IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

PLANNED PARENTHOOD MINNESOTA, NORTH DAKOTA, SOUTH DAKOTA, and SARAH A. TRAXLER, M.D.;	)	
Plaintiffs,	)	
v.	)	**CASE NO.** 4:22-cv-4009
KRISTI NOEM, Governor, JOAN ADAM, Interim Secretary of Health, Department of Health, and PHILIP MEYER, D.O., President, South Dakota Board of Medical and Osteopathic Examiners, in their official capacities,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Planned Parenthood Minnesota, North Dakota, South Dakota ("PPMNS" or "Planned Parenthood"), and Sarah A. Traxler, M.D., by and through their undersigned counsel, bring this Complaint against the above-named Defendants, their employees, agents, and successors in office, and in support thereof state the following:

1. Plaintiffs are health care providers in South Dakota who bring this civil rights action, seeking declaratory and emergency injunctive relief, on behalf of themselves and their patients, under the United States Constitution and 42 U.S.C. § 1983, against portions of South Dakota Department of Health Rule 44:67:04:13 (the "Rule"), attached hereto as **Exhibit A**. Absent relief from this Court, the Rule will take effect on January 27, 2022.

2. Under current law, South Dakota patients seeking to terminate an early pregnancy, like patients nationwide, have the option of choosing a safe, non-surgical method of abortion using medications alone. This is referred to as "medication abortion."

3. With no medical justification or authority, the South Dakota Department of Health (the "Department") has promulgated a Rule that would force patients seeking a medication abortion to be dispensed medication in a manner that is unduly burdensome and contrary to the standard of care and the recommendations of the U.S. Food & Drug Administration ("FDA") and other leading medical organizations, including the American College of Obstetricians and Gynecologists ("ACOG"). The Rule's practical effect will be to make it impossible for Plaintiffs to provide, and their patients to receive, medication abortions in South Dakota. At the very least, the Rule will place significant barriers—on top of those already imposed by South Dakota law—on patients' ability to have a safe medication abortion.

4. To complete a medication abortion, patients take a regimen of two FDA-approved prescription drugs: 1) mifepristone (also known by its brand name, Mifeprex), which blocks progesterone, a hormone necessary to continue a pregnancy, and 2) misoprostol (also known by its brand name, Cytotec), which softens the cervix and causes the uterus to contract and empty.

5. Although there are numerous problematic elements of the Rule, this action concerns changes imposed by the Rule to the dispensation of the second drug of the regimen. Misoprostol is an extremely common and safe drug, used not only for medication abortion, but also other indications, including miscarriage treatment and the treatment of gastric ulcers.

6. Under existing South Dakota law, patients seeking a medication abortion are dispensed both mifepristone and misoprostol on the same day, by a licensed physician, during an in-person visit at a licensed abortion facility. The medications are dispensed at the second of two

mandatory clinic visits (which by law must be a minimum of 72 hours apart). Patients take mifepristone at the abortion clinic, and are given misoprostol with oral and written instructions to take it 24 to 48 hours later at a location of their choosing, which is usually their home.

7. The dispensing of both medications at the same time is in accordance with the regimen that appears on the label approved by the FDA, and decades of research demonstrating that women are capable of following instructions on when and how to take misoprostol and that allowing patients to have both medications dispensed at the same time gives them more control over the process and reduces barriers to care, thereby improving health outcomes.

8. The Rule departs from this evidence-based protocol by prohibiting Plaintiffs from dispensing, and patients from receiving, both medications at the same clinic visit. Instead, patients would be forced to make an additional, *third* visit to the clinic to obtain the misoprostol from a physician, no sooner than 24 hours after receiving the mifepristone. There is no medical justification for imposing a mandatory delay and separate, in-person visit requirement for misoprostol. On information and belief, no other state currently imposes such a requirement.

9. The Rule's deviation from the standard of care hampers patients' ability to follow the proper medication abortion regimen and may increase their risk of complications. Accordingly, because the Rule does not comport with best medical practices and burdens patients to their detriment, PPMNS will be forced to stop providing medication abortions at its Sioux Falls health center, the only generally available abortion provider in South Dakota. In addition, there are no generally available South Dakota-based physicians who provide abortion. Out-of-state physicians travel to Sioux Falls, and must do so twice in one week (due to existing laws) to provide abortion services. From an operational standpoint, PPMNS simply would not be able to staff the Sioux Falls health center in a way that would allow it to comply with the Rule.

10. Even if Plaintiffs could comply, the Rule would impose severe burdens on patients seeking a medication abortion. Many of PPMNS's patients have limited financial means and many already struggle to travel significant distances to reach the health center, twice. For some, the trip is hundreds of miles each way. Forcing patients to expend additional time and resources to make an *additional, third trip* to comply with the Rule will result in delays in accessing medication abortion or having to forego it altogether, and increased medical risks.

11. The Rule only applies to misoprostol when dispensed for the purpose of providing medication abortions, and does not apply to any other application of misoprostol, including miscarriage management. There is no rational basis for this distinction.

