associated with All Families. As a nurse practitioner licensed to practice in Montana, I practice autonomously, with no requirement for physician oversight for any care I provide. As evidence and experience, including in Montana, consistently demonstrate, advance practice clinicians including nurse practitioners provide abortion care safely and effectively, and there is no health reason to mandate physician involvement in that care or to oversee that care.

30. DPHHS does not explain the reason for imposing this requirement solely because I provide abortion care. All DPHHS states is that it exists for outpatient centers for surgical services and outpatient centers for primary care. *See* Final Rules, Response #45, at 2255. Yet, as stated

previously, this requirement does not apply when I provide miscarriage care, by medication or procedure, to my patients.

31. There is no medical or other reason for me to hire or contract with a physician to oversee care I have been providing safely, effectively, and autonomously in this state for six years. Imposing this requirement on All Families would end our abortion care practice and threaten the rest of the care we provide.

*Unnecessary Tests and Threats to Telehealth*

32. Rule VII requires All Families to document—and thus have the patient undergo—various unnecessary tests and exams. For example, Rule VII requires the patient to have a physical exam, tests for Rh factor, and a pregnancy test or pathological exam to "verify pregnancy." *See* Proposed Rule VII, at 1771 (adopted in relevant part as proposed).

33. A physical exam prior to a medication abortion is not medically necessary. Requiring one would eliminate telehealth and propel abortion access backward—eliminating the flexibility and privacy from which patients benefit.[2] The increased uptake in telehealth and provision of medication abortion by mail highlights the difficulty patients have in accessing care in the clinic.

34. Before launching the telehealth abortion program, patients would cancel or not show up to in-person appointments. A number of life-events would made making the appointment impossible: they could not take off from work, a family member did not show up to take care of the kids, their car broke had broken down or could not handle the weather, they could not afford gas to travel to the clinic, or they could not discretely attend the appointment for fear of someone

[2] *E.g.*, Ushma D. Upadhyay, et. al., *Safety and Efficacy of Telehealth Medication Abortions in the U.S. During the Covid-19 Pandemic*, JAMA Network Open (2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783451.

finding out. Since starting our telehealth program, cancellations or no-shows are far more rare.

35. Rh testing, which the Rule also mandates, is likewise medically unnecessary prior to all abortion care. Rh testing is a blood test that determines whether a person's blood has the Rh factor (or Rhesus factor) protein on the surface of the red blood cells. If a person's blood has the Rh factor, they are Rh positive. If a person's blood doesn't have the Rh factor, they are Rh negative. Rh incompatibility occurs when a person who is Rh negative becomes pregnant with a baby that is Rh positive. During pregnancy, it is possible for some of the baby's blood to pass through the placenta into the mother's body, causing the mother's immune system to create antibodies that attack the baby's red blood cells. This antibody response is called Rh sensitization or alloimmunization. Rh sensitization can be prevented by giving the pregnant person a shot of immune globulin (trade name RhoGAM) that suppresses the formation of antibodies.

36. Recent research indicates there is a very low likelihood of Rh alloimmunization associated with abortion or pregnancy loss at less than 12 weeks gestation, therefore major medical organizations suggest that Rh testing is not necessary prior to 12 weeks. Consistent with that research, NAF updated its 2022 Clinical Care Guidelines to state that Rh testing and RhoGAM need not be provided for patients seeking abortion care before 12 weeks.[3] The Society of Family Planning, and World Health Organization, and American College of Obstetrics and Gynecology likewise updated their recommendations.[4] Nonetheless, Rule VII mandates Rh testing for all

[3] *See* National Abortion Federation, 2024 Clinical Policy Guidelines, 12-13 (2024), https://prochoice.org/wp-content/uploads/2024-CPGs-FINAL-1.pdf; *see also* Alice Mark et al., *Foregoing Rh Testing and Anti-D Immunoglobulin for Women Presenting for Early Abortion: A Recommendation from the National Abortion Federation's Clinical Policies Committee,* 99 Contraception 265 (2019).

[4] *See* Sarah Horvath et al., *Society of Family Planning Committee Consensus on Rh Testing in Early Pregnancy*, 114 Contraception P1-5 (Oct. 2022), https://www.contraceptionjournal.org/article/S0010-7824(22)00197-4/fulltext; World Health Organization, *Abortion Care Guideline*, Clinical Services Recommendation 8 (2022), https://iris.who.int/bitstream/handle/10665/349316/9789240039483-eng.pdf?sequence=1; American College of Obstetricians and Gynecologists, *Rh D Immune Globulin Administration After Abortion or Pregnancy Loss Less Than 12 Weeks of Gestation*, Clinical Practice Update (December 2024),

patients, which, at a minimum requires an unnecessary blood draw and lab tests–and at least one in person visit to a clinician. *See* Proposed Rule VII, at 1771 (adopted in relevant part as proposed).

37. Even the Proposed Rules' Statement of Reasonable Necessity in the Proposed Rules, at 1780 acknowledges this testing is unnecessary for all patients, as it states: "RH Negative Factor is recommended for gestational ages of eight weeks or more." That the Rules incorporate outdated recommendations also demonstrates the problems with micro-managing patient care and leaving no room for patient circumstances or clinician judgment.

38. Rule VII also requires documentation of a pregnancy test. *See* Proposed Rule VII, at 1771 (adopted in relevant part as proposed). Patients do not need to produce pregnancy tests results to me prior to obtaining an abortion. I trust patients to tell me the results of a pregnancy test. This is another example of medically unnecessary micromanagement that does not enhance patient safety, but creates more barriers.

39. Rule VII further provides that as an alternative to a pregnancy test, abortion clinics document a "pathological exam of tissue . . . to verify pregnancy." Proposed Rules, at 1771 (adopted in relevant part as proposed). It is not clear what this could mean. A pathological exam of pregnancy tissue occurs after abortion, not to verify pregnancy. In any event, All Families does not and cannot conduct a pathological exam for patients who access medication abortion. Medication abortion patients pass their pregnancy at home, not the clinic. All Families conducts a tissue exam for patients for whom I provide in-clinic abortion procedures, but does not conduct a pathological exam, which is not necessary and would require sending out tissue to a

https://journals.lww.com/greenjournal/fulltext/9900/rh_d_immune_globulin_administration_after_abortion.1145.aspx.

third-party pathology lab at additional and unnecessary cost to the patient.

40. DPHHS states that these requirements do not threaten telehealth access because the physical exam and Rh testing need not be done at the abortion clinic. *See* Final Rules, Response #44, at 2254. DPHHS is incorrect. These tests and exams must still be done in person, requiring a patient to make an unnecessary visit to a clinician—which requires time away from work, school, or family, and at additional cost—for no benefit for patients. As a practical matter, imposing that unnecessary clinician visit as a condition of accessing abortion will impede patients' access to abortion care.

*Written Transfer Agreement with a Hospital*

41. Rule IX requires All Families to have a written transfer agreement with a hospital for transfer of patients experiencing a medical emergency. Proposed Rule IX, at 1772 (adopted as proposed). All Families does not have such a written transfer agreement, nor is one necessary to meet patients' health and safety needs. All Families has transfer protocols, which includes calling emergency medical services for transfer of a patient to the hospital emergency department. The transfer protocol applies to both abortion patients and non-abortion patients, as in the case of a patient experiencing an allergic reaction to an antibiotic used in treating a sexually transmitted infection.

42. As noted above, the vast majority of All Families patients obtain medication abortion and pass their pregnancy at home or another location of their choosing—not at All Families. A written transfer agreement with a hospital near All Families is unrelated to keeping those patients safe.

43. Patients who access care via telehealth or at the clinic are counseled on what to

expect following their abortion, including what is normal and what may be abnormal. Patients are instructed to reach out to All Families with any concerns, including concerns that they are experiencing a complication, or to go to the emergency room. This is the same approach All Families and other health care providers take for any patient experiencing a complication or emergency—it is not unique to abortion.

44. A written transfer agreement is also medically unnecessary for patients who obtain procedural abortions at All Families. There is no greater risk of medical emergency when providing abortion care compared to treating miscarriage with the *same* medications and procedures. Yet, as with the other requirements, All Families only needs a written transfer agreement because it provides abortion care.

45. The requirement also puts All Families' future in the hands of a hospital that has no reason to enter into such an agreement with us. Even if we were to secure such an unnecessary agreement, All Families would forever be dependent on the hospital not merging, closing, or deciding to sever the agreement.

*Anesthesia*

46. Rule X relates to the use of anesthesia, and, among other things, restricts the administration of anesthesia to only a physician or a certified registered nurse anesthetist (CRNA). Proposed Rule X, at 1772-73 (adopted as proposed). The Final Rules do not define anesthesia. DPHHS dismisses in its responses to comments any need to define anesthesia. *See* Final Rules, Response 65, at 2260.

47. At All Families, I administer lidocaine, a local anesthetic, to numb the cervix prior to a procedural abortion and occasionally offer minimal sedation. I do the same for patients I see for IUD insertions or miscarriage management. Absent a definition of "anesthesia" in the Final

Rules, it is not clear to me whether the Final Rules prohibit me from administering this local anesthetic or minimal sedation because I am neither a physician nor a CRNA.

48. There is no medical basis for restricting the administration of local anesthesia or minimal sedation as Rule X does: only when provided in connection with abortion care. *See* Proposed Rule X, at 1772-73 (adopted as proposed). Doing so simply deprives patients seeking abortion care basic pain management.

*Inspections and Additional Investigations upon "Complaints,"*
*Risk of Harassment by Anti-Abortion Activists*

49. HB 937 and Final Rule state that DPHHS must inspect licensed abortion clinics at least once each calendar year. As with the other requirements, there is no health or safety reason to require inspection of facilities that provide abortion, but not identical or comparable care, including miscarriage care. Further, annual inspections—in particular without notice—can disrupt and intimidate patients from receiving not only abortion care, but also the other care that All Families provides.

50. HB 937 also provides that DPHHS may conduct additional investigations if the Department receives a complaint involving an abortion clinic. Neither HB 937 nor the Final Rules limit or specify the degrees or types of complaints that would trigger additional investigation, and I am concerned about the possibility of overreach. All Families, its providers, and patients are already subject to harassment and threats by anti-abortion organizers and protesters. Providing a mechanism for these anti-abortion organizers and protesters to complain to DPHHS and encourage unnecessary and baseless investigations, HB 937 and the Final Rules serve only to further disrupt and restrict All Families' ability to provide medical services, including abortion care, to its patients.

51. As already stated, there are mechanisms by which to investigate or discipline

licensed health care providers in the State, and no reason to single out for additional scrutiny those providers whose practice includes abortion care.

52. Abortion is essential care that requires no special licensure or oversight by DPHHS. At a time when abortion access is being restricted across the country, Montana should be finding ways to increase abortion access, not restrict or take it away.

*Other Requirements that Single Out Abortion for No Reason*

52. To highlight a few additional examples: Rule II(4) requires abortion clinics to pay an initial licensure fee of $450 and $450 each year that follows. *See* Proposed Rule II, at 1768. (adopted in relevant part as proposed). That fee is not insignificant for All Families. It is also far more than the licensure fees for other facilities, who pay $20, or $1 per bed.

53. Rule IV requires that All Families policy and procedure manual be available not only to DPHHS and clinic staff, but also patients. *See* Proposed Rule IV, at 1769-70 (adopted as proposed). There is no reason that a clinic's entire policy and procedure manual be available to patients. There is also a real risk that anti-abortion activists posing as patients will use this to access All Families' policies for illegitimate purposes.

*Waivers and Timing*

54. The Final Rules make some references to waivers. Specifically, Rule III indicates that the physical plant requirements may be waived for existing clinics if DPHHS determines that compliance would be "extremely difficult or impossible" or that "the level of safety to patients and staff is not diminished." *See* Proposed Rule III, at 1769, (adopted as proposed). Rule I also states that "certain" requirements may be waived "if not necessary in light of the scope of, and any gestational limits on," the abortion care provided by the clinic. *See* Proposed Rule I, at 1767, (adopted as proposed). Rule I, however, further states that "general requirements and provisions

and requirements pertaining to the abortion services provided by the abortion clinic may not be waived." *See* Final Rule I, at 2242.

55. DPHHS does not provide any guidance as to what information is required to be submitted to seek a waiver, the standard by which DPHHS will determine whether to grant one, or what it means by "general requirements." The only example DPHHS gives is that it would consider waiving requirements it states are associated solely with procedural abortion—specifically, anesthesia requirements and requirements to maintain pre- and post-operative notes. *See* Final Rules, Response #23, 68, at 2248, 2261.

