FORM 10

SOUTH DAKOTA DEPARTMENT OF HEALTH
MINUTES OF PUBLIC HEARING

The Department of Health (DOH) convened a public hearing at 11:00 a.m. CST on Thursday, December 8, 2021, at the South Dakota Department of Health, Hayes Building Conference Room, 600 E. Capitol Avenue, Pierre, SD. Attendees also had the option to appear telephonically. The purpose of the hearing was to conduct a public hearing to accept comments and discussion regarding the adoption of ARSD 44:67:04:13.

Hearing Officer: Ali Tornow, Staff Attorney, South Dakota Department of Health.

Persons in Attendance: Lynne Valenti, Deputy Secretary, Department of Health; Kt Gross; Sarah Traxler, Planned Parenthood; Kristen Hayward, Planned Parenthood; Tammy Hatting, SDAHO; Stephanie Rissler, SDAHO; Bob Mercer, Keloland.

Exhibits: Two exhibits were offered and received into evidence.
(1) Exhibit A: The South Dakota State Medical Association submitted written comments via letter, received on November 19, 2021.
(2) Exhibit B: An anonymous individual of Chicago, IL, submitted written comments on December 6, 2021.

Oral Testimony:

(1) Sarah Traxler testified in opposition of the draft rule on behalf of Planned Parenthood. She stated that the proposed rule is unconstitutional and unnecessary, and that the department lacks authority to implement the rule. Her oral testimony had 3 points. 1) The rule is not warranted because the FDA has not taken action yet to rescind the official Risk Evaluation and Mitigation Strategy ("REMS"), 2) the rule does not implement federal REMS and is more restrictive, and 3) existing state law makes the rule unnecessary.

No other proponent or opponent testimony was provided.

Adjournment: 11:18 a.m.

Respectfully submitted,

Ali Tornow, Staff Attorney
Department of Health

Dated: December 20, 2021

#1

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The Honorable Kim Malsam-Rysdon
Secretary, South Dakota Department of Health
600 E Capital Avenue
Pierre, SD 57501

RE: Formal Comments of South Dakota State Medical Association on Proposed Mifepristone and Misoprostol Administration for Medical Abortion Rule (44:67:04:13)

Dear Sec. Malsam-Rydson:

I am writing in my capacity as general counsel for the South Dakota State Medical Association ("SDSMA"). Please consider the following as SDSMA's formal comments under SDCL 1-26-4 concerning the proposed rule relating to Mifepristone and Misoprostol administration for medical abortions, which rule is scheduled for a public hearing on December 8, 2021.

As noted in our prior informal comments previously provided to the Department, our members are concerned about the scope of the proposed rule. While the formal proposal does much to address our members' comments, we continue to have concerns about the following sentence in the formal proposal: "Neither medication may be dispensed in any manner contrary to this section."

The context of that statement implies it is intended to refer only to the use of the two medications for medical abortions. On its face, however, the sentence appears to prohibit any use of Mifepristone and Misoprostol other than in conformity with the disclosure, location, and time limitations set out in the proposed rule.

Our Supreme Court applies the "plain language" standard when interpreting administrative rules. See, e.g., *Citibank, N.A. v. S.D. Dep't of Revenue*, 2015 SD 67, ¶ 12, 16, 868 NW2d 381, 388-389 (SD 2015). The worry is that a court may apply the "plain language" rule to the worrisome

sentence in isolation, resulting in the unintended consequence of limiting the use of the medications for purposes other than medically-induced abortions.

While Mifepristone may be used to initiate a medication abortion, it is more commonly used for medical management of miscarriage. Approximately 10 percent of clinically recognized pregnancies and an estimated 20-25 percent of all pregnancies result in miscarriage. And Mifepristone is often used in cervical preparation for surgical management of miscarriage up to 20 weeks.

Safety data demonstrates that requiring in-person dispensation for Mifepristone and Misoprostol use in connection with a miscarriage is not necessary and leads to unnecessary stress and hardship for already grieving parents. The in-person dispensation requirement is not only unnecessary, but also burdensome on weekends and holidays, when miscarriages still happen, and most acute care settings do not manage Mifepristone due to the onerous regulations already in place. This concern also comes into play when a patient is scheduled on a Monday for surgical management of second trimester loss due to a miscarriage, and they cannot receive Mifepristone the day prior (Sunday) as medically indicated.

Similar to Mifepristone, Misoprostol is used for indications other than abortion and miscarriage management. Misoprostol is used to prevent stomach ulcers in patients who are at risk or have a family history of ulcers and are taking NSAIDS (e.g. aspirin, ibuprofen, naproxen). Misoprostol protects the stomach lining by lowering the amount of acid that comes in contact with it. Additionally, it is used in cervical preparation for diagnosis and treatment of endometrial and cervical cancer via endometrial biopsy, endocervical curettage, and gynecologic hysteroscopy or D&C (D&C in a non-pregnant patient for abnormal bleeding and/or cancer risk). It is also used for cervical preparation for IUD placement and removal. There is no clinical reason for in-person dispensation of Misoprostol to these patients.