12. The Department claims that the Rule is necessary to implement Governor Noem's Executive Order 2021-12, which is targeted at preventing patients from accessing medication abortion via telemedicine. However, because South Dakota law already requires patients to meet in-person with a physician twice before they can have a medication abortion, telemedicine cannot be used for abortion. Moreover, the Rule's mandatory delay requirement on the dispensing of misoprostol in no way relates to the Governor's effort to prohibit telemedicine.

13. If allowed to take effect, the Rule will violate Plaintiffs' and patients' due process and equal protection rights under the 14th Amendment of the United States Constitution. These harms will be felt immediately, as abortions are next scheduled to take place at the health center on January 27, 2022, the same day the Rule is scheduled to take effect.

14. To protect the health of South Dakota women and the constitutional rights of Plaintiffs and their patients and to avoid irreparable harm, Plaintiffs seek declaratory and emergency and permanent injunctive relief against the Rule and its enforcement.

SUBJECT MATTER JURISDICTION AND VENUE

15. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1343.

16. Plaintiffs' claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, Rules 57 and 65 of the Federal Rules of Civil Procedure, and the general legal and equitable powers of this Court.

17. Venue is appropriate under 28 U.S.C § 1391(b) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurs in this judicial district.

PARTIES

18. Plaintiff PPMNS is a not-for-profit Minnesota corporation registered as a foreign corporation doing business in South Dakota. PPMNS operates the Sioux Falls health center located in Sioux Falls, South Dakota, which is licensed as an abortion facility by the South Dakota Department of Health. The Sioux Falls health center provides a broad range of reproductive health services, including physical exams, pregnancy testing and options education, contraception and contraceptive education, testing for HIV and sexually transmitted infections ("STI") and STI treatment, screening for cervical and breast cancer, and medication and procedural abortion. All of the physicians who practice at the Sioux Falls health center, including Dr. Traxler, are licensed to practice medicine in South Dakota by the South Dakota Board of Medical and Osteopathic Examiners (the "Board"). Plaintiffs sue on their own behalf and on behalf of PPMNS's current and future physicians, employees, staff, servants, officers, and agents who participate in abortions, and on behalf of their current and future patients seeking medication abortion services.

19. Plaintiff Sarah A. Traxler, M.D., is a Board-certified obstetrician and gynecologist licensed to practice medicine in Minnesota, North Dakota, South Dakota, Connecticut, Iowa, Maine, Nebraska, and Rhode Island. She is the Medical Director of PPMNS, and travels from

Minneapolis to Sioux Falls to provide medical services at the Sioux Falls health center. Dr. Traxler is one of the few people who provides medication and procedural abortions at the Sioux Falls health center. Dr. Traxler sues on behalf of herself and her current and future patients seeking abortion services.

20. Defendant Kristi Noem is the Governor of the State of South Dakota. She is responsible, under South Dakota law, to "supervise the official conduct of all executive and ministerial officers" and to "see that the laws of the state are faithfully and impartially executed." S.D. Codified Laws §§ 1-7-1(1) to (2); *see also* S.D. Const. art. IV, § 3. Defendant Noem is sued in her official capacity as Governor of the State of South Dakota.

21. Defendant Joan Adam is the interim Secretary of Health for the State of South Dakota. She is the "head of the Department of Health." S.D. Codified Laws § 1-43-2. The South Dakota Department of Health has authority to engage in rulemaking "to protect the health and safety of a patient," *id.* § 34- 23A-51, and is responsible for the licensing of abortion facilities, including PPMNS's Sioux Falls health center, *id*. Each year, as part of renewing the health center's clinic license, the Department undertakes an exhaustive, unannounced multi-day series of clinic inspections for compliance with the State's abortion regulations. The Department "may suspend or revoke a license issued under SDCL chapter 34-23A"—the chapter of South Dakota law governing the performance of abortions—on account of the licensee's "[v]iolation of any of the provisions of SDCL chapter 34-23A or [Chapter 44:67 of the Administrative Rules, which regulates abortion facilities]." S.D. Admin. R. 44:67:01:05(1); S.D. Codified Laws § 34-23A-51 (directing the Department of Health to "adopt rules . . . for the . . . suspension[] and revocation of a license to operate an abortion facility"). The Rule, if promulgated, would be codified in Chapter

44:67 of the Administrative Rules. Defendant Adam, her employees, agents, and successors in office, are sued in their official capacities.

22. Defendant Philip Meyer, D.O. is the President of the South Dakota Board of Medical and Osteopathic Examiners, the agency which is responsible for the licensure of Planned Parenthood's physicians, including Dr. Traxler. Under South Dakota law, the Board may "cancel, revoke, suspend, or limit the license . . . of any physician . . . upon satisfactory proof . . . of . . . unprofessional or dishonorable conduct." S.D. Codified Laws § 36-4-29. The Board has broad discretion to determine what behavior constitutes "unprofessional or dishonorable conduct." S.D. Att'y Gen. Op. No. 88-37 (Aug. 15, 1988), 1988 WL 483271; *see also In re Setliff*, 645 N.W.2d 601, 606 (S.D. 2002). The Eighth Circuit has held that violation of an abortion statute could be grounds for action by the Board as conduct "unbecoming a person's license to practice medicine." *Planned Parenthood, Sioux Falls Clinic v. Miller*, 63 F.3d 1452, 1467 (8th Cir. 1995) (citing S.D. Codified Laws § 36-4-30(22)). Defendant Meyer is sued in his official capacity as President of the Board.