56. It is unclear whether DPHHS will consider waiving requirements like those for a physician medical director or written transfer agreement as, according to DPHHS, as it depends on what DPHHS means by "general requirements." It is also unclear whether will consider waiving requirements that each patient undergo, and the clinic document, a physical exam, Rh testing, and a pregnancy test or pathological exam; whether these are "general requirements," requirements DPHHS would waive for clinics providing only medication abortion care, or requirements DPHHS would waive as applied to medication abortion patients accessing care from clinics that also offer procedural abortion care. In any event, many of these provisions have just as little to do with safe, effective abortion care (whether by procedure or medication) as the anesthesia requirements do for medication abortion.

57. DPHHS also states that existing abortion clinics have 30 days to apply for a license, and that DPHHS will act on that application within 60 days of receipt. *See* Final Rules, at 2267. It is not clear whether DPHHS will take initial action on a license application—i.e., getting in touch with a clinic to discuss waivers—within 60 days, or whether DPHHS must take final action to approve or deny a license within 60 days.

58. On October 1, 2024, All Families applied for a license and waiver of certain requirements in Rules II, III, IV, V, VII, IX, and X. (application attached as Exhibit 1).

Impact of HB 937 and the Final Rules on All Families and Our Patients

59. Under these circumstances, absent a temporary restraining order or preliminary injunction, All Families may be forced to cease providing abortion care. Suspending All Families' abortion practice, even temporarily, will impact patients across Montana who seek out abortion care from All Families. Those who have the time and means will be forced to seek care elsewhere.

60. Gathering funds for logistical arrangements to travel for abortion care takes time, which will delay access to time-sensitive abortion care and will force patients seeking abortion care to stay pregnant and experience the symptoms and risks that come along with pregnancy. Abortion is safe throughout pregnancy, but the risks increase incrementally as pregnancy progresses, so delay can increase risks. Delay can also mean patients are no longer eligible for medication abortion. For many patients, these increased financial, childcare, or transportation challenges will be insurmountable. Making the logistical arrangements, for childcare, missed work, or for an appointment that can be kept confidential from an abusive family member, brings another set of challenges and stressors.

61. Ultimately, some patients may be unable to access abortion care and may be forced to carry their pregnancies to term against their will. Evidence demonstrates that people denied an abortion they seek are more likely to face health and economic hardship, and that there are long-term economic consequences for their children as well. Imposing that future on any Montanan is unconscionably cruel.

62. HB 937 and the Rules are also a serious threat to All Families. Abortion care makes up most of the care I provide, and with the uncertainty as to how long it would take to obtain a

license from the Department, if I am able to obtain one at all, I likely would not be able to keep All Families open. This would have devastating consequences for both my patients who seek abortion and those for whom I provide birth control, miscarriage care, and gender-affirming care. All Families has become a critical resource for young people and families, where patients know they can get confidential and safe care from a trusted provider. Closing All Families would be a tremendous loss for the community as well as myself.

63. HB 937 and the Final Rules harm All Families and our patients even if we obtain a license or waivers this year. Singling out abortion for targeted, bureaucratic restriction simply because it is abortion harms our patients—for example, it adds to the stigma surrounding abortion care, can delay patients from seeking care, and confuses patients into thinking abortion is unsafe, or inaccessible in Montana.

64. Moreover, the process imposed by the scheme is not a one-time effort. HB 937 and the Final Rules require we obtain a license each year; securing one this year is no guarantee we will receive one next year. No health and safety benefit comes from my expending time, effort, and resources to ensure compliance with a duplicative set of regulations—time, effort, and resources I could be spending on patient care.

65. HB 937 and the Final Rules are the latest in a series of efforts to attack abortion care and take me away from patient care. When my clinic opened, I had to sue the State to block a criminal law that prevented me from providing abortion care because I am a nurse practitioner, rather than a physician or physician assistant. No similar law prohibited me from providing the identical care to patients who need that care to manage a miscarriage. The law prevented me from providing abortion care, and my patients from accessing that care from me, simply because it is abortion care. That law has been blocked since shortly after All Families opened in 2018. But, with

each step in the judicial process, I had to wait for a court to decide whether I would be able to continue to provide abortion care that I have been providing safely in Montana for six years.

66. In 2021, during the COVID-19 pandemic—which itself caused health care practices to quickly adjust to new circumstances—I and other Montana abortion providers waited to learn whether a court would block a new set of abortion restrictions. One of those laws would have ended All Families' medication abortion by mail program, which had then become (and remains) critical to reach patients for whom it is challenging to visit an in-person clinic, or who opt to have an abortion in the privacy of their home.

67. Again, in 2023, the State passed multiple restrictions on abortion, some with immediate or near-immediate effective dates. Individually and together, these policies could—on a moment's notice—decimate access to abortion care in Montana, which, today is bordered on all sides by states that have banned abortion, or where a court order has blocked a ban (and in North Dakota, where a court order blocked a ban but no abortion clinic exists). The instability that HB 937 and the Final Rules cause for my clinic and my patients is no different.

68. Each year, I am forced to confront increasingly hostile policies meant to undermine the care I provide my patients. The legal back and forth on the numerous legislative and judicial restrictions on abortion causes chaos for All Families. Unlike most other healthcare providers, I devote significant time and resources to monitoring rapid legal developments for cases in which I am a plaintiff and those in which I am not.

69. This is not how any other type of health care is practiced. It is not how any other small business is expected to operate. And it is not how any other patients are treated. The main exception is gender-affirming care which, like abortion, is stigmatized and subject to political attacks.

70. Patients need to know whether they will be able to have their appointment the next day. I need to know whether I will see a patient the day they are scheduled. Especially as a small, solo practice, I need to know that when I buy medication, I will be able to use it. The instability and disruption my patients and I face simply because I provide, and they seek, abortion care is unrelenting, unjust, and unnecessary. It is also a deliberate effort to eliminate access to safe, compassionate abortion care.

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I declare under penalty of perjury that the foregoing is true and correct.

Dated: 10-3-24

Helen Weems MSN, APRN-FNP

State of Montana )
)
County of Flathead )

Signed and affirmed to me this 3 day of 10, 2024.

JAZMINE CHRISTENSEN
NOTARY PUBLIC for the
State of Montana
Residing at Kalispell, Montana
My Commission Expires
December 2, 2025

Notary Public

Tara Wooten, Licensure Bureau Chief
Department of Public Health and Human Services
tara.wooten@mt.gov

*Via email and US mail*

October 1, 2024

Dear Ms. Wooten:

I write to apply for an abortion clinic license for All Families Healthcare and waivers from certain rules published on September 20, 2024. Consistent with Rule II(2), the application requirements are set out below, and consistent with Rule II(4), I will mail a check to DPHHS for the $450 initial license fee, from which I am also requesting a partial waiver.

Because the current court order enjoining enforcement of HB 937's licensure requirement expires on November 19, 2024, All Families requests a response from DPHHS by October 18, 2024. *See* Order Extending Temporary Restraining Order, All Families Healthcare v. State, No. 23-592 (Oct. 18, 2023).[1]

**Application requirements:**

(a) Name of applicant: Helen Weems

(b) Location of abortion clinic: 737 Spokane Ave., Whitefish, MT 59937

(c) Administrator of abortion clinic: Helen Weems, APRN

(d) Medical director of abortion clinic: Helen Weems, APRN

Please see below for request for a waiver from the requirement that the medical director be a physician.

(e) Qualifications of the administrator, medical director, and professional staff:

I am the only professional staff at All Families. I am an advanced practice registered nurse (APRN), licensed to practice in Montana.

(f) Disclosures: Neither I nor my staff have any relevant disclosures to make.

[1] The order states that the current temporary restraining order remains in force for "a period of sixty (60) days beyond the effective date of the final rules" promulgated to implement HB 937.

(g) Types of abortion and gestational limits: All Families provides medication abortion up to 11 weeks LMP and procedural abortion up to 12.6 weeks LMP.

(h) Attestation: I attest that I am of reputable and responsible character and should a court order permit HB 937 and the Rules to be enforced, All Families will comply with the rules applicable to abortion clinics to the extent All Families is not seeking waivers of certain requirements, as set out below.

**Request for waivers:**

For more than six years, All Families has been operating as a clinicians' office, regulated by federal, state, and professional authorities, including the Board of Nursing, the Board of Pharmacy, and DPHHS through its implementation of CLIA and enforcement of the State's abortion reporting requirements. In addition to abortion care, All Families provides identical care for miscarriage management, which is subject to none of the new DPHHS rules.

Mainstream medical authorities including the National Academies of Sciences, Engineering, and Medicine and the American College of Obstetricians and Gynecologists recognize that abortion, whether by medication or procedure, is safely provided in office-based settings like All Families' and that there is no reason to regulate abortion differently than identical or comparable care.[2] (Despite sometimes being referred to as "surgical abortions," abortion procedures are not surgical: they do not involve any incision, are routinely performed in office settings, and involve minimal recovery.[3])

The National Academies summarized that the "clinical evidence . . . on the provision of safe and high-quality abortion care stands in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services," including the requirement that "care take place in costlier and more sophisticated settings than are clinically necessary."[4] These requirements "go beyond the accepted standards of care in the absence of evidence that they improve safety."[5] The DPHHS rules, as a whole, are precisely the types of rules to which the National Academies refers.

The Rules reference waivers. Specifically, Rule III indicates that the physical plant requirements may be waived for existing clinics if DPHHS determines that compliance

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[2] *See, e.g.*, Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 77, 162 (2018), https://nap.nationalacademies.org/read/24950; Am. Coll. Obstet. & Gynecol., *Committee Opinion 815: Increasing Access to Abortion* e107 (Dec. 2020), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion.

[3] *See, e.g.*, Am. Coll. Obstet. & Gynecol., *Definition of "Procedures" Related to Obstetrics and Gynecology* (2023), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology.

[4] Nat'l Acads., *supra*, at 77.

[5] *Id*.

would be "extremely difficult or impossible" and that "the level of safety to patients and staff is not diminished." Proposed Rules, at 1769 (adopted as proposed). Rule I also states that "certain" requirements may be waived "if not necessary in light of the scope of, and any gestational limits on," the abortion care provided by the clinic. Proposed Rules, at 1767 (adopted as proposed).

The rules, as a whole, are unnecessary to protect patient health and safety, and single out abortion care for arbitrary and discriminatory regulation. Imposing the rules on All Families threatens to end or significantly curtail the abortion care I have provided for over six years. For that reason, and as explained below, All Families requests waivers from the following requirements:

Rule II(4): $450 licensure fee

Rule II(4) requires an abortion clinic to submit a $450 license fee with its initial application and with each annual renewal application.

Enclosed with this application, I include a check for $450. However, this fee is exponentially higher than the licensure fee for other licensed health care facilities, which is $20 for facilities with 20 beds or fewer, and $1 per bed for facilities with 21 beds or more. § 50-5-202, MCA. Accordingly, I request a waiver of the full licensure fee and a refund of $430 in parity with the fees for other licensed facilities of similar size.

Rule III(2), (4): Physical plant requirements

Rule III requires all "patient rooms" be 100 square feet, with 4 feet available on one side of the exam table and 3 feet on all other sides, and that corridors be at least 6 feet wide. DPHHS does not define "patient room," but states in responses to comments on the Rules that "patient rooms" are rooms "in which a patient is assessed or treated." Final Rules, Response # 65, at 2260.

All Families counsels patients and prescribes, administers, and dispenses medication abortion to patients in a room that does not have an exam table and does not meet the mandated dimensions, but has sufficient space for its purpose. All Families also counsels patients and prescribes, administers, and dispenses medication in that same room for patients who are seeking care other than abortion care. There is no reason to single out abortion as Rule III does.

All Families' existing procedure room has an exam table, which has adequate space around it for equipment and personnel necessary for the care we provide, including procedural abortion, miscarriage management by procedure, and IUD insertions and removals, among other procedures. The procedure room does not, however, have 3 feet at the head of the exam table. In general, the dimensions of rooms where health care services are provided are based on the care being provided, including equipment and personnel

needed to support the patient during the procedure. There is no medical basis to mandate abortion procedures but not any other gynecological care, including miscarriage care, be provided in a room of a certain size.

All Families' hallways are not 6 feet wide, as Rule III requires. DPHHS does not explain the rationale for this dimension. This width requirement is not necessary, for example, to allow passage by emergency services or wheelchairs—for which All Families' hallways allow passage.