SDSMA's concerns would be addressed by changing the sentence at issue to read as follows: "Neither medication may be dispensed for the purpose of inducing a medical abortion in any manner contrary to this section."

SDSMA thanks you and your staff for your consideration of our comments. SDSMA reserves the right to present oral testimony at the hearing scheduled for December 8, 2021, and to provide additional written comments after the public hearing.

Sincerely,

MAY, ADAM, GERDES & THOMPSON LLP

TIMOTHY M. ENGEL

TME:drm

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Planned Parenthood
Care. No matter what.

Planned Parenthood North Central States

The State of South Dakota Department of Health
Kim Malsam-Rysdon, Secretary of Health
600 East Capitol Avenue
Pierre, SD 57501-2536

December 6, 2021

RE: Proposed Rule: § 44:67:04:13

Dear Secretary Malsam-Rysdon:

As experts in reproductive health care, and as the primary provider of abortions in the State of South Dakota for the last 27 years, Planned Parenthood Minnesota, North Dakota, South Dakota ("Planned Parenthood") aims to ensure that South Dakotans can receive the health care they need. In this role, we are writing to comment on the Department of Health's Proposed Rule § 44:67:04:13 (together, "the Department" and the "Proposed Rule" or "Rule"). The comment below builds on our previous comments and addresses both the changes made to the proposed emergency rule as well as our continued concerns with many problems that remain in this Proposed Rule.

The Department asserts that this Proposed Rule is intended to implement South Dakota Codified Laws sections 34-23A-10.1(3); 34-23A-19; and 34-23A-56. On October 28, 2021, we submitted a similar comment to the department's "Emergency Proposed Rule Re: Telemedicine and Chemical Abortion per EO 2021-12." The agency also asserts that the Rule is now necessary "to protect the health and safety of women that is at-risk due to the expected FDA lifting of additional safety protocols regarding the use of mifepristone and misoprostol."[1] The Department further claims that the Proposed Rule is "required per the Governor's Executive Order 2021-12."[2]

However, the Proposed Rule is unnecessary and counterproductive to the agency's asserted goal of protecting the health and safety of South Dakotans, and far exceeds the scope of the Executive Order and other existing statutes it purports to implement. Specifically, the Rule sets forth requirements that deviate drastically from the federal Risk Evaluation and Mitigation Strategy (the "REMS") discussed in EO 2021-12, and these new requirements are premature, given that the U.S. Food and Drug Administration ("FDA") has not made any changes to the

[1] S.D. Dept. of Health, *Form 6, Notice of Public Hearing to Adopt Rules § 44:67:04:13*, https://rules.sd.gov/Uploads/684_PublicNotice.pdf.
[2] S.D. Dept. of Health, *Form 14, Small Business Impact Statement Form*, https://rules.sd.gov/Uploads/684_BusinessImpactStatement.pdf.

REMS. Moreover, existing state laws already heavily regulate the provision of medication abortion and do not allow for medication abortion to be delivered via telemedicine without an in-person physician interaction. The Proposed Rule is medically unnecessary in light of the well-established safety of medication abortion, and it is out of line with standard medical practice. Finally, the Rule suffers from numerous legal flaws, including that the Department lacks the authority to promulgate the Rule; the Rule is arbitrary and capricious; the Rule constitutes an unconstitutional undue burden on access to abortion; and the Rule violates patients' and health care providers' rights to equal protection under the Fourteenth Amendment.

Medication Abortion is a Safe and Common Method of Abortion.

Medication abortion is a standard method of terminating a pregnancy, and is preferred by some patients because it does not require anesthesia or sedation, is less invasive, more private, and allows patients to safely control their own bodies and health care. The most common method of medication abortion is a regimen of two prescription drugs: mifepristone and misoprostol. Together, these two pills cause the patient to expel the pregnancy in a manner similar to a miscarriage. Mifepristone, which is also commonly known by its commercial brand name, Mifeprex, was approved by the FDA in 2000 as an effective method of abortion in early pregnancy when used in conjunction with misoprostol. The current Mifeprex label recommends that, between 24 and 48 hours after taking the mifepristone dose, the patient takes misoprostol at home or at another safe and appropriate location of their choosing. Misoprostol is typically taken buccally, but, in some circumstances, a health care provider may see fit to administer it vaginally.