FACTUAL ALLEGATIONS

A. Plaintiffs and Current Abortion Services in South Dakota

23. PPMNS's Sioux Falls health center is the only generally available abortion provider in South Dakota.

24. In 2020, the last year for which state-wide abortion vital statistics are available, PPMNS's Sioux Falls health center provided 96% of abortions in the state. For calendar year 2021, there were 190 abortions performed at the Sioux Falls health center. Approximately 40% of these were medication abortions.

25. The health center provides medication abortions through 77 days of pregnancy as measured from the first day of the patient's last menstrual period ("LMP"). It schedules procedural (sometimes referred to as surgical) abortions through 13.6 weeks LMP. This means that all abortions performed at the health center are first trimester abortions.

26. The health center schedules patients for abortions approximately four weeks out. Abortions are next scheduled at the health center for January 27, 2022.

27. Because of the political stigma and hyper-regulation associated with performing abortions in South Dakota, there has been no generally available South Dakota-based abortion provider in more than 20 years. As a result, physicians, including Plaintiff Dr. Traxler, travel from other states to Sioux Falls to ensure that abortion services remain available in South Dakota. Prior to the pandemic, four physicians took turns traveling to Sioux Falls each month so that the health center could offer abortions once per week. At the height of the pandemic, abortion services stopped altogether in South Dakota, though they are gradually resuming. Currently, there are three physicians traveling to Sioux Falls to perform abortions, with services being offered at the health center twice a month. In 2022, the health center plans to expand these services.

28. Under existing South Dakota laws, in order to obtain an abortion, patients must have two in-person visits with the same physician at the health center, three days apart. First, patients must meet with a physician for a mandatory counseling visit. A minimum of seventy-two hours later (excluding weekends and holidays), they must meet with the same physician again to obtain their abortion. For medication abortions, patients receive both drugs in the regimen (mifepristone and misoprostol) from a physician at this second, in-person appointment. They take the mifepristone at the health center, and take the misoprostol twenty-four to forty-eight hours later at a location of their choosing, usually their home.

29. Patients are provided with the medical support they need throughout the process. Patients are given a telephone number to call, staffed 24/7 by a medical professional, and encouraged to call that number with any concerns. If and when patients need to use that number, staff are able to help them manage and reduce side effects, offer them reassurance when those effects are within the expected range, assess when a patient may be experiencing a rare complication, and in those cases help the patient access follow-up care as needed.

30. There are many reasons why patients may prefer a medication abortion to a procedural abortion. A medication abortion may feel more private, and allow them to complete what for some is a difficult process at home, where they can be more comfortable and surround themselves with their chosen support network. It also affords patients more flexible timing so that they can meet their parenting and work obligations. Some patients fear invasive procedures because they have had negative surgical experiences in the past, or because they have suffered sexual violence and do not want instruments inserted into their bodies, as is required for procedural abortions. Other patients need to conceal their abortion from an abusive partner or family member, or from a partner or family member who does not agree with their decision to terminate their pregnancy; this is easier to do with medication abortion than with procedural abortion because medication abortion resembles a miscarriage.

31. For some patients, medication abortion is not only the preferred option, but the safest one. For example, for patients with conditions like cervical stenosis, uterine fibroids, or obesity, a procedural abortion carriers more risk than a medication abortion. And for patients with vulvodynia or vaginismus, the instrumentation involved in procedural abortion would be quite painful.

32. Patients travel to the Sioux Falls health center from all over South Dakota as well as several surrounding states in order to obtain a medication abortion. Of patients seeking a medication abortion, close to 24% travel more than 150 miles round trip to get to the Sioux Falls health center for each visit. Approximately 11% travel more than 300 miles round trip. This means that in order to comply with South Dakota's two-trip requirement, these patients must travel more than 300 miles and 600 miles total respectively.

33. Many of the health center's patients have low incomes. In 2021, 31% of patients who obtained a medication abortion at the Sioux Falls health center had incomes below 110% of the federal poverty level ("FPL"). For reference, in 2021, 110% of the FPL was an annual income of $14,168 for a family of 1, and $29,150 for a family of 4.

34. Many of the patients who seek abortions in Sioux Falls are already mothers, and a number of them are single mothers. Many have jobs. Some go to school. These responsibilities must be put on hold while the patient travels to Sioux Falls for multiple appointments in order to obtain an abortion.

35. Plaintiffs' patients also include women who are victims of sexual assault and women who are victims of domestic abuse. South Dakota has the third highest incidence of rape in the country, nearly twice the national rate. Spending additional time and resources trying to obtain an abortion increases the risk to their confidentiality.