It would be extremely difficult if not impossible for All Families to alter the size of its corridors and the rooms in which patients are assessed and treated.

Rule IV: Policies and procedures

Rule IV requires the policy and procedure manual be available not only to staff and DPHHS, but also to patients. There is no reason that our policy and procedure manual should be available to patients, and this requirement does not apply to other facilities licensed by DPHHS, such as outpatient centers for primary care. Admin. R. M. 37.106.1008(2) (policy and procedure manual must be available to "all personnel"). There is also a real risk that anti-abortion activists will use this access to All Families' policies for purposes of harassment.

In addition, All Families requests a waiver from the requirement to have policies and procedures consistent with rules from which it is also seeking waivers.

Rule V: Medical director

Rule V requires a physician medical director to oversee the facility. All Families does not have a physician as a clinician or as a medical director; I am the sole clinician associated with All Families. As a nurse practitioner licensed to practice in Montana, I practice autonomously, with no requirement for physician oversight for any care I provide. As evidence and experience, including in Montana, consistently demonstrate, nurse practitioners provide abortion care safely and effectively, and there is no health reason to mandate physician involvement in the care I provide or to oversee that care. *See, e.g.*, *Weems v. State*, 2023 MT 82, 412 Mont. 132, 529 P.3d 798 (holding unconstitutional law that restricted patients' choice of abortion provider, including when that provider was an APRN).

Rule VI: Staff files

The requirement to conduct a background check on every employee does not apply to outpatient centers for primary care or outpatient centers for surgical services, *see* Admin. R. M. 37.106.315 (requirements for all health facilities), and there is no reason for it to apply to All Families' staff. All Families has a thorough process for vetting staff and will

continue to use that process—a process that All Families would and could still use if it ceased providing abortion care and continued to offer identical miscarriage care.

Rule VII: Patient files

Rule VII requires All Families to document—and thus have patients undergo—various unnecessary tests and exams, including physical exams, tests for Rh factor, and pregnancy tests or pathological exams to verify pregnancy. Mandating these tests for every patient would end All Families' provision of medication abortion via telehealth, which is a safe and critical option for our patients.[6] Permitting patients to obtain these medically unnecessary tests from a provider other than All Families still requires patients to make an in-person visit to a provider, delaying and impeding access to necessary telehealth care.

Patients can, are, and have been evaluated prior to a medication abortion without a physical exam. That assessment includes reviewing the patent's history and confirming the patient is eligible for medication abortion, including based on their point in pregnancy. In some cases, I may refer a patient for an ultrasound, but in most cases, the patient and I can date their pregnancy and determine eligibility for medication abortion based on their last menstrual period. There is no need for a physical exam.

Recent research indicates there is a very low likelihood of Rh alloimmunization associated with abortion or pregnancy loss at fewer than 12 weeks. Major medical organizations suggest that Rh testing is not necessary prior to 12 weeks.[7] Consistent with that research, the National Abortion Federation updated its Clinical Guidelines to state that Rh testing and RhoGAM need not be provided for patients seeking abortion care before 12 weeks.[8] The Society of Family Planning, World Health Organization, and American College of Obstetrics and Gynecology likewise updated their recommendations.[9]

The Proposed Rules' Statement of Reasonable Necessity at 1780 acknowledges this testing is unnecessary for all patients: "RH Negative Factor is recommended for gestational ages of eight weeks or more." Although that is outdated, it reflects DPHHS's understanding that the Rule imposes Rh testing on at least some patients for whom it is not necessary.

Patients do not need to provide pregnancy test results to All Families prior to

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[6] *See, e.g.*, Elizabeth G. Raymond et al., *Commentary: No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 J. Contraception 361, 361, 364-65 (2020).
[7] Sarah Horvath et al., *Society of Family Planning Committee Consensus on Rh Testing in Early Pregnancy*, 114 Contraception 1, 3 (Oct. 2022), https://www.contraceptionjournal.org/article/S0010-7824(22)00197-4/fulltext
[8] National Abortion Federation, 2024 Clinical Policy Guidelines for Abortion Care 12-13, https://prochoice.org/wp-content/uploads/2024-CPGs-FINAL-1.pdf.
[9] World Health Organization, Abortion Care Guidelines 44-45 (2022), 9789240039483-eng.pdf (who.int); Horvath et al., *supra*, at 4; Am. Coll. Obstet. & Gynecol., Clinical Practice Update: Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation, Obstet. & Gynecol. (2024).

obtaining an abortion. Patients self-report whether they are pregnant. All Families refers for or conducts an ultrasound for patients when appropriate. There is no patient health benefit to mandating All Families document a pregnancy test, and mandating that patients produce such results can delay care.

It is not clear what DPHHS means by the requirement that, as an alternative to a pregnancy test, abortion clinics document a "pathological exam of tissue . . . to verify pregnancy." Proposed Rules, at 1771 (adopted as proposed). A pathological exam of pregnancy tissue occurs after abortion care, not to verify the patient is pregnant. In any event, All Families does not and cannot conduct a pathological exam for patients who access medication abortion. These patients pass their pregnancy at home or a location of their choosing, not the clinic. All Families conducts a tissue exam for patients for whom we provide in-clinic abortion procedures, but does not conduct a pathological exam, which is not necessary and would require sending out tissue to a third-party pathology lab at additional and unnecessary cost to the patient.

Rule IX: Emergency procedures

Rule IX(2) requires certain emergency equipment to be available to the operating room. All Families does not have an operating room or an emergency call system. All Families has oxygen, assistance equipment, sonography, and emergency drugs and supplies.

Rule IX(3) requires All Families to have a written transfer agreement with a hospital, which it does not have, nor is one necessary to meet patients' health and safety needs. All Families has transfer protocols, which provide for calling emergency medical services for transfer of a patient to the hospital emergency department. The transfer protocol applies to both abortion patients and non-abortion patients, as in the case of a patient experiencing an allergic reaction to an antibiotic used in treating a sexually transmitted infection.

Rule X: Anesthesia

Rule X refers to anesthesia but does not define anesthesia, so it is unclear whether DPHHS means for the rule to apply to local anesthesia, minimal and conscious sedation, and general anesthesia, or only some of these. The Rule then restricts the provision of anesthesia, as well as assessments related to anesthesia, to a physician or CRNA.

At All Families, I administer local anesthesia to numb the cervix prior to a procedural abortion. Occasionally, I administer minimal sedation (anxiolysis) with an oral medication. I also conduct the relevant patient assessments prior to and after administering anesthesia. I administer the same local anesthetic and minimal sedation, and conduct the same assessments, in connection with IUD insertions or miscarriage management. There is no reason to deny my patients seeking abortion care basic pain management because I am a nurse practitioner.

* * *

Considering the significant impact on All Families' practice and our patients' access to abortion and the other health services we provide, and the absence of any benefit to patient safety from imposing the above requirements on All Families and our patients, I urge DPHHS to grant All Families a waiver from these requirements.

Sincerely,

Helen Weems, APRN-FNP
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**Admitted pro hac vice*

**MONTANA FIRST JUDICIAL DISTRICT COURT,**
**COUNTY OF LEWIS & CLARK**

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| ALL FAMILIES HEALTHCARE; BLUE MOUNTAIN CLINIC; AND HELEN WEEMS MSN APRN-FNP on behalf of themselves and their patients,<br><br>Plaintiffs,<br><br>vs.<br><br>STATE OF MONTANA; MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; and CHARLIE BRERETON, in his official capacity as Director of the Department of Public Health and Human Services,<br><br>Defendants. | Cause No. DDV-2023-592<br><br>Hon. Judge Christopher D. Abbott<br><br>**AFFIDAVIT OF JOEY BANKS, MD, IN SUPPORT OF PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION** |

I, Joey Banks, MD, being duly sworn, affirm as follows:

1. I submit this affidavit in support of Plaintiffs' Application for a Temporary Restraining Order and Preliminary Injunction against enforcement of HB 937 and its Final Rules, related to the licensure of clinics that provide abortion care.

Background and Experience

2. I am a board-certified family medicine physician licensed to practice in Montana, where I have practiced for over a decade. I have nearly 25 years' experience providing primary care and reproductive health care and have been performing and supervising abortion care for more than 17 years.

3. I received my medical degree from Indiana University School of Medicine and am board-certified as a family physician by the American Board of Family Medicine. I completed my residency in family medicine at the Alaska Family Medicine Residency in Anchorage, Alaska, where I also served as chief resident. I have previously been a faculty member at the Alaska Family Medicine Residency and the Central Maine Medical Center Family Medicine Residency, as well as a community preceptor for Family Medicine Residency Western Montana. I have been the lead and assistant-lead on two reproductive health education in family medicine ("RHEDI") grants for educating family medicine residents in abortion care. In addition to Montana, I am currently licensed to practice medicine in Illinois and New Mexico

4. I have been a clinician at Blue Mountain Clinic for over 13 years, where I provide primary care, and sexual and reproductive health care, including abortion care. Blue Mountain first opened in 1977 as the first and only abortion clinic in Montana. By 1991, Blue Mountain had expanded its services to offer primary care for the entire family, in addition to continuing to offer abortion services. On March 29, 1993, the Clinic was firebombed and destroyed by an anti-

abortion arsonist. Over two years later, in September 1995, the Clinic reopened at its current location and has been providing services there ever since.

5. A current version of my curriculum vitae, which sets out my experience and credentials more fully, is attached to this affidavit as Exhibit 1.

6. The opinions in this affidavit are my expert medical opinions, based on my education, training, clinical experience, ongoing review of relevant, peer-reviewed professional literature on reproductive health, discussions with colleagues, and my attendance at professional conferences.

7. I am familiar with HB 937 and the final Department of Public Health and Human Services ("DPHHS") rules which relate to licensure for abortion clinics in Montana (collectively, "the Challenged Laws" or "the Laws"). Blue Mountain testified at the public hearing on August 16, 2024, in opposition to the Proposed Rules and submitted a written comment in opposition on August 23, 2024.

8. The requirement that clinics that provide abortion care obtain facility licensure in order to continue offering abortion care is unnecessary to protect patient health and safety. The Final Rules are similarly unnecessary and interfere with patients' access to high quality, compassionate abortion care in this state.

9. Abortion is one of the safest types of medical care available in the United States, and there is no medical reason to single it out for additional regulation. In particular, there is no medical reason to single out abortion for unique and additional regulation when those requirements do not apply to nearly identical care, such as miscarriage care; other comparable gynecological and non-gynecological procedures; or even care that can entail more risk than abortion care, such

as colonoscopy, EKG stress tests, or labor and delivery/out of hospital birth.

10. Abortion is exceedingly safe, including when provided in clinicians' offices—as it has been in Montana for decades. Abortion is also identical to miscarriage care, and comparable to other gynecological care and to vasectomies—none of which is subject to unique regulation in Montana. Abortion also carries far less risk than labor and delivery of a child—but a pregnant person can decide to deliver at home or in a birth center not subject to mandatory facility-licensure requirements in Montana. Many other clinicians, such as dentists and dermatologists, also provide care in their offices or clinics without facility licensure.

11. HB 937 and the Final Rules would not apply to Blue Mountain at all if we ceased providing abortion care but continued to provide every other service we offer—including identical miscarriage care—under existing laws and in the same physical facility.

12. Blue Mountain has been providing abortion care for nearly 50 years, and almost 30 years at the same location. Neither HB 937 nor the Final Rules identify any problem with the abortion care Blue Mountain has provided throughout that long history of serving its community. Yet, HB 937 and the Final Rules threatens to end or disrupt the care we have been providing for decades and to destabilize our entire practice.

Abortion in the United States and Montana

13. Abortion is common and safe medical care. The vast majority of legal abortions in the United States are provided during the first trimester of pregnancy. In Montana in 2022, more than 90% of the 1,702 abortions were performed at 13 weeks or earlier.[1]

14. Abortion care provided in the United States is either through the use of medication (medication abortion) or via an outpatient procedure (procedural abortion). Both methods are safe

[1] Mont. Dep't of Pub. Health and Hum. Servs., *2022 Montana Vital Statistics*, Tbl. A2 (p. 91 of PDF), https://dphhs.mt.gov/assets/publichealth/Epidemiology/VSU/2022MTVitalStatisticsFinal.pdf.

and effective.

15. Medication abortions are typically indicated up to 11 weeks of pregnancy, as measured from the first day of the patient's last menstrual period ("LMP") and involve the ingestion of medication to terminate the pregnancy, expelling the pregnancy via vaginal bleeding, akin to a heavy period or spontaneous miscarriage. The medications used in a medication abortion are the same medications that providers use to manage a patient's spontaneous miscarriage.