Medication abortion is incredibly safe and effective. According to the FDA, in the United States there is a 97.4% success rate for medication abortion administered through the two-drug regimen in accordance with the 2016 Mifeprex label.[3] Even in the 2.6% of patients that required intervention following a medication abortion, that intervention was typically non-urgent.[4] The FDA has also acknowledged that complications resulting from the use of medication abortion are "extremely rare."[5] Multiple studies have confirmed that far less than one percent of patients experience serious complications from medication abortion—a number that is significantly lower than that experienced by patients that go through childbirth.[6]

[3] FDA, Ctr. for Drug Evaluation & Rsrch., *MIFEPREX (mifepristone) Tablets Label* (2016), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf
[4] FDA, *MIFEPREX (mifepristone) Tablets Label* at 13 tbl. 3.
[5] FDA, Ctr. for Drug Evaluation & Rsrch., *Clinical Review of NDA020687/S020-Mifeprex* (2016) at 12, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.
[6] *See* Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics & Gynecology 778, 780 (2017) (finding that only 0.26% of patients in the study experienced clinical significant adverse events, defining significant adverse events as those that required treatment given in an emergency department, hospital admission, surgery, blood transfusion or death, and finding zero incidents of reported deaths or need for surgery); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125

Since mifepristone was first approved by the FDA in 2000, more than four million patients in the United States have relied on the mifepristone–misoprostol regimen to end their pregnancies. In 2020, approximately 40% of abortions in South Dakota were medication abortions.[7]

The Proposed Rule

The Proposed Rule sets out a series of requirements for the provision of medication abortion. To summarize, the Proposed Rule:

- Allows mifepristone to be "prescribed and dispensed" by only a "licensed physician in a licensed abortion facility," and requires a patient to "only take Mifepristone at an abortion facility," following patients' receipt of statutorily-required "informed consent."
- Requires that patients receive information about so-called abortion "revers[al]" as part of statutorily-required informed consent.
- Imposes a 24- to 72-hour waiting period on patients before allowing them to receive the appropriate misoprostol dosage[8].
- Further restricts the dispensation of misoprostol by directing that the patient "shall return to the abortion facility to receive the proper amount of Misoprostol dispensed by a licensed physician in the same manner as Mifepristone."
- Effectively requires patients to make *three* visits to a health center to have a medication abortion, the third of which would be simply to get the misoprostol, given that South Dakota law already requires every abortion patient to make two visits to the health center under S.D. Codified Laws § 34-23A-56.
- Requires clinic staff to schedule a follow-up appointment 14 days after the patient completes the regimen (in addition to the three visits noted above).

Although Planned Parenthood maintains that the Proposed Rule as a whole is medically unnecessary and inappropriately interferes with the practice of medicine, Planned Parenthood's comments focus mainly on the Rule's mandate that patients must return to the health center for the dispensing of misoprostol 24–72 hours after receiving the mifepristone at the health center, thereby necessitating an additional visit to the health center. This

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Obstetrics & Gynecology 175, 178 tbl. 3 (2015) (finding only a 0.31% risk of major complications and defining major complications as those unexpected adverse events that required hospital admission, surgery, or blood transfusion); Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 Obstetrics & Gynecology 166, 169 tbl. 2 (2013) (finding that only 0.06% of patients experienced complications resulting in hospital admission).

[7] S.D. Dep't of Health Off. of Health Stats., *Annual Report of Induced Abortions* 9 fig.10 (2020), available at https://doh.sd.gov/documents/statistics/2020_SD_InducedAbortion_Report.pdf.

[8] The initial proposed emergency rule required misoprostol to be dispensed and administered between 36 and 72 hours after mifepristone. While the updated Proposed Rule widens the timeline to 24–72 hours, which hews closer to evidence-based regimens, the Rule still deviates from the standard of care by directing that the patient "shall return to the abortion facility to receive the proper amount of Misoprostol dispensed by a licensed physician in the same manner as Mifepristone," as further discussed in this comment.

requirement drastically departs from the standard of care, is found nowhere in the current federal REMS requirement that the Executive Order directs the Department to implement at the state level, and is contrary to the FDA-reviewed regimen that appears on the mifepristone label. Planned Parenthood's comments additionally address the Rule's attempt to modify the language required to be provided to abortion patients under the existing informed consent law, SDCL § 34-23A-10.1.

A Proposed Rule Is Not Warranted as the FDA Has Taken No Definitive Action on the Federal REMS.

The Governor's Executive Order states, "[p]ermitting the dispensing of mifepristone through the mail or through a mail-order pharmacy is very likely a preview of how the FDA is expected to change the REMS on November 1, 2021" and the "South Dakota Department of Health must act quickly to adopt rules to protect women of South Dakota[.]"[9]

If the Proposed Rule is intended to fill a gap in safety measures that the Executive and the Department believe may be left by the FDA's impending action, it would be prudent to wait and see what action, if any, the FDA takes before rushing through the Proposed Rule.[10] As explained further below, there are numerous components to the REMS requirements and it is not clear which, if any, will be modified by the FDA. Thus, the Department cannot claim this rule is necessary when the FDA has not announced any decision on the federal REMS. Finally, even assuming the FDA does eventually announce its intention to lift or alter the federal REMS requirements, these changes cannot occur immediately because there is an administrative process that must first be undertaken to allow for a modification of this nature.[11] Simply put, the Department does not know if or when any federal changes will be announced or implemented, and there is no relevant and competent evidence justifying or supporting the Department's decision to promulgate this Proposed Rule. Acting now, in reaction to mere suspicion, is premature, arbitrary and capricious, and will create confusion for patients and providers.