36. As a result of the distances they must travel, their limited financial resources, their obligations to their families, employers, and communities, and their concerns about confidentiality, many of the patients seeking abortions in South Dakota already find it very difficult to come to Sioux Falls to access abortion services.

B. Medication Abortion Background

37. Legal abortion is one of the safest medical procedures in the United States, and is far safer than continuing a pregnancy through to childbirth.

38. Medication abortion in particular is comparable in safety to the use of over-the-counter medications like ibuprofen and to antibiotics.

39. Legal abortion is not only extremely safe but also extremely common; approximately one in four women in this country will have an abortion by age forty-five.

40. In many states, medication abortion is widely accessible. For example, a number of states allow providers to screen patients by telemedicine and provide them with medications by mail-order pharmacy to avoid travel-related delays. In states like Minnesota and Iowa, providers can also offer medication abortion via "site-to-site" telemedicine, where the patient is at one health center and the physician at another health center. Moreover, in many states, medication abortion can be provided by advanced practice clinicians. None of these options are available in South Dakota, despite being supported by research demonstrating their safety.

41. ACOG has stated that abortion is essential health care. ACOG guidance endorses modes of delivery that increase access to provide medication abortions, as safe and highly beneficial for patients. ACOG also advocates against burdensome government restrictions that make it harder for patients to access evidence-based care, such as mandatory waiting periods.

42. People seek abortion for a multitude of complicated and personal reasons that are closely tied to their values, culture and religion, health and reproductive history, family situation and support system, educational and/or career goals, and resources and financial stability.

43. Since mifepristone's approval by the FDA in 2000, more than four million people in the United States have obtained a medication abortion using mifepristone and misoprostol to end an early pregnancy.

44. Medication abortion accounted for 39% of all U.S. abortions in 2017, the last year for which data is available.

45. Mifepristone, which is taken first, blocks the body's receptors to progesterone, a hormone necessary to sustain pregnancy. This causes the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall.

46. Misoprostol, which is the subject of this litigation, is taken 24–48 hours after the mifepristone at a location of the patient's choosing, usually their home. Twenty-two to 38% of patients abort within 3 hours, and 50–60% do so within 5 hours of taking the misoprostol buccally (i.e., dissolving the tablets between the cheek and gum). The process is clinically similar to miscarriage.

47. In the rare instance when mifepristone and misoprostol fail to terminate a pregnancy fully, the abortion may be completed by procedure, which is also a safe method to terminate pregnancy. For reference, patients who have a first trimester procedural abortion typically lie on an examination or operating table in a dorsal lithotomy position (on their backs with their hips and knees flexed and thighs apart), most often with their feet or legs in stirrups. The abortion is performed by vacuum aspiration; the patient's cervix is dilated, a tube is inserted through the vagina and cervix into the uterus, and suction is applied through the tube to empty the uterus. Patients having a procedural abortion in early pregnancy are often given pain medication and/or a sedative prior to the procedure.

48. Misoprostol is not only used in medication abortions; it is also routinely prescribed as part of the management of incomplete abortions, miscarriage management, postpartum hemorrhage, difficult IUD insertion and removal, and gastric ulcer treatment. The drug is considered so safe that it is on the World Health Organization's Model List of Essential Medicines. Prescription of misoprostol in connection with management of incomplete abortion, management of postpartum hemorrhage, and miscarriage management involves a higher risk of bleeding than does its prescription for medication abortion.

49. Failing to take misoprostol after taking mifepristone may put patients at an increased risk of significant complications. A study of the effects of interrupting the medication abortion regimen was recently halted at an early stage because some of the enrolled subjects hemorrhaged. The authors concluded: "Patients in early pregnancy who use only mifepristone may be at high risk of significant hemorrhage."

C. Federal Regulation of Mifepristone

50. Despite decades of research demonstrating the safety and efficacy of mifepristone, since its approval in 2000, the FDA has subjected mifepristone to a federal Risk Evaluation and Mitigation Strategy (the "REMS"). While the REMS has been modified over the years, it significantly restricts how mifepristone can be distributed. It requires that mifepristone be prescribed under the supervision of a health care provider who has registered with the drug manufacturer and attested to their ability to safely prescribe mifepristone.

51. Prior to the COVID-19 pandemic, the REMS required that mifepristone be dispensed to patients in clinics, medical offices, or hospitals. However, the FDA has recently eliminated the in-person dispensing requirement altogether because it unnecessarily restricts access to care.

52. Notably, out of more than 20,000 FDA-approved drugs, mifepristone was, until now, the only medication that the FDA forced patients to pick up in a clinical setting even though they are free to self-administer it at the time and location of their choosing. However, the FDA retained the other REMS requirements; this means that mifepristone will still be treated differently than other medications of the same safety profile and will not be readily available in pharmacies. Rather, providers and mail-order pharmacies will still be required to register with the FDA to provide mifepristone through the mail.