16. The most common regimen of medication abortion in the U.S. is a combination of two prescription drugs, mifepristone and misoprostol. Mifepristone was first approved by the U.S. Food and Drug Administration in 2000 for use, in conjunction with misoprostol, to terminate an early pregnancy. Typically, in a medication abortion, a patient takes the first medication, mifepristone, then the second medication, misoprostol, up to 72 hours later, and passes the pregnancy in a process similar to a miscarriage. Medication abortion can also safely and effectively be provided with misoprostol-only.

17. Medication abortion is safely and effectively provided in-clinic or via telehealth.[2] When it is accessed via telehealth, a patient with internet access connects with a health care provider from their home, health center, or other location. After screening the patient for their eligibility for medication abortion, and obtaining informed consent, medication abortion pills are mailed to the patient. Access to abortion via telehealth improves abortion access, particularly for underserved communities, including patients living in rural areas, and patients who face challenges accessing transportation and arranging the logistics associated with in-clinic abortion care.

18. Under these regimens, the patient completes the abortion process outside a clinical setting in a location of their choice, usually at home. Medication abortion requires no anesthesia

[2] *See* Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States*, 57-58 (2018), https://nap.nationalacademies.org/read/24950 / [hereinafter "Nat'l Acads."].

or sedation; the patient simply takes the pills.

19. As the FDA and dozens of studies have found, medication abortion is exceedingly safe, with complications occurring in a fraction of a percent of cases.[3] The risks of medication abortion are low and similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications, such as antibiotics and non-steroidal anti-inflammatory drugs ("NSAIDS").[4] Mifepristone and misoprostol are substantially safer than aspirin, Tylenol, and Viagra. Because of mifepristone's track record of safety and efficacy, in January 2023, the FDA took the long overdue action of removing medically unnecessary restrictions that required medications to be dispensed in-person by a certified health care provider.[5]

20. Procedural abortion can be provided to patients in the first and second trimesters. It involves dilating (opening) the uterine cervix and then evacuating the uterus using suction aspiration, instruments, or some combination. Dilation is done either the same day or the day before and the procedural abortion typically takes around ten minutes in the first trimester of pregnancy and twenty minutes in the second trimester. Despite sometimes being referred to as "surgical abortions," these procedures are not surgical: they do not involve any incision, are routinely performed in office-based settings, and involve minimal recovery.[6]

21. Procedural abortion commonly involves administration of a local anesthetic to numb the cervix. Patients may also be offered mild to moderate sedation, where they are relaxed,

[3] *Id.* at 55.
[4] *Id.* at 58, 79.
[5] *See* U.S. Food & Drug Admin., *Information About Mifepristone for Medical Termination of Pregnancy Through 10 Weeks Gestation* (Aug. 9, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.
[6] *See, e.g.*, ACOG, Definition of "Procedures" Related to Obstetrics and Gynecology, https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology.

but awake.

22. Regardless of the method of abortion used, abortion is extremely safe. Indeed, the National Academies of Sciences, Engineering, and Medicine ("National Academies")—a body of experts established by Congress to provide independent, objective expert analysis and advice to inform public policy that is "focused on finding reliable, scientific information"—conducted an analysis of the full range of abortion care in the United States and concluded that abortion continues to be one of the safest, most common forms of medical care provided in the nation.[7]

23. Abortion is far safer than continuing a pregnancy through to childbirth, which carries a risk of death that is approximately 13 times higher than that associated with abortion.[8] Abortion-related mortality (0.7 per 100,000) is also significantly lower than that for other common outpatient medical procedures, including colonoscopy (2.9 per 100,000) and adult tonsillectomy (2.9 to 6.3 per 100,000).[9] Abortion also entails less risk of death than driving a motor vehicle, which in Montana has a fatality rate of 19 per 100,000.[10]

24. Complications associated with abortion are also not common. Major complications are exceptionally rare—less than a fraction of one percent.[11] The overall rate of abortion-related complications is approximately 2%, with most complications minor and easily treatable.[12] This is far lower than the overall rate of complications for such common procedures as wisdom tooth removal (7%) and tonsillectomy (between 8–9%).[13] It is similar to or lower than the overall rate

[7] Nat'l Acads. at 77–78; *see also id.* at 161–63.
[8] *Id*. at 74.
[9] *Id.* at 74-75.
[10] Insurance Institute for Highway Safety (IIHS), Fatality Facts 2022 State by State (posted June 2024), https://www.iihs.org/topics/fatality-statistics/detail/state-by-state.
[11] *S*ee, e.g., Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); *see also* Nat'l Acads. at 55-56, 60.
[12] *S*ee, e.g., Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); *see also* Nat'l Acads. at 55, 60, 63.
[13] *See* Advancing New Standards in Reprod. Health, *Issue Brief #6: Safety of Abortion in the United States* 1, 2 (Dec. 2014), https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf (citing studies).

of complications associated with vasectomy, a surgical procedure that is associated with an overall low risk of complications.[14]

25. Abortion is time-sensitive care. Delayed access to abortion care means patients must endure the symptoms and risks associated with continued pregnancy. Pregnancy puts significant stress on the body, causes a variety of physiological changes, and impacts every organ system. Beginning in early pregnancy, even an uncomplicated one, organs work harder for both the pregnant person and the fetus. As the uterus expands, organs shift, which can create pain and discomfort. Pregnancy can also exacerbate underlying medical conditions, or patients can develop conditions as a result of pregnancy. Each day a person remains pregnant means they continue to experience these symptoms and risks, as well as the potential complications of pregnancy.

26. Delays can also push patients past the point in pregnancy during which they are eligible for a medication abortion. For others, delays may make patients ineligible for a one-day procedure and instead mean they have a two-day procedure involving overnight dilation. Additionally, delays can push a patient past the point in pregnancy where abortion is available in Montana, which would force patients to have to travel to providers in Oregon, Washington, or Colorado. The cost and logistics of accessing abortion out of state can be insurmountable for some patients.

Abortion Is Comparable to Other Outpatient Care, Including Care Provided at Blue Mountain

27. Abortion by medication or procedure abortion is essentially identical to the care provided to manage a patient's spontaneous miscarriage or following fetal demise. Gynecology or family practice providers routinely refer to abortion clinics for treatment following a fetal demise,

[14] *See, e.g.*, Christopher E. Adams & Moshe Wald, *Risks and Complications of Vasectomy*, 36(3) Urol Clin North Am. 331 (2009).

to provide safe care that is also cost-efficient and timely.

28. Managing miscarriage by medication involves the *same* medications as an induced abortion: mifepristone and misoprostol, or misoprostol alone. The same procedures are used to manage a patient's miscarriage as to induce an abortion.

29. Procedural abortion is also comparable to other gynecological procedures, including insertion and removal of intrauterine devices (a long-acting, reversible method of birth control), endometrial biopsy, LEEP (a procedure in which abnormal cells from the cervix are removed to prevent cancer), and dilation and curettage for abnormal uterine bleeding. It is also comparable in some respects to vasectomy—although that is a minor surgical procedure that involves an incision, unlike an abortion procedure. Each of these procedures may involve in-office administration of local anesthesia and/or moderate sedation. Like abortion care and miscarriage care, these other procedures can be and are safely and effectively provided in clinicians' offices, including in Montana.

30. Because of the safety of legal abortion, mainstream medical authorities including the American College of Obstetricians and Gynecologists ("ACOG") recognize that abortion may appropriately be provided in clinicians' offices and clinics and oppose unnecessary regulations that limit or delay access to care.[15] The National Academies agrees, concluding that most abortions can be provided safely in office-based settings,[16] and that the "clinical evidence . . . on the provision of safe and high-quality abortion care stands in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services," including the requirement that "care take place in costlier and more sophisticated settings than are clinically

[15] Am. C. Obstet. Gynecol., *Committee Opinion 815: Increasing Access to Abortion* (Dec. 2020), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion.
[16] Nat'l Acads. at 162.

necessary."[17] As the National Academies made clear, these requirements "go beyond the accepted standards of care in the absence of evidence that they improve safety."[18]

31. As to medication abortion in particular, the National Academies found "no evidence that the dispensing or taking of mifepristone tablets requires the physical presence of a clinician or a facility with the attributes of an [Ambulatory Surgical Center] or hospital to ensure safety or quality."[19] Medication abortion may occur wholly outside the clinic setting, and extensive research shows that complications are exceedingly rare, similar to those of common over-the-counter medications (which can be taken at home).[20]

32. Procedural abortions likewise are provided safely and effectively in clinicians' office settings.[21]

33. A recent study investigated the safety of abortions performed in ambulatory surgical centers ("ASCs") compared to office-based settings.[22] It analyzed data from 50,311 abortions performed between 2011 and 2014 in ASCs or office-based settings.[23] There was no statistically significant difference in complication rates or major complication rates between abortions performed in ASCs and abortions performed in office-based settings.[24] There was also no significant difference in complication rates for first trimester aspiration abortions between ASCs and office-based settings (2.2% vs. 2.6%) or in complication rates for second trimester or later abortions between ASCs and office-based settings (2.8% vs. 2.6%).[25] This confirms that the

[17] *Id.* at 77.
[18] *Id.*
[19] *Id.* at 79.
[20] *Id.*
[21] *Id.*
[22] *See* Sarah C.M. Roberts, *et al.*, *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 J. Am. Med. Assoc. 2497 (2018).
[23] *Id.*
[24] *Id.*
[25] *Id.*, at Tbl. 2.

safety of abortion does not differ depending on the type of facility in which the abortion is performed and corroborates previous studies indicating that there is no difference in patient safety for outpatient procedures performed in ASCs rather than office-based settings.[26]

34. Moreover, in the rare event of a complication, nearly every complication associated with abortion can be safely managed in an outpatient setting.[27] For example, in the rare event of a hemorrhage, most are managed in the clinic with medications that increase uterine contractions and reduce bleeding, or by repeat aspiration. Incomplete abortion can also generally be managed in an outpatient setting with medication or repeat aspiration. Infection can be managed with outpatient antibiotic treatment.

Blue Mountain Clinic and Our Patients

35. Blue Mountain fully integrates family medicine, mental health counseling, reproductive and sexual health care and gender-affirming care into our medical practice.

36. Blue Mountain is subject to oversight and regulation by numerous federal and State authorities, including the Montana Board of Medical Examiners and the Montana Board of Nursing, the U.S. Drug and Enforcement Administration ("DEA"), and the DPHHS, to the extent it implements and conducts inspections for the Clinical Laboratory Improvement Amendments ("CLIA"), as well as Montana's abortion-reporting laws. The Clinic is licensed as a limited-service pharmacy by the Montana Board of Pharmacy and dispenses medications. Additionally, Blue Mountain provides abortion care consistent with the clinical standards set by the National Abortion Federation ("NAF"), the professional association for abortion providers, and is inspected by NAF.

37. The Clinic serves approximately 3,000 patients per year, accounting for over 7,000

[26] *See e.g.*, Nancy F. Berglas, *et al.*, *The effect of facility characteristics on patient safety, patient experience, and severe availability for procedures in non-hospital-affiliated outpatient settings: a systematic* review, 13 PloS ONE 1 (2018) (citing studies).
[27] *See* Nat'l Acads. at 56, 59–62, 166.

visits per year. For many of our patients, Blue Mountain is their medical home—they turn to us whenever they need health care.

38. About 25 percent of Blue Mountain's patients travel more than 50 miles (which takes approximately one hour or longer one-way, given weather and road conditions) to access services at the Clinic. Some travel even further. Others make use of the telehealth program for abortion care, and for other primary care and mental health services, and do not need to make this in-person trip.

39. Blue Mountain's family medicine practice offers pediatric care to elder care, and includes wellness exams, internal medicine, preventative care, and mental health. The practice performs procedures such as miscarriage management, loop electrosurgical excisions (where abnormal cells are removed from the cervix to prevent cancer), colposcopies, and Nexplanon and IUD insertions and removals.

40. In 2023, Blue Mountain provided more than 350 abortions.

41. Blue Mountain's abortion care practice offers two options. Blue Mountain offers medication abortion up to 11 weeks LMP and procedural abortion up to 21 weeks and 6 days LMP. Patients may access medication abortion in person at Blue Mountain or via our direct-to-patient telehealth program. For procedural abortions, clinicians administer a local anesthetic and offer moderate sedation. The same moderate sedation is also offered to patients who come to Blue Mountain for IUD insertions and removals, and gynecological procedures such as miscarriage management, colposcopies, and loop electrosurgical excision procedures ("LEEPs").