The Proposed Rule Does Not Implement the Federal REMS at the State Level.

The Department asserts that the Proposed Rule is intended to maintain dispensing requirements for mifepristone in South Dakota in the event that the federal government sees fit to remove the federal REMS restrictions currently applied to this drug. However, **intentionally or inadvertently, the Proposed Rule goes far beyond the restrictions imposed by the federal REMS by establishing requirements for the provision of both mifepristone and misoprostol—whereas the REMS addresses *only* mifepristone. Therefore, in actuality,**

[9] Exec. Order No. 2021-12 (S.D. 2021).
[10] The earliest the FDA is expected to provide any update on the status of its review of the REMS requirement is December 16, 2021. Joint Status Report, *Chelius v. Becerra*, No. 1:17-cv-00493-JAO-RT (D. Haw. Nov 3, 2021).
[11] FDA, *Risk Evaluation and Mitigation Strategies: Modifications and Revisions Guidance for Industry* (June 2020), https://www.fda.gov/media/128651/download

the Proposed Rule does not match the asserted goals and exceeds the scope of the Executive Order.

As background, the current FDA-approved label for Mifeprex includes a recommended regimen in which the patient first takes mifepristone (Mifeprex) orally, and 24 to 48 hours later takes misoprostol at home or in another appropriate location.[12] Despite the safety and efficacy of mifepristone, the FDA has subjected mifepristone to a REMS requirement, known as an "Elements to Assure Safe Use" ("ETASU"), since its approval in the United States in 2000. The REMS with ETASU significantly restricts how mifepristone can be distributed. It requires that mifepristone be dispensed to patients in clinics, medical offices, or hospitals under the supervision of a health care provider who has registered with the drug manufacturer, attested to their ability to safely prescribe mifepristone, and then arranged to order and stock mifepristone in their health care facility according to stringent specifications. This means that unlike almost any other medication, mifepristone cannot be distributed to or dispensed at pharmacies under the REMS.

Planned Parenthood maintains that the application of the REMS to mifepristone is medically unnecessary.[13] Regardless, and importantly, **the REMS does not currently limit, and has never limited in any way, the prescribing or dispensing of misoprostol, the second medication in the medication abortion regimen. The REMS applies only to mifepristone.**

Thus, while the Proposed Rule purports to codify in state law the REMS "safety standards" that the Executive Order is concerned with, the Proposed Rule actually does not impose a state law version of the REMS requirements. Instead, the Proposed Rule goes well beyond the REMS by restricting the dispensing of *misoprostol*. The Proposed Rule exceeds the REMS by dictating that *misoprostol* can only be dispensed by a physician between 24 and 72 hours after the patient takes the mifepristone, which is wholly outside the scope of the current REMS and deviates from the accepted standard of care. **No state currently requires a patient to return to the health center for a separate visit solely for the purpose of getting the misoprostol. Nor does any state set a specific time frame during which misoprostol can be dispensed by a physician, further evidencing that the Proposed Rule is medically unjustified and wholly arbitrary.**

Furthermore, it is notable that while the Executive Order directs the Department to implement rules in keeping with the FDA's "medical protocols," the Proposed Rule is not actually consistent with the FDA-approved mifepristone label. Although the FDA label is not viewed as

[12] In some instances, it may be indicated for some patients that misoprostol should be administered vaginally on the same day as the patient takes the mifepristone dosage.
[13] Planned Parenthood Fed'n of Am., *Federal Court Blocks Medically Unnecessary Barriers to Abortion During COVID-19* (July 13, 2020), https://www.plannedparenthood.org/about-us/newsroom/press-releases/federal-court-blocks-medically-unnecessary-barriers-to-abortion-during-covid-19

binding, or even as "best practice" for all patients,[14] the FDA-approved mifepristone label makes clear that as part of the medication abortion regimen, "misoprostol does not need to be restricted to in-clinic administration."[15]

By instituting a medically-unjustified, in-person dispensing requirement for misoprostol, thereby requiring patients to make *yet another trip* to a clinic, the Proposed Rule increases the likelihood that a patient will be unable to return to the clinic to take the misoprostol within the recommended window of time. Patients who have abortions at Planned Parenthood in South Dakota already travel significant distances to reach the health center as they currently must make two round trips in order to have an abortion; in some cases, patients travel over 500 miles. Forcing patients to make multiple trips to a clinic also requires them to make arrangements over a series of days for such things as: time off of school and/or work, childcare, and/or overnight accommodations. This is immensely burdensome on patient time, finances, employment, and their mental and physical well being. For some patients, navigating this maze of schedules and costs will make medication abortion more difficult, or even impossible, to access. Given that the FDA has made clear that there is no medical justification for in-person administration of misoprostol, this additional trip would exist only to burden patients.