53. The FDA's decision to remove the in-person dispensing requirement for mifepristone did not affect the dispensing of misoprostol because misoprostol was *never* subject to the REMS, and (where allowed by state law) could already be obtained by mail-order or at retail pharmacies.

54. Even the original FDA-approved label for Mifeprex in 2000 did not regulate the dispensation of misoprostol. This label, which was written based on clinical trials conducted by the manufacturer in the 1980s, described patients returning to the health center to have the misoprostol administered, even though this was never the standard of care. Although the label described this regimen, it did not impose a requirement on misoprostol. The standard of care in 2000 was, and still is today, to allow patients to self-administer misoprostol at a location of their choosing, thereby removing the need for patients to return to the clinic.

55. In 2016, the FDA updated the Mifeprex label to reflect this standard and removed any reference to patients returning to the clinic for the misoprostol. The FDA explained its decision to update the label, stating: "There is no medical rationale against permitting the woman to be given the misoprostol on the day of the initial clinic/office visit and self-administer it at a convenient time in the next 24–48 hours at home. This would avoid another visit and the time,

transportation, loss of work, inconvenience, etc. that such a visit would involve. Furthermore, given the fact that 22–38% of women abort within 3 hours and 50–60% within 5 hours of buccal misoprostol, it is preferable for the woman to be in a convenient, safe place (home or at a support person's location) for the expected uterine cramping and vaginal bleeding to occur." (citations omitted). The FDA label for mifepristone now specifically provides that as part of the medication abortion regimen, "misoprostol does not need to be restricted to in-clinic administration."

56. ACOG has also stated that patients can safely take both the mifepristone and the misoprostol at home, which means there is no need for patients to make a separate visit to the clinic to be dispensed the misoprostol.

D. Governor Noem's Executive Order

57. In anticipation of the FDA's decision to modify the REMS to eliminate in-person dispensing for mifepristone, Governor Noem issued Executive Order 2021-12 on September 7, 2021 ("EO 2021-12"), attached hereto as **Exhibit B**.

58. EO 2021-12 states that the REMS change would "put South Dakotan women at risk of serious health complications from abortion-inducing drugs." EO 2021-12 further directs the Department to "begin emergency rulemaking to be implemented pursuant to the [then] current FDA REMS, which has had a 20-year track record of helping to protect women's health with sound medical practice." In a public statement, Noem stated: "They are working right now to make it easier to end the life of an unborn child via telemedicine abortion. . . That is not going to happen in South Dakota."[1]

[1] Stephen Groves, *South Dakota governor orders restrictions on abortion meds*, ABC News (Sep. 7, 2021), https://abcnews.go.com/Health/wireStory/south-dakota-governor-orders-restrictions-abortion-meds-79883385.

59. As is relevant to this action, EO 2021-12 directs the Department to promulgate rules that "ensure that medicines, drugs, or any other substances prescribed or dispensed with the intent of terminating the pregnancy of a woman shall only be dispensed by a physician licensed in South Dakota to a patient after examining her in-person to rule out contraindications, including but not limited to, ectopic pregnancy[.]" EO 2021-12 also directs the Department to ensure that "no manufacturer, supplier, physician, or any other person may provide any abortion-inducing drugs directly to women in South Dakota via courier, delivery, telemedicine, or mail service."

60. As discussed above, current South Dakota laws already require two in-person visits with the physician who is providing the abortion, essentially ruling out the possibility of using telemedicine for abortion in South Dakota. S.D. Codified Laws §§ 34-23A-10.1(1), (3); *id.* § 34-23A-56.

61. Nothing in EO 2021-12 directs or even purports to authorize the Department to impose a mandatory delay on the dispensation of misoprostol.

E. The Department's Promulgation of the Rule

62. On October 21, 2021, Plaintiffs were first alerted to a proposed emergency rule drafted by the Department that was a precursor to the Rule at issue, attached hereto as **Exhibit C**. As relevant here, the draft emergency rule required medication abortion patients to return for an additional visit to pick up the misoprostol 36–48 hours after the first dose of mifepristone. The Department requested comments on the emergency rule by October 25, 2021, with the rule likely to go into effect shortly thereafter.

63. Plaintiffs and others, including the South Dakota State Medical Association, submitted comments opposing the Rule. The South Dakota State Medical Association's comments are attached as **Exhibit D**. Most relevant here, the South Dakota State Medical Association

explained that the Rule's dispensing restrictions on misoprostol were "clinically unnecessary" and do "nothing more than create another barrier for the patient that may result in an increased risk of hemorrhage and bad outcome." About two weeks later, Plaintiffs learned that the rule would no longer be proposed as an emergency rule, and instead go through the normal rulemaking process.

64. On November 8, 2021, the Department introduced a proposed rule that was similar to the emergency rule, though it reduced the required period between the second and third visit to 24-72 hours and specified that its application is limited to medication abortion.