42. Our patients seek abortion care for a variety of health, family, economic, and personal reasons. Many are parents who have decided that they cannot parent another child at that time, and some are young people who do not feel ready to carry a pregnancy to term because they want

to pursue school or work opportunities. Others face serious health issues that make it dangerous to continue a pregnancy; some are in abusive relationships; and some patients we care for are pregnant as a result of incest or rape.

43. The availability of abortion care enables patients not to forego educational and economic opportunities due to unplanned childbirth, to provide care to existing family members, to avoid raising children with an absent, unwilling, or abusive partner, and to prevent health harms, pain, and suffering that can arise from carrying pregnancies to term and giving birth. Over the years, our patients have raised all of these concerns as reasons why they have made the decision to end a pregnancy.

44. Blue Mountain's patients, many of whom qualify for public insurance, are more likely to already have trouble making financial ends meet. Even if insurance covers the cost of their abortion care, it does not cover other associated costs—especially those that arise for an in-person visit—like transportation, childcare, or lost wages for taking time off work. And those without insurance coverage face decisions about whether to pay for basic necessities like food and rent to afford accessing abortion.

HB 937 and the Final Rules

45. There is no medical justification for arbitrarily singling out clinics that provide abortion care for facility licensure, as HB 937 and the Final Rules do. Should they take effect, the Challenged Laws will make it more difficult, if not impossible, for Blue Mountain to continue offering abortion care. As a result, our patients will face increased costs, delays, or experience other needless interferences with the quality care Blue Mountain has provided for decades.

46. As a whole, the regulatory scheme has little do to with abortion care. Throughout, DPHHS refers to standards for outpatient centers for surgical services, and uses language like

"operating room," which is not appropriate for outpatient abortion care.

47. The requirements also have no unique application to abortion care—but do not apply to gynecology or family practice offices, or other facilities. For example, staff at all of those health care facilities may interact with people who are pregnant, or who are survivors of rape, incest, or sex trafficking. Yet, DPHHS requires only staff at an abortion clinic to have this training. *See* Proposed Rule IV, at 1769-70 (adopted as proposed). Survivors of rape, incest, or sex trafficking may interact with health clinics across the state—yet only abortion clinics must document that they have provided information about assistance for survivors.

*Physical Plant Requirements*

48. Rule III requires all "patient rooms" be 100 square feet, with 4 feet available on one side of the exam table and 3 feet on all other sides, and that corridors be at least 6 feet wide. Blue Mountain does not meet each of these requirements. Proposed Rule III at 1769 (adopted as proposed)

49. The Rule does not define "patient room" but states in the Final Rules that these are rooms where "a patient is treated or assessed." Final Rules, Response 65, at 2260. Blue Mountain counsels and prescribes medication abortion to patients in rooms that do not meet the square footage requirements. Rooms for procedural abortion do not meet the 4 feet and 3 feet requirements. There is sufficient space in the room for personnel and equipment, which does not include 3 feet at the head of the exam table.

50. Blue Mountain's hallways are not 6 feet wide. They are, however, wide enough for emergency medical services (EMS), including a gurney, to pass through. Although it is rare, Blue Mountain has had to call EMS to the clinic. Many of these rare transfers for patients not seeking abortion care—including for chest pain, mental health psychosis, or allergic reactions, to name a

few.

51. None of these physical plant requirements would apply if Blue Mountain did not provide abortion care but continued to provide similar gynecological procedures and the *same* care to manage miscarriage, and to see a diverse range of patients for pediatric to elder care—any of whom could experience medical events that might require Blue Mountain to call EMS.

52. Blue Mountain does not have the resources to overhaul our clinic to meet these building requirements. We are a small, non-profit clinic that invests our time and resources into patient care. We cannot afford to divert any resources to meet arbitrary requirements that do not benefit our patients.

*Medically Unnecessary Exams and Tests, and Risk to Telehealth*

53. Rule VII requires documentation of—and for every patient to therefore have—exams and tests that are not medically necessary. This includes requirements to document, and have a patient undergo, physical exam, tests for Rh factor, and a pregnancy test or pathological exam to "verify pregnancy." Proposed Rule VII, at 1771 (adopted as proposed)

54. The requirement for a physical exam would eliminate the option for telehealth, because the physical exam must be done in person. Blue Mountain's telehealth program has been critical for our patients, in particular those who face the most challenges accessing in-person care—people in more rural areas, people with disabilities, and people who struggle with gas money or who do not have adequate transportation (like vehicles that can handle Montana's harsh winter weather). People who need to keep their abortion confidential because they live with an abusive partner, people who do not have control over their work schedule, or those who have to arrange for childcare also benefit from the comparative ease of our telehealth program.

55. For some, the requirement of an in-person visit will be insurmountable and will

force them to forgo abortion care. Others will try to manage the logistical arrangements—from work or school, to childcare, and adequate transportation—but gathering the money for all of that can take time, pushing people further into pregnancy, and increasing the actual costs of obtaining an abortion later in pregnancy. Delay means a person continues to endure the symptoms and risks of pregnancy and can mean they are pushed too far to be eligible for a medication abortion or pushed beyond the point at which abortion is available in Montana.

56. Rh testing, which the Rule also mandates, is likewise medically unnecessary prior to all abortion care.[28] Rh (Rhesus) factor is a protein some people have in their blood. If the patient is Rh negative and the fetus is Rh positive, the patient can develop antibodies against Rh-positive blood, which can cause problems if the patient becomes pregnant again. To mitigate the risk in subsequent pregnancies, patients who are Rh negative may receive RhO(d) immune globulin (RhoGAM), to stop the body from producing antibodies against the Rh-positive blood.

57. The most recent research shows that fetal red blood cell exposure before 12 weeks is below the threshold needed for Rh sensitization to occur, and the evidence supporting RhO(d) immune globulin (RhoGAM) is limited. The National Abortion Federation (NAF) updated its Clinical Guidelines to state that Rh testing and RhoGAM need not be provided for patients seeking abortion care before 12 weeks. ACOG, the Society of Family Planning and World Health Organization agree.[29]

58. Nonetheless, Rule VII mandates Rh testing for all patients, which, at a minimum

[28] National Abortion Federation, 2024 Clinical Policy Guidelines, at 12-13, 2024-CPGs-FINAL-1.pdf (prochoice.org); *see also* Alice Mark et al., *Foregoing Rh Testing and Anti-D Immunoglobulin for Women Presenting for Early Abortion: A Recommendation from the National Abortion Federation's Clinical Policies Committee,* 99 Contraception 265 (2019).

[29] *See* Sarah Horvath et al., *Society of Family Planning Committee Consensus on Rh Testing in Early Pregnancy*, 114 Contraception P1-5 (Oct. 2022), https://www.contraceptionjournal.org/article/S0010-7824(22)00197-4/fulltext; World Health Organization, *Abortion Care Guideline*, Clinical Services Recommendation 8 (2022), https://iris.who.int/bitstream/handle/10665/349316/9789240039483-eng.pdf?sequence=1; American College of

requires an unnecessary blood draw and lab tests. *See* Proposed Rule VII, at 1771 (adopted as proposed). Like the physical exam, mandatory Rh testing requires an in person visit to a clinician and thus eliminates access to telehealth.

59. The Statement of Reasonable Necessity in the Proposed Rules, at 1780, acknowledges that "RH Negative Factor is recommended for gestational ages of eight weeks or more." Although this is not consistent with the standard of care today, it is a recognition that Rh testing is not necessary for all patients seeking abortion care. Yet, Rule VII contains no flexibility for clinician discretion or patient circumstances. *See* Proposed Rule VII, at 1771 (adopted as proposed).

60. Rule VII also requires documentation of a pregnancy test. Patients do not need to produce pregnancy test results to obtain abortion care. *See* Proposed Rule VII, at 1771 (adopted as proposed). For patients accessing medication abortion via telehealth, patients self-report the results of a pregnancy test. Mandating patients produce the results of a pregnancy test at their telehealth appointment may delay their appointment. For patients who access abortion care in clinic, Blue Mountain typically performs an ultrasound to confirm pregnancy. In general, patients take a pregnancy test only if we are unable to see an intrauterine pregnancy on the ultrasound. There is no need to make patients spend more time taking a pregnancy test, when an ultrasound confirms pregnancy.

61. It is not clear what DPHHS means by the requirement that, as an alternative to a pregnancy test, abortion clinics document a "pathological exam of tissue . . . to verify pregnancy." Proposed Rule VII, at 1771 (adopted as proposed). A pathological exam of pregnancy tissue occurs

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Obstetricians and Gynecologists, *Rh D Immune Globulin Administration After Abortion or Pregnancy Loss Less Than 12 Weeks of Gestation*, Clinical Practice Update (December 2024), https://journals.lww.com/greenjournal/fulltext/9900/rh_d_immune_globulin_administration_after_abortion.1145.aspx.

after abortion care, not to verify the patient is pregnant. In any event, Blue Mountain does not and cannot conduct a pathological exam for patients who access medication abortion. These patients pass their pregnancy at home or a location of their choosing, not the clinic. Blue Mountain conducts a tissue exam for patients for whom we provide in-clinic abortion procedures, but does not conduct a pathological exam, which is not necessary and would require sending out tissue to a third-party pathology lab at additional and unnecessary cost to the patient.

62. DPHHS comments that a patient need not undergo these tests at the abortion clinic, so there is no threat to telehealth. *See* Final Rules, Response #44, at 2254. That ignores the practical realities of patients' lives: the tests and exams must be done in person, which requires patients to make an unnecessary trip to a clinician, with all the attendant logical arrangement telehealth avoids. (The clinician may also provide these services in a facility not licensed by DPHHS.) Sending patients to another clinician also does not address the mandate to have unnecessary tests and exams, an invasion into a person's body without medical basis, that also increases costs and causes delay.

*Written Transfer Agreement with a Hospital*

63. Rule IX requires Blue Mountain to have a written transfer agreement with a hospital for transfer of patients experiencing a medical emergency. Proposed Rule IX, at 1772 (adopted as proposed). Blue Mountain does not have an agreement, and it is not necessary to protect patient health and safety.

64. Blue Mountain has emergency transfer protocols for patients who need to be transferred to a hospital while at Blue Mountain. Blue Mountain calls the emergency room in advance, shares information with the emergency room, and facilitates transfer of care.

65. Nearly all transfers, which are rare as a whole, are for patients *not* seeking abortion

care. For example, Blue Mountain has transferred patients who faint or who have experienced suspected cardiac events. In each instance, the absence of a written transfer agreement has no effect on the transfers. And, despite the frequency of transfers for patients not seeking abortion care, Rule IX would not apply to Blue Mountain but for its provision of abortion care. *See* Proposed Rule IX, at 1772 (adopted as proposed). No similar requirement is imposed on Blue Mountain or other clinicians' offices in connection with a patient experiencing chest pain, who experience a perforation during an IUD insertion or removal or hysteroscopy, or vasectomy with a hematoma, among other examples.

66. Further, a written transfer agreement with a hospital has no relevance for patients who obtain medication abortion, who pass the pregnancy at home, which may be hours from Blue Mountain. Likewise, patients who have a procedural abortion and experience a rare complication that requires immediate attention should go to the ER. This is the same instruction given to any patient coming to Blue Mountain for other care, or indeed any care provided by other clinicians: if a patient is experiencing an emergency, patients should go to the ER.

67. Entering into a transfer agreement with a hospital is not only unnecessary, but also places the future of Blue Mountain abortion care in the hands of a third party hospital—which may be hostile to abortion, may change leadership from one year to the next, merge, or close. There is no reason to subject Blue Mountain to that additional uncertainty simply because we provide abortion care.

*Staffing Requirements, Including for Anesthesia*

68. Rule X, relating to anesthesia and Rule XII relating to infection control both include unnecessary staffing requirements. Proposed Rule X, at 1772-73 (adopted as proposed); Proposed

Rule XII, at 1774 (adopted as proposed)

69. A medical practice, just like any other business, can only stay afloat if it has an appropriate distribution of labor: that is, if it distributes tasks among staff according to the level of expertise that each task demands. For example, requiring a physician to perform a task that can safely and appropriately be performed by a nurse makes no sense. It increases the cost of providing health care without adding any benefit to the patient, and it keeps the physician from performing tasks that the physician is qualified to perform. If a physician is occupied with tasks someone else could do and currently does, she is not spending time with a patient providing care the physician would typically provide.