Equally importantly, there is no basis in fact or in South Dakota law to promulgate the misoprostol elements of the Proposed Rule. Because neither the REMS, nor any FDA rule, restricts or ever has restricted the dispensing of misoprostol to in-clinic settings, there has been no change in the facts or the law that would justify rule promulgation at this time. The Rule is thus arbitrary and capricious as the Department has failed to put forth any relevant or competent evidence to support the Proposed Rule. To the extent that the Department believes that new regulations addressing misoprostol delivery are warranted, it has not provided any explanation of or justification for such a belief.

For these reasons, the Department should halt efforts to adopt the Proposed Rule. However, if the Proposed Rule is to be adopted, we urge the Department to edit the rule such that it does not go beyond the REMS, and the law of every other state, by requiring

[14] The FDA's regulatory authority with respect to drugs is limited to approving them for marketing; the FDA does not regulate the practice of medicine. Nor does the FDA evaluate the best regimens for different drugs. Rather, physicians have this responsibility. Thus, the FDA label is not viewed as binding, or even as "best practice" for all patients. The American Medical Association's policy is that a physician may use an FDA-approved product "off-label" when such use is based on sound scientific evidence and sound medical opinion. Am. Med. Ass'n, *Patient Access to Treatments Prescribed by Their Physicians, AMA Policy H-120.988* (2020), available at https://policysearch.ama-assn.org/policyfinder/detail/h-120.988?uri=%2FAMADoc%2FHOD.xml-0-201.xml. A 2006 national study estimated that up to 21% of all uses for commonly prescribed medications were off-label. David C. Radley, et al., *Off-label prescribing among office-based physicians*, 166 Arch Intern Med. 1021, 1024 (2006).

[15] FDA, Ctr. for Drug Evaluation & Rsrch., *Application Number: 020687Orig1s020* (Mar. 29, 2016), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf.

in-person dispensing of misoprostol during an additional trip to a clinic at least 24 hours after receiving mifepristone.

Existing State Law Renders the Proposed Rule Unnecessary.

The Department should abandon promulgating the Proposed Rule for the additional reason that the Rule is not necessary to accomplish the goals set forth in EO 2021-12. The EO states, "[p]ermitting the dispensing of mifepristone through the mail or through a mail-order pharmacy is very likely a preview of how the FDA is expected to change the REMS on November 1, 2021" and the "South Dakota Department of Health must act quickly to adopt rules to protect women of South Dakota[.]"[16] Yet, existing state laws already heavily regulate the provision of medication abortion, including by imposing a minimum 72-hour delay and precluding the delivery of medication abortion via telemedicine without an in-person physician interaction. *See* SDCL § 34-23A-56.

Therefore, even without the Proposed Rule, telehealth abortion (which has been extensively studied and proven safe and effective, *see infra* note 34) is already legally impermissible in South Dakota. The Rule cannot be justified by a purported need to ensure telemedicine abortion does not proliferate in the absence of the federal REMS, in light of the fact that such practice is statutorily barred in the state. Indeed, as the Executive Order recognizes, the federal REMS in-person dispensing requirement for mifepristone has been suspended since April 2021 and there is zero evidence that medication abortion has been provided in South Dakota "via courier delivery, telemedicine or mail service."[17] The reality of medication abortion provision in South Dakota simply does not warrant the promulgation of this Rule.

The Proposed Rule also requires patients to be advised that it is possible to reverse the effects of mifepristone, though there is no scientific evidence supporting the assertion.[18] South Dakota law already imposes a similar requirement, directing that patients be advised that "even after a pregnant mother takes Mifepristone, or another drug approved by the United States Food and Drug Administration for the same use, it is still possible to discontinue a drug-induced abortion by not taking the prescribed Misoprostol."[19] The Proposed Rule cannot be justified because it is both redundant and more extreme than the statute. Patients are already informed of the potential to "discontinue" a medication abortion, and there is no reason or medical basis to advise them that the procedure can be "reverse[d]." The requirement would be false and misleading, and would go beyond the scope of the statutory authority for this rule.

[16] Exec. Order No. 2021-12 (S.D. 2021).
[17] Exec. Order No. 2021-12 (S.D. 2021).
[18] The American College of Obstetricians and Gynecologists ("ACOG") describes "so-called abortion 'reversal' procedures [as] unproven and unethical." Indeed, ACOG and the American Medical Association agree that there is no reliable evidence that medication abortions can, in fact, be 'reversed' through a course of treatment.
[19] SDCL § 34-23A-10.1(1)(h).