65. In its notice to the public of the hearing to adopt the Rule, the Department stated that the Rule was "required per the Governor's Executive Order 2021-12,"[2] and that the Rule is necessary "to protect the health and safety of women that is [sic] at-risk due to the expected FDA lifting of additional safety protocols regarding the use of mifepristone and misoprostol."[3]

66. As authority for its promulgation, the Rule cites S.D. Codified Laws §§ 34-23A-51(7), (10), and (11) for the Department's general rulemaking authority and S.D. Codified Laws §§ 34-23A-10.1(3), 34-23A-19, and 34-23A-56 for its specific rulemaking authority. S.D. Codified Laws § 34-23A-10.1(3), titled "Voluntary and informed consent required–Medical emergency exception–Information provided," relates solely to the information regarding medication abortion that must be provided as part of South Dakota's mandatory informed consent disclosure. S.D. Codified Laws § 34-23A-19, titled "Performance of abortion–Required reports–Rules," deals with statistical information that must be reported to the State. And S.D. Codified Laws § 34-23A-56, titled "Scheduling of abortion–Prior requirements," is the law that imposes a 72-hour waiting period between the initial clinic visit and when an abortion can be performed. In no way does the

[2] S.D. Dep't of Health, *Form 14, Small Business Impact Statement Form*, https://rules.sd.gov/Uploads/684_BusinessImpactStatement.pdf.

[3] S.D. Dep't of Health, *Form 6, Notice of Public Hearing to Adopt Rules § 44:67:04:13*, https://rules.sd.gov/Uploads/684_ PublicNotice.pdf.

Department's new restriction requiring a third, in-person visit for the dispensing of misoprostol implement any of these statutes.

67. Nor does the Governor's Executive Order provide the Department with authority to promulgate the Rule. State law does not provide the Governor the right to create new law, nor to order the Department to create new, specific laws to implement an executive order. Rather, the Governor shall be responsible for the faithful *execution* of the law.

68. The Department held a public hearing on the Rule on December 8, 2021, at which Dr. Traxler testified in opposition to the Rule. Additional written comments were submitted in opposition, including from Dr. Traxler and the South Dakota Section of ACOG, composed entirely of practicing physicians in South Dakota. The South Dakota Section of ACOG recommended the removal of barriers to obtaining misoprostol—including the requirement that patients would need to return to the health center to obtain the medication at a separate visit—to ensure that patients complete the two-drug regimen.[4]

69. The Department submitted the final proposed rule to the Legislative Research Council and the Legislature's Interim Rules Review Committee (the "Committee") on December 20, 2021. The Committee, composed of six members of the Legislature, is responsible for declaring that the rulemaking process is complete before an agency can finalize the rule.

70. The Department presented the Rule to the Committee on December 27, 2021. The Department stated that "the purpose of the rule" is to "requir[e] in-person dispensing of both of

[4] Comments submitted by email and first-class mail to the Honorable Kim Malsam-Rysdon on behalf of South Dakota Section of ACOG by Mark Ballard, M.D., F.A.C.O.G.; Amy Kelley, M.D., F.A.C.O.G.; Erica Schipper, M.D., F.A.C.O.G.; and Elizabeth Hultgren, M.D. Materials attached to minutes of December 8, 2021 public hearing, p. 24, available at https://rules.sd.gov/Uploads/684_AgencyHearingMin.pdf.

these drugs," and that "[t]he drugs must be prescribed, dispensed in a licensed abortion facility."[5] Plaintiffs again offered testimony in opposition to the Rule. Additional written comments were submitted to the Committee in opposition, including from the American Civil Liberties Union of South Dakota.

71. A motion to deem the administrative process complete resulted in a 3-3 tie at the December 27th meeting. After confusion as to whether the Department was authorized to go forward with the Rule, one Committee member, Senator Timothy R. Johns, who had voted that the process was not complete, stated that sufficient medical evidence had not been presented to properly consider the Rule. The Committee agreed to reconvene on January 6, 2022.

72. On January 6, 2022, the Committee met again. A representative from the Department testified, again, that the Department promulgated the Rule "to implement Governor Noem's Executive Order 2021-12," that "[t]he purpose of this rule is to protect the health and safety of women in South Dakota by requiring in-person dispensing of both [mifepristone and misoprostol]," and that the Rule would "protect the women of South Dakota by maintaining the requirement that women receive these drugs in-person by a licensed physician for the purpose of a medical abortion."[6] Additional testimony was provided by members of the public, including both proponents and opponents (including Dr. Traxler) of the Rule. Although Senator Johns continued to express concern that the Department was usurping the role of the Legislature by issuing the Rule, the Committee voted 4-2 to deem the administrative process complete.

73. At every step of this process, Plaintiffs made clear to the Department and the Committee that South Dakota law already bans abortion by telemedicine and that both

[5] *Four Hundred Fourth Meeting, Interim Rules Rev. Comm.*, (S.D. Dec. 27, 2021) (statement of Ally Turnow, Staff Att'y, S.D. Dep't of Health).

[6] *Four Hundred Fifth Meeting, Interim Rules Rev. Comm.*, (S.D. Jan. 6, 2022) (statement of Ally Turnow, Staff Att'y, S.D. Dep't of Health).

mifepristone and misoprostol *are already* dispensed by a physician at a health center. This is just not done at a *separate* visit for the misoprostol, which Plaintiffs explained was not only medically unnecessary but actually contrary to the standard of care and patients' best interests.