70. Rule X provides: "Anesthesia must be administered only by a physician qualified to administer anesthetic agents or a certified registered nurse anesthetist (CRNA)." "Anesthesia" is not defined. *See* Proposed Rule X, at 1772-73 (adopted as proposed).

71. Blue Mountain provides local anesthesia to procedural abortion patients and offers minimal and moderate sedation to those patients as well. Moderate sedation is a combination of a sedative (to help patients relax) and an anesthetic (to block pain) and is sometimes referred to as moderate sedation. A physician typically administers local anesthesia prior to the procedure. A physician prescribes but does not administer medications for minimal and moderate sedation. A Blue Mountain registered nurse administers those medications, through an injection or IV, which is well within the scope of her RN license. Mandating a physician do this instead takes the physician's time away from other patient care. And mandating a physician do this only when it comes to moderate sedation for abortion care—the same moderate sedation we offer to patients undergoing other gynecological procedures—is irrational.

72. Rule XII requires that the clinic's infection control program be under the direction

of a "licensed health care professional." *See* Proposed Rule XII, at 1774 (adopted as proposed). Blue Mountain's infection control program is directed by a medical assistant (who is not required to be licensed in Montana). There is no need for an infection control program to be under the direction of a "licensed" health professional—the key requirement is that the person is trained.

73. All clinicians' offices should have infection control programs—including gynecology offices, birth centers, family practice offices—under the direction of a trained professional. There is no reason whatsoever to mandate that, if a clinic that provides abortion care, the infection control program be directed by a "licensed" professional.

*Annual Inspections and Additional Investigations*

74. HB 937 and Rule II also require that abortion clinics be inspected annually and will be subject to additional inspections in response to complaints. Final Rule II, at 2242-43. As is true of the entire scheme, there is no health or safety reason to require such annual inspections only for facilities that provide abortion care, but not miscarriage care, other gynecological care, and the host of other outpatient care provided in clinics throughout the State. These requirements are meant to stigmatize abortion care by singling it out. Inspections, without notice, also risk disrupting access for patients seeking abortion or other care. This also confuses patients—leading them to question why we are subject to more scrutiny than their OB/GYN or dermatologist's office.

75. The absence of any limit on or description of the types of complaints that would trigger additional investigation by DPHHS is concerning. Anti-abortion organizers and protesters already target Blue Mountain's providers and patients with harassment and threats. By providing a mechanism for anti-abortion organizers and protesters to complain to the DPHHS, HB 937 will encourage unnecessary and baseless investigations that will further disrupt and restrict Blue

Mountain's ability to provide medical services, including abortion care, to its patients.

*Waivers*

76. The Final Rules reference waivers: Rule III states that DPHHS may waive the physical plant requirements for existing clinics if DPHHS determines that compliance would be "extremely difficult or impossible" or that "the level of safety to patients and staff is not diminished." *See* Proposed Rule III, at 1769 (adopted as proposed). Rule I states that DPHHS may waive "certain" requirements "if not necessary in light of the scope of, and any gestational limits on," the abortion care provided by the clinic. *See* Proposed Rule I, at 1767 (adopted as proposed). Rule I then states that "general requirements and provisions and requirements pertaining to the abortion services provided by the abortion clinic may not be waived." Final Rule I, at 2242.

77. DPHHS has provided no guidance about what information is needed for a clinic to seek waivers. I am also not sure what DPHHS is referring to when it says the "general" requirements are not waivable. DPHHS notes, by way of example, that some requirements may be waivable for clinics that only provide medication abortion care. *See* Final Rules, Response #23, 68, at 2248, 2261. But DPHHS does not indicate that the requirements are waivable for the medication abortion care Blue Mountain may provide, even if they continue to apply to its procedural abortion care. And many of what appear to be "general requirements"—like the written transfer agreement, unnecessary tests and exams, and staffing requirements—have no more relation to procedural abortion than medication abortion.

78. Abortion clinics have 30 days to apply for a license, and DPHHS states it will act on that application within 60 days of receipt. It is not clear whether, when DPHHS gives itself 60 days to act on an application after receipt, that is the date DPHHS will give a clinic a final decision on whether to grant or deny a license or whether DPHHS must take some initial action on the

application within those 60 days. Once again, the process DPHHS has outlined risks chaos and uncertainty, in the face of no threat to patient health.

79. On October 1, 2024, Blue Mountain applied for a license and waiver of certain requirements in Rules II, III, IV, VI, VII, IX, and X. The application is attached as Exhibit 2.

Impact of HB 937 and the Final Rules

80. Without a temporary restraining order or preliminary injunction, Blue Mountain once again is at risk of having to stop providing abortion care to Montanans and patients travelling from surrounding states.

81. The harms HB 937 and the Final Rules are causing is not new. They are part and parcel of the disruption that Blue Mountain has had to endure simply because it provides abortion care. The 2023 legislative session was one of the most heated on record. Multiple proposed laws and policies included immediate or near-immediate effective dates, threatening to require Blue Mountain to immediately retool or fundamentally overhaul our practice. Fortunately, the laws that passed and about which we were most concerned have been blocked by court orders.

82. Nonetheless, the threat of ever-changing laws and policies disrupts and strains our clinicians, administrative staff, and confuses our diverse patient population, to the point where patients may believe abortion is no longer a legal option for them. Each of us needs to be able to plan, to know what our schedule will look like the next day or the next week (to the best we are able), and so any energy spent on emergencies is about emergent issues our patients bring to us. We should not additionally need to address emergencies foisted upon us by the State.

83. Even if Blue Mountain is able to secure a license or waivers this year, Blue Mountain and our patients remain injured by the scheme. A license or waivers from certain requirements does not address the harm of being targeted simply because we provide abortion care

for our community, and our patients seek that care. And it does not end with a license or waiver this year: Blue Mountain must go through this process every year, confronting the uncertainty of whether DPHHS will grant or deny a license.

84. The impact of changes mandated by HB 937 and the Final Rules inevitably ripple out to our patients. Ultimately, HB 937 and the Final Rules may force Blue Mountain to decide between continuing to provide abortion care subject to this separate, new regulatory scheme, or eliminating the abortion services we have provided since our founding so that the entire clinic is not forced to overhaul our practice or physical facility. As a non-profit clinic, we do not have funding available for infrastructure remodels and unnecessary changes in staffing. Increased costs associated with the Laws will inevitably be passed on to patients. And there is simply no justification for subjecting our patients to unnecessary exams and tests or eliminating their access to the latest health care delivery systems (i.e., telehealth) because they seek abortion care.

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I declare under penalty of perjury that the foregoing is true and correct.

Dated: 10/3/24

Joey Banks, MD

State of Montana )
)
County of Missoula )

Signed and affirmed to me this 3 day of 10 2024.

Sundi J. Hamilton
Notary Public

SUNDI JO HAMILTON NOTARIAL SEAL STATE OF MONTANA

SUNDI JO HAMILTON
NOTARY PUBLIC for the
State of Montana
Residing at Missoula, MT
My Commission Expires
November 08, 2024.

# Exhibit 1

**Joey Banks, MD ABFM (she/her)**
[redacted]

## Employment

**Oct 2022 to May 2023 Western Montana Clinic**
**Staff family physician**
**Missoula MT**

- Full family medicine practice with procedures

**Oct 2021 to June 1,2021 University of Montana Genomics Core Lab**
**Laboratory Director- High Complexity Lab**
**Emergent Covid- 19 testing site for Montana**

- Provided QA and QI for lab and supervised testing and staff

**Jan 23, 2019, to July 2021 Planned Parenthood of Montana**
**Chief Medical Officer**
**Missoula Montana**
**April 2021 became interim medical director only**
**July 2021 became contract doctor for abortion care only, Principal Investigator for Gynuity research, Moderate Complex Lab director, physician consult for US cases and as needed for other cases.**
**Jan 2022 Contract doctor only**

- Staff physician- primary care and abortion
- Supervise medical staff at all statewide sites (MD, ANP, PA, RN, LPN, CA)
- Lab director Moderate Complex Lab for 5 sites. Trains and hires personnel. Provides quality assurance. Develops policy and protocol for new tests PPMT uses.
- Ensure guidelines and standard protocols are fulfilled per PP Medical Standard and Guidelines.
- Staff Clinician
- New project supervision
- PI Gynuity Research project
- PA staff supervisor
- Train residents and students
- Hire and train contract physicians
- Serve as senior leadership for PPMT and work with team to help with state-wide initiatives

**July 2012—current Blue Mountain Clinic**
**Reproductive Health Medical Director**
**Missoula Montana**
**Jan 2019 became contract doctor only**

- Staff physician- primary care
- Community preceptor for Family Medicine Residency Western Montana
- Gender affirming care hormone therapy including youth care and blockers
- Youth gender affirming care community organizer/lecturer
- Western Montana Family Medicine Resident Community Attending- award for best community attending in 2014/2020
- Awarded RHAP Miscarriage Care Initiative Grant for WMFMR and our clinic
- Assisted in RHEDI grant application and implementation
- Partnered with OAA as medical supervisor for GC/CT program testing and treatment
- LEEP, vasectomy, cryo-therapy, skin lesions, primary care, reproductive care, aspiration abortion to 18 weeks EGA, medical abortion, Accutane
- Assisted in Lab Management with lab director to hire and train personnel and to provide quality assurance and training for moderate complex lab.

**February 2010- July 2012 Arusha Lutheran Medical Center**
**Arusha Tanzania**
**Family Physician**

- Outpatient clinic volunteer and school-based clinic/educator

- Grounds for Health volunteer for VIA training
  Prenatal, gynecology, pediatrics, family medicine
- **Sexual Abuse and Rape Care Committee chair**
  - ✓ Wrote medical policy, training program, and curriculum
- ALSO- Advanced Life Saving Obstetrics instructor

**2007-December 2009 Central Maine Medical Center Family Medicine Residency**
**Lewiston ME**
**Family Physician Faculty- Inpatient/Outpatient/Obstetrics**

- Faculty
- Curriculum Committee Chair
- Gynecology Curriculum Coordinator
- **RHEDI grant coordinator**- IPAS MVA abortion, miscarriage, and ultrasound training director (200,000$ grant)- wrote curriculum, policy and initiated

**2005-2007 Planned Parenthood of Alaska**
**Anchorage AK**
**Medical Director for State of AK (2 clinics)**

- Supervised medical staff at 4 clinics (MD, ANP, RN, LPN, RHS)
- Colposcopy, LEEP, vasectomy, Implanon master trainer, family practice, abortion, and gynecology health service clinician
- Assisted in writing Men's Reproductive Health Protocol for medical care for National Planned Parenthood of America
- Worked with Patient Service Director on drug formularies, lab manuals, education issues for staff, coding and billing.
- Helped with statewide education, public policy, and fundraising issues
- Lab Director for 2 sties. Moderate Complexity. Helped to establish moderate complex lab and develop policy and protocols for the lab. Hired personnel and trained staff on testing. Maintained quality assurance for the lab.