The Department Lacks Legal Authority to Promulgate the Proposed Rule.

South Dakota law does not provide legal authority for the Department to promulgate this Proposed Rule. Indeed, to the extent that the Department identifies a source of its authority to issue this rule, the source varies across the multiple forms submitted alongside the Proposed Rule, and this Rule falls outside the scope of each of them. The Notice of Public Hearing broadly identifies Chapter 23A of Title 34 of the South Dakota code as the basis of this Proposed Rule, while the Rule itself points more specifically to Sections 34-23A-51(7), (10), and (11) of the South Dakota Code for its general authority and purports to implement Sections 32-23A-10.1(3); 34-23A-19; and 34-23A-56 of the Code. Meanwhile, however, Form 14—the Small Business Impact Statement Form—states that the reason for the new Proposed Rule is that it is "required per the Governor's Executive Order 2021-12."[20] None of these statutory provisions, nor the Executive Order, supply proper authority for a rule imposing restrictions of the breadth and scope of this Proposed Rule.

First, although Section 34-23A-51 grants the Department authority to adopt rules, it specifies that these rules can relate only to the "issuance, renewal, denial, suspension, and revocation of a license to operate an abortion facility," not to the treatment and prescription of medication to patients nor to informed consent—which is what the Proposed Rule addresses.[21]

Next, Sections 32-23A-10.1(3); 34-23A-19; and 34-23A-56 govern "informed consent" prior to abortion services, the reporting requirements imposed on abortion providers, and requirements prior to the scheduling of abortion. However, none of these provisions include any requirements related to the prescription, dispensing, or administration of misoprostol. And while 32-23A-10.1(3) requires that patients be provided information about discontinuing a medication abortion, it does not require that patients be told "it is possible to reverse the effects of Mifepristone"—these words are nowhere to be found in 32-23A-10.1.[22] Moreover, the provisions the Department points to have been in effect for years. Yet, the Department has never—until now—taken the position that this statutory language calls for any of the stringent requirements set forth in this Proposed Rule. Plainly, that is because the statutes do not impose such requirements and do not delegate to the Department the power to invent additional restrictions wholecloth. If the Department were to do so by implementing this Proposed Rule, it would effectively be acting in a legislative capacity beyond its authority.

[20] S.D. Dept. of Health, *Form 14, Small Business Impact Statement Form.*
[21] Section 34-23A-51(7) provides the Department authority to promulgate rules related to "medication control," which the Department has interpreted to relate to the handling, stocking, labeling, and storage of prescription drugs in abortion facilities, as well as to the record-keeping about items purchased and dispensed. *See* ARSD 44:67:04:09. The Department has never interpreted 34-23A-51(7) to relate to the prescription, dispensation, or administration of medication or to establish requirements related to patient care.
[22] The language in the Proposed Rule additionally points to 32-23A-10.1(1)(h) as support. However, like 32-23A-10.1(3), 32-23A-10.1(1)(h) does not require that patients be told about so-called abortion reversal.

Finally, Chapter 23A of Title 34 more broadly does not set forth any role, responsibility, or authority of the Department with regard to the prescription, dispensation, or administration of medication abortion, nor does that chapter provide the Department the authority to impose restrictions on the provision of abortion care that are outside of the scope of the requirements set forth in the code. Rather, in Chapter 23A of Title 34, the Legislature clearly delineated the Department's role in implementing the provisions of that chapter, providing the Department with the responsibility to: license and inspect abortion facilities;[23] develop and maintain a website with specified information;[24] develop a patient notification form for the prevention of sex trafficking;[25] publish specified educational materials;[26] promulgate rules governing the attainment and reporting of abortion data;[27] monitor, analyze, and promulgate rules regarding the reporting of data related to pregnancy outcomes and maternal mortality;[28] include particular, detailed information in its annual vital statistics reports;[29] prepare physician reporting forms containing specified information;[30] provide information on its website about the inspection of abortion facilities;[31] and maintain a registry of "pregnancy help centers."[32] None of these include the authority to impose substantive restrictions on the provision of abortion services. The specificity of this delegation of responsibility demonstrates that the Department has limited authority to promulgate rules, and should adhere to the responsibilities explicitly provided to it in the South Dakota code.

Indeed, not only did the Legislature, in Chapter 23A, refrain from granting the Department the authority to promulgate rules imposing new requirements that would restrict the delivery of medication abortion, it also set out that "[t]he abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician during the first twelve weeks of pregnancy." SDCL § 34-23A-3. The promulgation of these rules runs directly counter to this mandate by undercutting health care providers' judgment and imposing requirements that contravene best medical practice. In doing so, the Proposed Rule seizes control of patient care from the hands of the attending physician, and denies South Dakotans who seek medication abortion the assurance that they are receiving medical care that is specific to their individual needs and best interests.