74. On January 11, 2022, Plaintiffs first learned that the Department had filed the Rule on January 7, 2022. The Rule was uploaded onto the Secretary of State's website on January 13, 2022.

75. The final rule, Rule 44:67:04:13, titled "Mifepristone and Misoprostol Administration for Medical Abortion," states "[b]etween 24-72 hours after taking Mifepristone, if the pregnant woman decides to continue with the medical abortion, the pregnant woman must return to the licensed abortion facility to receive the proper amount of Misoprostol. . . . Neither Mifepristone nor Misoprostol may be dispensed for the purpose of inducing a medical abortion in any manner contrary to this section."

76. Violating the Rule is a basis for revoking Plaintiffs' license. S.D. Admin. R. 44:67:01:05(1).

77. As per South Dakota administrative procedure, the Rule will become effective on January 27, 2022.

78. On information and belief, South Dakota does not impose a mandatory delay on the dispensation of any other drug, except, of course, mifepristone.

79. On information and belief, no other state currently imposes a mandatory delay and separate, in-person dispensing requirement for the use of misoprostol, for any medical indication.

F. The Rule Will Impose Significant Burdens on Abortion Access and Irreparably Harm Plaintiffs and their Patients.

80. The Rule will have a profound and devastating impact on the provision of medication abortion in South Dakota: because Planned Parenthood cannot comply with the Rule,

it will have to stop providing medication abortion at the Sioux Falls health center. The result will be that patients in South Dakota seeking a medication abortion will be denied their method of choice and, in some cases, the method that is medically indicated. The elimination of medication abortion will also lead to a significant reduction in abortion appointments. Even if compliance were possible, the Rule would impose significant barriers on patients' ability to access medication abortions.

81. Plaintiffs cannot comply with the Rule for several reasons. First, the Rule unnecessarily imposes significant harms on patients. It deviates from the standard of care by potentially interrupting the mifepristone-misoprostol regimen and requiring the medications to be dispensed at two separate visits, 24 to 72 hours apart. This goes against guidance from both ACOG and the FDA, as well as the accepted best medical practices of the last two decades, which make clear that misoprostol is safe and effective for patients to self-administer at their homes. Such a requirement only serves to make it more difficult for patients to access medication abortion.

82. Second, the Rule would severely burden medication abortion patients, creating insurmountable obstacles for some. Requiring a third trip to the health center means that a patient's ability to obtain the drugs necessary to complete the medication abortion regimen, beginning with the mandatory informed consent visit, would take a *minimum* of 96 hours from start to finish.

83. Requiring a third trip to the health center in one week would require time and resources that many of PPMNS's patients do not have. Some patients would be forced to choose between making an additional round trip (bringing their total mileage to over 450 miles for about 24% of PPMNS's medication abortion patients, and over 900 miles total for 11%) or finding accommodations in Sioux Falls. Both options require not only additional financial resources, but also additional time away from personal responsibilities, including child care, work, and school.

84. Other patients would opt to unnecessarily delay care, which will in turn increase medical risks. Additionally, while the medication abortion failure rate is low, it increases with gestational age.

85. The Rule would be particularly burdensome for low-income patients. If the Rule takes effect, some patients will not have the financial resources to pay for a third trip to the health center, given the associated travel costs, lost wages, and increased child care costs.

86. In addition, many survivors of abuse and sexual assault find it very difficult to explain absences from school, work, or home, as their abusers keep close tabs on their whereabouts. Having to make a third trip to the Sioux Falls health center in a short period of time would be extremely burdensome to these patients.

87. The burden of additional travel is compounded during the pandemic. Many patients use public transportation, ride-sharing, or a borrowed car to reach the health center, all of which expose the patient to risks of infection. If the patient is driving and stopping for gas or a restroom on the way (which will necessarily occur given the distances many patients travel to reach Sioux Falls), this will increase the likelihood of being exposed to COVID-19.

88. Research shows that barriers to care delay, and in some cases altogether prevent, people from accessing that care. Specifically, when states require residents to make multiple trips to an abortion provider to obtain care, many people are delayed in or prevented from making those additional trips.

89. As discussed above, adding trips required to complete a medication abortion may pose an unsurmountable obstacle for some patients. Travel plans can also be upended by unforeseen circumstances, such as severe weather (particularly in the winter), road closures, emergency orders, obstacles in obtaining child care or time off work, or illness, including COVID-

19. For patients who are unable to come back to the health center and therefore take mifepristone without taking misoprostol, this Rule may unnecessarily increase their chance of hemorrhage.

90. There is also the possibility that some patients who are delayed in returning to the health center may not be able to make the third trip to get the misoprostol during the medically-appropriate 24 to 48 hour window. Because the health center is only able to provide abortion services two to three times per month, these patients may have to wait 1–2 weeks to see a physician. For some, this delay may mean that they are no longer within the gestational-age limit for medication abortion and would need a procedural abortion. Because the next available physician may be different from the physician the patient originally saw, these patients may be required to restart the informed consent process.