**2005-2007 Providence Family Medicine Residency**
**Anchorage AK**
**Faculty and Gynecology/Elective/Evaluation Coordinator**

- Supervised residents in clinic and inpatient care for pediatric, obstetrical, and medical admissions.
- Developed curriculum for gynecology rotations for the residents
- " Faculty of the Year Award"- for 2006 (voted by residents)
- Managed panel of patients and did clinic outpatient visits
- Faculty for 2005-2006, then volunteer faculty 2006-2007

**2001-2005 ANMC-Primary Care Center**
**Anchorage AK**
**Family Practice Clinician**

- Medical Student Supervisor through University of Washington
- Secretary Medical Staff ANMC 2002-2003
- PCC liaison for women's health and obstetrical care
- Village MD for Sandpoint AK (pop 3000)
- Team physician for panel of approximately 1400 patients
- Family practice care including prenatal and obstetrics
- Member of Quality Assurance PCC committee

**1998-2001 Alaska Family Practice Residency**
**Anchorage AK**
**Providence Family Practice Resident**

- Chief Resident
- Third Year Resident Teacher of Year (2001) and Intern of the Year (1998)
- AAFP National Resident Rural Committee representative 2000

## Contract Doctor Employment Positions:

**Jan 2022 to current** **Alamo Clinic**
**Carbondale IL and Albuquerque NM**

- Medical abortion, surgical abortion first and second trimester, IV sedation provider, Ultrasound provider, telehealth

**July 2022 to Jan 2023** **Whole Woman's Health**
**Contract doctor**
**NM, IL**

- Medical abortion telehealth

**February 2021 to June 2022** **Tulsa Women's Clinic**
**Tulsa, Oklahoma**

- Medical abortion, surgical abortion first and second trimester, IV sedation provider, Ultrasound provider

**April 2021 to current** **Planned Parenthood of Montana**
**Billings, Missoula, Helena Montana**

- Medical abortion, surgical abortion first and second trimester, IV sedation provider, Ultrasound provider, Abortion trainer for other physicians or residents

**March 2019 to current** **Blue Mountain Clinic Family Medicine**
**Missoula Montana**

- Medical abortion, surgical abortion first and second trimester, IV sedation provider, Ultrasound provider, Abortion trainer for other physicians or residents

**Dec 2019 to March 2020** **Trust Women**
**Oklahoma City, Oklahoma**

- Medical abortion, surgical abortion first and second trimester, IV sedation provider, Ultrasound provider

**2008-December 2009** **Planned Parenthood NNE**
**Portland ME**

- Colpo, Cryo, miscarriage care, LEEP, fetal demise and abortion care, family planning

**2001-2003** **Providence Seward ER**
**Seward AK**
**ED Locum Physician**

## Education

●1998-2001 Alaska Family Medicine Residency
●1994-1998 Indiana University School of Medicine
●1986-1989 Baylor University- BA Sociology

## Certifications

- Board Certification Family Medicine current exp 1/1/2028
- State of Alaska, Maine, Idaho previous MD license
- DEA current
- COLA Lab Director Certification- Lab Director course completion
- ACLS current

## Licenses

| | | | |
|---|---|---|---|
| Montana | Physician License | 12588 | active |
| Wyoming | Active License | 15373C | Non active |
| New Mexico | Medical Doctor License | MD2022-0903 | active |

| | | | |
|---|---|---|---|
| **Illinois** | **Physician** | **036161340** | **active** |
| **Oklahoma** | **Full Physician License** | **34204** | **non active** |

**Previous** Maine 017531, Idaho 15247, Alaska 4340- all expired

## Other/Lectures and Associations

●Family Medicine Resident preceptor FMRWM Missoula MT
● Speaker for MT AFFP meetings/statewide hospital CME (contraception update, miscarriage care, care, gender dysphoria)
●Co- Author Gynuity Research articles 2021
●Community Preceptor for WMFMR
●Ultrasound training for basic gynecology and prenatal care Lecturer STFM
●Member of AAFP, RHAP, SFP, ACOG, MT AAFP
●Peace Corps Volunteer Ghana West Africa- teacher (1990-1993)
●Merck Nexplanon master trainer 2006- current Contract MD
●Residency International Experience Cameroon
●Medical School International Experience Kenya

# Exhibit 2

Tara Wooten, Licensure Bureau Chief
Department of Public Health and Human Services
tara.wooten@mt.gov

*Via email and US mail*

October 1, 2024

Dear Ms. Wooten:

I write to apply for an abortion clinic license for Blue Mountain Clinic and waivers from certain rules published on September 20, 2024. Consistent with Rule II(2), the application requirements are set out below, and consistent with Rule II(4), I am mailing a check to DPHHS for the $450 initial license fee, from which Blue Mountain is also requesting a partial waiver.

Because the current court order enjoining enforcement of HB 937's licensure requirement expires on November 19, 2024, Blue Mountain requests a response from DPHHS by October 18, 2024. *See* Order Extending Temporary Restraining Order, All Families Healthcare v. State, No. 23-592 (Oct. 18, 2023).[1]

**Application requirements:**

(a) Name of applicant: Jodi Tucker, C.P.C., Executive Director of Operations

(b) Location of abortion clinic: 610 N. California St., Missoula, MT 59802

(c) Administrator of abortion clinic: Jodi Tucker, C.P.C., Executive Director of Operations

(d) Medical director of abortion clinic: Joey Banks, M.D.

(e) Qualifications of the administrator, medical director, and professional staff:

Administrator: Jodi Tucker, C.P.C., Executive Director of Operations
Medical director for abortion care: Joey Banks, M.D., licensed to practice in Montana
Professional staff involved in abortion care:

- Two locum physicians who provide abortion care when Dr. Banks is out;
- One physician assistant licensed to practice in Montana, who provides medication abortion;
- Two registered nurses licensed to practice in Montana

[1] The order states that the current temporary restraining order remains in force for "a period of sixty (60) days beyond the effective date of the final rules" promulgated to implement HB 937.

(f) Disclosures: Blue Mountain Clinic is a non-profit and does not have an owner. Neither I nor my staff have relevant disclosures to make.

(g) Types of abortion and gestational limits: Blue Mountain provides medication abortion up to 11 weeks and procedural abortion up to 21.6 weeks.

(h) Attestation: I attest that I am of reputable and responsible character and should a court order permit HB 937 and the Rules to be enforced, Blue Mountain will comply with the rules applicable to abortion clinics to the extent Blue Mountain is not seeking waivers of certain requirements, as set out below.

**Request for waivers:**

For nearly 50 years, Blue Mountain has been operating as a clinicians' office, and our practice is regulated by federal, state, and professional authorities, including the Board of Medical Examiners, Board of Nursing, the Board of Pharmacy, and DPHHS through its implementation of CLIA and enforcement of the State's abortion reporting requirements. In addition to abortion care, Blue Mountain provides numerous other health services, including identical care for miscarriage management, which is not subject to the new DPHHS rules.

Mainstream medical authorities including the National Academies of Sciences, Engineering, and Medicine and the American College of Obstetricians and Gynecologists recognize that abortion, whether by medication or procedure, is safely provided in office-based settings like Blue Mountain, and that there is no valid reason to regulate abortion differently than identical or comparable care.[2] (Despite sometimes being referred to as "surgical abortions," abortion procedures are not surgical: they do not involve any incision, are routinely performed in office settings, and involve minimal recovery. [3])

The National Academies summarized that the "clinical evidence . . . on the provision of safe and high-quality abortion care stands in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services," including the requirement that "care take place in costlier and more sophisticated settings than are clinically necessary."[4] These requirements "go beyond the accepted standards of care in the absence of evidence that they improve safety."[5] The DPHHS rules, as a whole, are just

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[2] *See, e.g.*, Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States*77, 162 (2018), https://nap.nationalacademies.org/read/24950; Am. Coll. Obstet. & Gynecol., *Committee Opinion 815: Increasing Access to Abortion* e107 (Dec. 2020), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion.

[3] *See, e.g.*, Am. Coll. Obstet. & Gynecol., *Definition of "Procedures" Related to Obstetrics and Gynecology* (2023), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology.

[4] Nat'l Acads., *supra*, at 77.

[5] *Id*.

the types of medically unnecessary rules to which the National Academies refers.

The Rules reference waivers. Rule III indicates that the physical plant requirements may be waived for existing clinics if DPHHS determines that compliance would be "extremely difficult or impossible" and that "the level of safety to patients and staff is not diminished." Proposed Rules, at 1769 (adopted as proposed). Rule I also states that "certain" requirements may be waived "if not necessary in light of the scope of, and any gestational limits on," the abortion care provided by the clinic. Proposed Rules, at 1767 (adopted as proposed).

The Rules, as a whole, are unnecessary to protect patient health and safety, and single out abortion care for arbitrary and discriminatory regulation. Imposing the Rules on Blue Mountain, our providers, and our patients threatens to end or significantly curtail the abortion care we have provided for nearly 50 years. For that reason, and as explained below, Blue Mountain requests waivers from the following requirements:

Rule II(4): $450 licensure fee

Rule II(4) requires an abortion clinic to submit a $450 license fee with its initial application and with each annual renewal application.

Enclosed with this application is the $450 license fee. However, this fee is exponentially higher than the licensure fee for other licensed health care facilities, which is $20 for facilities with 20 beds or fewer, and $1 per bed for facilities with 21 beds or more. § 50-5-202, MCA. Accordingly, Blue Mountain requests a waiver of the full licensure fee and a refund of $430 in parity with the fees for other licensed facilities of similar size.

Rule III(2), (4): Physical plant requirements

Rule III requires all "patient rooms" be 100 square feet, with 4 feet available on one side of the exam table and 3 feet on all other sides, and that corridors be at least 6 feet wide. DPHHS does not define "patient room," but states in responses to comments on the Rules that "patient rooms" are rooms "in which a patient is assessed or treated." Final Rules, Response # 65, at 2260.

Blue Mountain counsels patients and prescribes, administers, and dispenses medication abortion to patients in rooms that do not have an exam table and do not meet the mandated dimensions, but have sufficient space for these purposes. Blue Mountain also counsels patients and prescribes, administers, and dispenses medication in those same rooms for patients who are seeking care other than abortion care. There is no reason to single out abortion as Rule III does.

Blue Mountain's existing procedure rooms do not meet the 4 feet and 3 feet requirements. In general, the dimensions of rooms where health care services are provided

are based on the care being provided, including equipment and personnel needed to support the patient during the procedure. Blue Mountain's procedure rooms meet our patients' needs. There is no medical basis to mandate abortion procedures be provided in rooms with certain dimensions, and no medical basis to apply that requirement only to abortion care and not any other gynecological care, including identical miscarriage care.

Blue Mountain's hallways are not 6 feet wide, as Rule III requires. DPHHS does not explain the rationale for this dimension. This width requirement is not necessary, for example, to allow passage by emergency services or wheelchairs—for which Blue Mountain's hallways allow passage.

It would be extremely difficult if not impossible for Blue Mountain to alter the size of the clinic's corridors and the rooms in which patients are assessed and treated.

Rule IV: Policies and procedures

Rule IV requires the policy and procedure manual be available not only to staff and DPHHS, but also to patients. There is no reason that our policy and procedure manual should be available to patients, and this requirement does not apply to other facilities licensed by DPHHS, such as outpatient centers for primary care. Admin. R. M. 37.106.1008(2) (policy and procedure manual must be available to "all personnel"). There is also a real risk that anti-abortion activists will use this access to Blue Mountain's policies for purposes of harassment. Accordingly, Blue Mountain requests a waiver from the requirement that the policy and procedural manual be available to our patients.

In addition, Blue Mountain requests a waiver from the requirement to have policies and procedures consistent with rules from which it is also seeking waivers.

Rule VI: Staff files

The requirement to conduct a background check on every employee does not apply to outpatient centers for primary care or outpatient centers for surgical services, *see* Admin. R. M. 37.106.315 (all health facilities), and there is no reason for it to apply to Blue Mountain. Blue Mountain has a thorough process for vetting staff and will use that process for staff involved in abortion care and those involved in other care Blue Mountain provides. There is no valid basis for mandating a different vetting process for staff involved in abortion care or all staff at Blue Mountain simply because we also provide abortion care.

Rule VII: Patient files

Rule VII requires Blue Mountain to document—and thus have patients undergo—various unnecessary tests and exams, including physical exams, tests for Rh factor, and pregnancy tests or pathological exams to verify pregnancy. Mandating these tests for every patient would end Blue Mountain's provision of medication abortion via telehealth, a safe

and critical option for our patients.[6] Permitting patients to obtain these medically unnecessary tests from a provider other than Blue Mountain still requires patients to make an in-person visit to a provider, delaying and impeding access to necessary telehealth care.

Patients can, are, and have been evaluated prior to a medication abortion without a physical exam. That assessment includes reviewing the patent's history and confirming the patient is eligible for medication abortion, including based on their last menstrual period or conception date. In some cases, Blue Mountain may refer a patient seeking care via telehealth for an ultrasound, but in most cases, the patient and the Blue Mountain clinician can date the patient's pregnancy and determine eligibility for medication abortion based on their last menstrual period. There is no need for a physical exam.

Recent research indicates there is a very low likelihood of Rh sensitization associated with abortion or pregnancy loss at fewer than 12 weeks. Major medical organizations suggest that Rh testing is not necessary prior to 12 weeks.[7] Consistent with that research, the National Abortion Federation updated its Clinical Guidelines to state that Rh testing and RhoGAM need not be provided for patients seeking abortion care before 12 weeks.[8] The Society of Family Planning, World Health Organization, and American College of Obstetrics and Gynecology likewise updated their recommendations.[9]

The Proposed Rules' Statement of Reasonable Necessity at 1780 acknowledges this testing is unnecessary for all patients, as it states: "RH Negative Factor is recommended for gestational ages of eight weeks or more." Although that is outdated, it reflects DPHHS's understanding that the Rule imposes Rh testing on at least some patients for whom it is not necessary.

Patients do not need to provide pregnancy test results to Blue Mountain prior to obtaining an abortion. Patients self-report pregnancy test results. For in-clinic patients, Blue Mountain conducts an ultrasound when indicated, and, if necessary, a pregnancy test. There is no patient health benefit to mandating Blue Mountain document a pregnancy test, and mandating that patients produce such results can delay care.