This Proposed Rule is beyond the scope and inconsistent with the mandates of the South Dakota Code, and constitutes an unjustified use of the Department's rulemaking powers.

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[23] SDCL §§ 34-23A-51(7), §§ 34-23A-43, §§ 34-23A-48.
[24] SDCL §§ 34-23A-10.1(i) and 34-23A-10.4.
[25] SDCL § 34-23A-10.1(k).
[26] SDCL § 34-23A-10.3.
[27] SDCL §§ 34-23A-19, 34-23A-36, 34-23A-44.
[28] SDCL §§ 34-23A-24, 34-23A-25.
[29] SDCL § 34-23A-26.
[30] SDCL §§ 34-23A-34, 34-23A-37, 34-23A-39.
[31] SDCL § 34-23A-49.1.
[32] SDCL §§ 34-23A-58, 34-23A-58.4.

The Governor's Executive Order Goes Beyond Legal Authority and Does Not Grant the Department Authority to Promulgate the Proposed Rule.

Separate from the fact that the Proposed Rule does not actually carry out the Executive Order, there is no valid legal justification in South Dakota law for an Executive Order that requires the promulgation of this Rule (or related legislation).

As noted above, the Agency's Small Business Impact Statement states that the Rule's "change[s] [are] required per the Governor Executive Order 2021-12".[33] However, 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. She "may...enforce compliance with any constitutional or legislative mandate, or restrain violation of any constitutional or legislative power, duty or right by any officer, department or agency of the state or any of its civil divisions." S.D. Const. art. IV, § 3. In cases of a declared public health emergency, the Governor's role expands, but there is no such emergency facing South Dakotans at this time that can justify the Executive Order or the Department's Proposed Rule.

Moreover, contrary to the assertions in the Executive Order, the potential removal of the federal REMS does not present imminent peril to public health and creates no genuine need for this new Proposed Rule. First, the FDA has not announced its decision on the federal REMS, and even if the FDA were to announce its intention to alter the REMS requirement on mifepristone, the Department cannot predict what the new federal framework for prescribing and dispensing mifepristone might entail, or how it might interact with current state law. Second, medication abortion is extremely safe, including when misoprostol is dispensed the same day as the mifepristone and then self-administered by the patient at the location of their choosing.[34] Third, even if lifting the REMS were to broadly allow medication abortion to be provided via telemedicine—which would not apply in this state because of current South Dakota abortion laws—research consistently shows that medication abortion can be delivered via telehealth with no additional safety concerns. Indeed, presently, patients in more than 20 states are able to receive medication abortion through telemedicine.[35] There is no evidence that the safety of medication abortion has declined in any of these states. Therefore, there can

[33] S.D. Dept. of Health, Form 14, Small Business Impact Statement Form.

[34] In concluding that misoprostol should be self-administered at the location of the patient's choosing, the FDA looked at research that "evaluated a variety of mifepristone treatment regimens with different misoprostol doses, routes of administration and dosing intervals used in gestations through 63 days" in which "roughly half of the studies included in this review did not require women to take misoprostol in-clinic" and found that "rates of treatment failure and of ongoing pregnancy were very similar regardless of whether misoprostol was taken in-clinic or at another location." This led the clinical review team to conclude definitively that misoprostol does not need to be restricted to in-clinic administration. FDA, *Application Number: 020687Orig1s020.*

[35] These states include Montana, Washington, Illinois, Pennsylvania, Maryland, Virginia, Massachusetts, Nevada, Minnesota, Oregon, Colorado, New Mexico, Alaska, Delaware, Hawaii, Idaho, Iowa, Michigan, New York, Utah and the District of Columbia.

be no valid claim that an executive order issued by the Governor is needed to respond to any safety concerns impacting the public health of South Dakotans resulting from a predicted change in federal regulation of medication abortion.

In fact, the true threat to public health is posed by the Proposed Rule itself. By imposing medically unnecessary requirements, including that misoprostol be delivered to patients at a clinic and in the presence of a physician a certain time period after the mifepristone is taken, the Rule forces a patient to make three trips to a clinic in order to complete their medication abortion. As already discussed, among other concerns, this will likely put medication abortion out of reach for a number of patients, who may not be able to find childcare for their children for three days, afford to take three days off of work, or be able to travel the distance to a clinic and home a total of six times. It would also prevent health care providers from providing medication abortion to those patients for whom it is indicated that a better option is to deliver misoprostol vaginally (rather than buccally) on the same day as the patient takes the mifepristone dose. Inevitably, some patients will be unable to access the abortion method that they prefer or that is medically indicated for them.[36] Disallowing pregnant people to make this choice with their provider puts them in danger.

There is no public health emergency granting the Governor the right to authorize the Proposed Rule, and the Executive Order is inconsistent with the separation of powers under the South Dakota Constitution and cannot serve as appropriate legal authority for the Proposed Rule.