91. No other procedure for which misoprostol is indicated, including management of incomplete abortions, miscarriage management, management of postpartum hemorrhage, difficult IUD insertion and removal, and the treatment of stomach ulcers, requires a third, in-person visit before dispensation. However, prescription of misoprostol in connection with management of incomplete abortion, management of postpartum hemorrhage, and miscarriage management involves a higher risk of bleeding than does its prescription for medication abortion.

92. PPMNS will not subject patients to the increased health risks and other harms from providing care according to the Rule, with absolutely no medical benefits.

93. Even if PPMNS did not have ethical and safety concerns about the Rule, it logistically could not comply. The few physicians who provide abortion services at PPMNS in South Dakota would not be able to return to Sioux Falls to meet patients for a third appointment within the strict time frames mandated by existing South Dakota law (at least 72 hours between first and second visit), by the Rule (at least 24 hours between second and third visit), and by the

medication abortion regimen itself (at least 24 *but no more than* 48 hours between ingesting mifepristone and ingesting misoprostol). Because of other professional responsibilities, physicians are also unable to stay overnight in South Dakota for the required minimum 24-hour waiting period between the second and third visits.

94. As a result, Plaintiffs will be forced to stop providing medication abortions at the Sioux Falls health center. This means, if the Rule goes into effect, every patient seeking a medication abortion will be denied the method of their choice, and in some cases, the method that is medically indicated.

95. The elimination of medication abortion at the Sioux Falls health center will also have spill-over effects on PPMNS's capacity to provide abortion services. Because procedural abortion is more time-intensive than medication abortion, PPMNS cannot offer the same number of abortion appointments in one day if it can only provide procedural abortions.

96. Using a conservative estimate, PPMNS anticipates that it will have to reduce appointments by 30%. Given that PPMNS currently schedules patients approximately four weeks out, and (due to other legal restrictions) can only provide procedural abortions up to 13.6 weeks LMP, a 30% reduction in available appointments will have a devastating impact on access to abortion in South Dakota. This will cause delays for all patients, and some will be prevented from accessing care altogether.

97. Even though abortion is an extremely safe procedure, its risks increase with gestational age. Moreover, there are many patients for whom waiting for their abortion would not be medically advisable, including those who are suffering from pregnancy complications such as hyperemesis gravidarum, gestational diabetes, or gestational hypertension. Prolonged pregnancy can also exacerbate pre-existing conditions.

98. Those who are forced to carry unwanted pregnancies to term could face ensuing risks to their physical, mental, and emotional health, as well as to the health of their family. Pregnancy, childbirth, and an additional child may exacerbate an already difficult situation for patients who have experienced sexual assault or domestic violence. And research has found that women denied an abortion were four times more likely than women who received an abortion to experience economic hardship and insecurity lasting for years, with serious consequences for those women and their families.

99. On information and belief, this Rule was passed with the purpose of making it unduly burdensome for patients to have a medication abortion.

100. This Rule is in clear violation of federal constitutional law.

101. If the Rule is allowed to take effect, Plaintiffs and their patients will be subject to irreparable harm.

102. Enforcement of the Rule will cause irreparable harm for which no adequate remedy at law exists by—among other violations of Plaintiffs' and their patients' constitutionally protected rights as outlined in the claims for relief—depriving Plaintiffs' patients of their constitutional right to have an abortion and subjecting Plaintiffs to significant licensing penalties, including revocation of Planned Parenthood's license to operate a health care facility in Sioux Falls and its physicians' licenses to practice medicine.

FIRST CLAIM FOR RELIEF
(Substantive Due Process—Undue Burden)

103. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 102.

104. The Rule imposes an undue burden because it is not reasonably related to any legitimate state interest and also has the purpose and effect of placing a substantial obstacle on

women's right to choose abortion, in violation of their right to liberty and privacy guaranteed by the Fourteenth Amendment to the United States Constitution.

SECOND CLAIM FOR RELIEF
(Equal Protection)

105. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1 through 102.

106. The Rule imposes arbitrary classifications on physicians who prescribe (and patients who are prescribed) misoprostol for use in medication abortion without sufficient government interest in violation of the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution and must be enjoined.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs ask this Court:

A. To enter a judgment declaring that the Rule's mandatory delay and separate visit requirements for the dispensing of misoprostol violate the United States Constitution on its face and/or as applied to Plaintiffs and their patients.

B. To issue such interim injunctive relief as may be necessary to maintain the status quo pending award of a final judgment, and a permanent injunction restraining Defendants, their employees, agents, and successors in office from enforcing the Rule on its face and/or as applied to Plaintiffs and their patients.

C. To award Plaintiffs their attorneys' fees and costs pursuant to 42 U.S.C. § 1988.

D. To grant such other and further relief as the Court deems just and proper.

Dated: January 19, 2022

/s/ Stephanie Amiotte
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*Application for admission *pro hac vice* forthcoming

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