It is not clear what DPHHS means by the requirement that, as an alternative to a pregnancy test, abortion clinics document a "pathological exam of tissue . . . to verify

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[6] *See, e.g.*, Elizabeth G. Raymond et al., *Commentary: No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 J. Contraception 361, 361, 364-65 (2020).
[7] Sarah Horvath et al., *Society of Family Planning Committee Consensus on Rh Testing in Early Pregnancy*, 114 Contraception 1, 3 (Oct. 2022), https://www.contraceptionjournal.org/article/S0010-7824(22)00197-4/fulltext.
[8] National Abortion Federation, 2024 Clinical Policy Guidelines for Abortion Care 12-13, https://prochoice.org/wp-content/uploads/2024-CPGs-FINAL-1.pdf.
[9] World Health Organization, Abortion Care Guidelines 44-45 (2022), 9789240039483-eng.pdf (who.int); Horvath et al., *supra*, at 4; Am. Coll. Obstet. & Gynecol. Clinical Practice Update: Rh D Immune Globulin Administration After Abortion or Pregnancy Loss at Less Than 12 Weeks of Gestation, Obstet. & Gynecol. (2024).

pregnancy." Proposed Rules, at 1771 (adopted as proposed). A pathological exam of pregnancy tissue occurs after abortion care, not to verify the patient is pregnant. In any event, Blue Mountain does not and cannot conduct a pathological exam for patients who access medication abortion. These patients pass their pregnancy at home or a location of their choosing, not the clinic. Blue Mountain conducts a tissue exam for patients for whom we provide in-clinic abortion procedures, but does not conduct a pathological exam, which is not necessary and would require sending out tissue to a third-party pathology lab at additional and unnecessary cost to the patient.

Rule IX: Emergency procedures

Rule IX(2) requires certain emergency equipment to be available to the operating room. Blue Mountain does not have an operating room or an emergency call system. Blue Mountain has oxygen, assistance equipment, sonography, and emergency drugs and supplies.

Rule IX(3) requires Blue Mountain to have a written transfer agreement with a hospital, which it does not have, nor is one necessary to meet patients' health and safety needs. Blue Mountain has transfer protocols, which apply to both abortion patients and non-abortion patients, as in the case of a patient experiencing an allergic reaction to an antibiotic used in treating a sexually transmitted infection. There is no reason to mandate Blue Mountain obtain a written transfer agreement with a hospital solely because it provides abortion care.

Rule X: Anesthesia

Rule X refers to anesthesia but does not define anesthesia. It is thus unclear whether DPHHS means for the rule to apply to local anesthesia, minimal and moderate sedation, and general anesthesia, or only some of these. The Rule then restricts the provision of anesthesia, as well as assessments related to anesthesia, to a physician or CRNA.

At Blue Mountain, we offer minimal and moderate sedation to abortion procedure patients, and when desired, a registered nurse administers sedation prescribed by a physician. The registered nurse also conducts relevant patient assessments prior to and after administering anesthesia. The registered nurse could administer moderate sedation, and conduct the same assessments, in connection with IUD insertions or miscarriage management. There is no reason to deny patients seeking abortion care basic pain management because a registered nurse administers that care, or to divert physician time away from other patient care to provide care that a registered nurse is trained to provide.

* * *

Considering the significant impact on Blue Mountain's practice and our patients'

access to abortion and the other health services we provide, and the absence of any benefit to patient safety from imposing the above requirements on Blue Mountain and our patients, Blue Mountain urges DPHHS to grant our clinic a waiver from these requirements.

Sincerely,

Jodi Tucker, C.P.C.
Executive Director of Operations
Blue Mountain Clinic
610 N. California St.
Missoula, MT 59802
[redacted]

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*Attorneys for Plaintiffs All Families Healthcare, Blue Mountain Clinic, and Helen Weems*

**Admitted pro hac vice*

**MONTANA FIRST JUDICIAL DISTRICT COURT,**
**COUNTY OF LEWIS & CLARK**

| | |
|---|---|
| ALL FAMILIES HEALTHCARE; BLUE MOUNTAIN CLINIC; AND HELEN WEEMS MSN APRN-FNP, on behalf of themselves and their patients<br>Plaintiffs,<br>vs.<br>STATE OF MONTANA; MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES; and CHARLIE BRERETON, in his official capacity as Director of the Department of Public Health and Human Services<br>Defendants. | Cause No.: DDV-2023-592<br>Hon. Christopher Abbott<br><br>**AFFIDAVIT OF JENNIFER MAYO, MD, IN SUPPORT OF PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION** |

I, Jennifer Mayo, MD, affirm that:

1. I submit this affidavit in support of Plaintiffs' Application for a Temporary Restraining Order and Preliminary Injunction against the enforcement of HB 937 (the "Act") and final regulations related to the licensure of clinics that provide abortion services ("the Laws").

Background and Experience

2. I am a board-certified obstetrician-gynecologist licensed to practice in Montana. I obtained my medical degree from Oregon Health & Science University ("OHSU") in June 2006 and completed my ob-gyn residency at OHSU in June 2010. I am a fellow of the American College of Obstetricians and Gynecologists ("ACOG"), the leading professional organization of ob-gyns in the United States. Additionally, I have served as a clinical instructor for the University of Washington Medical School WWAMI (Washington, Wyoming, Alaska Montana, and Idaho), a collaborative medical education program among medical schools in those 5 states. Through that program, I train medical students during 6-week clerkships in obstetrics and gynecology.

3. I have been practicing medicine in Montana since September 2010. I currently practice at Western Montana Clinic, a clinicians' office that has been providing multi-disciplinary health services to the Montana community since 1922. In my office, I provide outpatient obstetric and gynecological care, including annual gyn exams, prenatal care; miscarriage management by procedure and medication; and surgical and non-surgical gynecological consultation. I also routinely care for patients in the operating room; many procedures I provide there can also be safely performed in the office. Additionally, I provide abortion care in the outpatient setting through the end of the first trimester and am trained to provide abortion care through the second trimester.

4. My *curriculum vitae*, which sets forth my experience and credentials in greater detail is attached as Exhibit 1.

5. The opinions in this affidavit are my expert medical opinions, based on my education, training, clinical experience, ongoing review of relevant, peer-reviewed professional literature, and discussions with colleagues.

6. I am familiar with HB 937 and the Department of Public Health and Human Services ("DPHHS") final rules about licensure for abortion clinics in Montana. HB 937 requires clinics that provide abortion services to obtain facility licensure from DPHHS in order to continue providing abortion services, and the Rules set out in more detail the requirements for licensure.

7. Individually and together, HB 937 and the Rules impose bureaucratic and medically unnecessary requirements that micro-manage patient care solely because it is abortion care. I also understand that the scheme would threaten to shut down or limit existing clinics' provision of abortions services, which would impose significant health harms on the many Montanans who rely on access to safe, essential abortion care each year.

8. Singling out clinicians' offices and clinics that provide abortion services with targeted and additional requirements has no medical justification. The procedures I perform in my office for management of miscarriage are identical in skill, technique, and risk to abortion procedures. Additionally, the medications I prescribe to manage miscarriage are identical to the medications used to induce an abortion. There is no medical reason that would necessitate different facility licensure or facility requirements for an induced abortion, as compared to management of miscarriage. The treatments are no different. Use of mifepristone, and the risks and benefits inherent in prescribing it, are identical whether it is indicated in managing spontaneous abortion

(miscarriage) or induced abortion. Even the language we use to discuss these clinical scenarios are nearly interchangeable.

Outpatient Gynecological and Other Services

9. In my office, I provide several procedures that are comparable to procedural abortion. The procedure to manage miscarriage (referred to as dilation and curettage, D&C, or aspiration) is identical to that which is performed in an induced abortion. My provision of this care as applied to miscarriage, does not trigger application of the Laws.

10. Managing miscarriage by procedure requires identical skill and carries the same risk as inducing an abortion by procedure. In both procedures, a clinician dilates the cervix and a curette is used to remove the uterine contents, usually through suction. At the same point in pregnancy, the procedure does not differ medically, in terms of risk or technique, for patients whose pregnancies end as a result of embryonic or fetal death, incomplete miscarriage, or induced abortion.

11. Abortion is also comparable to other outpatient gynecological procedures in terms of risk, invasiveness, duration, and instrumentation that I offer in my office. For example, it is similar in some ways to hysteroscopy (a procedure used to examine the inside of the uterus with a camera), loop electrosurgical excision procedures (LEEP; a procedure to remove abnormal cells from the cervix to prevent cancer), and insertion and removal of IUDs. For these procedures, I administer a cervical block with lidocaine to numb the cervix prior to the procedure. I also offer anxiolytic (anxiety) medication as necessary.

12. Some clinicians may provide these procedures in ambulatory surgical or hospital settings, but that is not necessary. In my experience, clinicians may perform these procedures in an ambulatory surgical or hospital setting because that is how they were trained or where they have

access to necessary equipment. Some patients are most comfortable receiving general anesthesia for these procedures. But there is no health or safety reason that miscarriage management needs to be performed in such settings. Likewise, there is no valid reason for the identical procedure performed to induce an abortion to be performed in such settings.

13. Managing miscarriage with prescription medications is also identical to medication abortion. Miscarriage can be managed with misoprostol, with or without mifepristone—the same medications used in a medication abortion. I currently prescribe mifepristone and misoprostol for miscarriage management, which is more effective than a misoprostol-only regimen, as research demonstrates, and my experience confirms.[1]

14. Abortion care, by medication or procedure, can be safely and effectively provided in a clinic setting such as a clinician's office, just as miscarriage care, and other similar gynecologic procedures, are routinely provided safely and effectively in that same setting.

15. I also refer to Blue Mountain Clinic for abortion care, including first and second trimester procedures. My patients have always received excellent and safe care at this outpatient facility.

16. Requiring facility licensure and additional requirements for clinicians' offices and clinics that provide abortion care is medically inappropriate. There is no medical reason to apply unique requirements to abortion care simply because it is abortion care.

[1] *See, e.g.*, ACOG, Early Pregnancy Loss, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: 10/4/24

Jennifer Mayo, MD

State of Montana )

)

County of Missoula )

Signed and affirmed to me this 4 day of October 2024.

Notary Public

STEPHANIE FOLEY
NOTARY PUBLIC for the
State of Montana
Residing at Missoula, Montana
My Commission Expires
November 16, 2027

# Exhibit 1

# Jennifer B. Mayo, M.D., F.A.C.O.G.

Western Montana Clinic
PO Box 7609
Missoula, MT 59807-7609

## Education and Training

| | | |
|---|---|---|
| 7/2006 – 6/2010 | **Oregon Health & Science University**<br>Obstetrics and Gynecology Residency | Portland, Oregon |
| 8/2001 – 6/2006 | **Oregon Health & Science University**<br>*Alpha Omega Alpha Honors Society*<br>Doctorate of Medicine | Portland, Oregon |
| 9/1995 – 12/1999 | **Oregon State University Honors College**<br>*Summa Cum Laude*<br>Bachelor of Science – Microbiology<br>Certificate of Applied Ethics | Corvallis, Oregon |
| 9/1997 – 6/1998 | **University of Sussex**<br>Microbiology | Brighton, England |

## Employment/Professional Work

| | |
|---|---|
| 9/2010 – present | Western Montana Clinic – Ob/Gyn<br>*2019 – present Executive Council Member* |
| 9/2015 – present | Saint Patrick Hospital Department of Surgery Representative |
| 2011 – 2012 | American College of Ob/Gyn, Montana Section Junior Fellow Chair |
| 2010 – 2011 | American College of Ob/Gyn, Montana Section Junior Fellow Vice Chair |

## Board Certification

| | |
|---|---|
| 12/2012 – present | American Board of Obstetrics and Gynecology |

## Teaching Experience

| | |
|---|---|
| 9/2010 – present | University of Washington Medical School, WWAMI Clinical Instructor |

## Awards

| | |
|---|---|
| 2020 | Association of Professors of Gynecology and Obstetrics (APGO)<br>*Excellence in Teaching Award* |
| 2018 | WWAMI Excellence in Teaching Award |
| 2013 – 2016 | Missoula Independent's "Best Gynecologist" |

## CERTIFICATE OF SERVICE

I, Alexander H. Rate, hereby certify that I have served true and accurate copies of the foregoing Answer/Brief - Brief In Support of Motion to the following on 10-07-2024:

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