The Proposed Rule is Unconstitutional.

Finally, the Department should halt efforts to adopt the Proposed Rule because, as proposed, it is plainly unconstitutional. The Proposed Rule is not reasonably related to patients' health and imposes a substantial obstacle in the path of people seeking a medication abortion. *June Med. Servs., LLC. v. Russo*, 140 S. Ct. 2103, 2133 (2020) (Roberts, C.J., concurring in the judgment). *See also Hopkins v. Jegley*, 968 F.3d 912, 914–16 (8th Cir. 2020). The Proposed Rule will impose significant, sometimes insurmountable, burdens on medication abortion patients, without improving health or safety in any way. The Proposed Rule will subject people seeking medication abortions to medically unnecessary delay, increased travel, and/or increased medical risks if they are forced to make a third visit to a health center to obtain misoprostol a minimum of 36 hours after the mifepristone is taken.

As discussed above, in South Dakota in particular, many of our patients travel long distances to get to the Sioux Falls health center. Making the two trips that are currently required under South Dakota law to Sioux Falls is already difficult for many of our patients. The Proposed

[36] If the Department does decide to continue with instituting an emergency rule, these safety concerns also counsel toward amending the rule so that it does not extend beyond the scope of the current federal REMS, and does not place additional restrictions on the delivery of misoprostol.

Rule would add to the burdens patients currently face by requiring patients seeking medication abortion to make not just two trips to the Sioux Falls health center, but a third trip, in order to have an abortion. This will simply be too much for some of our patients.

In particular, it will be hard for those patients who have trouble arranging additional time off from work or school and for those who cannot arrange childcare. Some patients will not have the financial resources to pay for a third trip—which will involve travel costs, as well as potentially lost wages and increased childcare expenses. Moreover, 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 in a short period of time would be extremely burdensome to these patients. Those women who are unable to access medication abortion because of these hurdles may be forced to carry unwanted pregnancies to term and could face the ensuing risks of health complications to themselves and their newborns.

The Proposed Rule further burdens access to abortion by creating a variety of administrative hurdles for health care providers. For instance, the Proposed Rule unnecessarily requires an additional in-person appointment with a physician, which will make it more difficult for the limited number of physicians providing abortion in South Dakota to schedule appointments with other patients. Worse, the Proposed Rule prevents providers from offering medical care to the highest standard by mandating a one-size-fits-all approach to medication abortion rather than allowing physicians to work with patients to make individualized health care choices, such as administering misoprostol vaginally when medically indicated. In doing so, the Proposed Rule will not only deny patients the care that is most responsive to their personal needs, it will also impede patient care by interfering with the physician-patient relationship.

The Proposed Rule is also not reasonably related to a legitimate state interest because, among other reasons, the Executive Order it claims to implement is focused on the REMS requirement, which itself is medically unnecessary, but even if that were a reasonable goal, the Rule does not actually impose the requirements set out in the REMS, as outlined above. Because the Proposed Rule will not help abortion patients—indeed, it will harm them by unduly burdening abortion access in South Dakota—the Rule violates patients' rights guaranteed by the Fourteenth Amendment to the U.S. Constitution.

The Proposed Rule further violates providers' equal protection rights by singling out health care providers who provide abortion services and subjecting them to requirements not imposed on any other similarly situated health care providers in South Dakota. Only health care providers who offer abortion are constrained to providing misoprostol in a physician's office despite the fact that it is safe for a patient to take at home, and are required to provide that medication at a particular time as dictated by the Department of Health in this Proposed Rule.

Moreover, the Proposed Rule violates the equal protection rights of people seeking a medication abortion, who are singled out and forced to receive health care services in a manner that diverges from best practices and patient safety, to receive information that is medically unnecessary and unjustified, and to receive that medication at a time and place mandated by the Department. These restrictions apply only to patients seeking medication abortion, and not those receiving any other health care services. Through this Proposed Rule, the state has imposed these regulations without any rational basis for doing so.

Because of these concerns, we urge you to reconsider adopting the Proposed Rule.

Sincerely,

Sarah Traxler, MD, MS, FACOG
Chief Medical Officer
Planned Parenthood North Central States

#3

December 10, 2021

To Whom It May Concern:

As medical students of the state of South Dakota, we have serious concerns regarding the proposed rule relating to Article 44:67:04:13.

We believe the state government would be egregiously overstepping its bounds in requiring in-person administration of these medications, particularly misoprostol. At this time, mifepristone requires in-person administration due to FDA requirements. That said, we firmly believe the FDA and physicians are the most qualified to determine which medications should be made available by prescription at a pharmacy, and which should require in-person dispensing.

Mifepristone has been used by over 3 million women in the U.S. since FDA approval in 2000, and robust evidence supports its safety. It is not only used in abortion, but also in management of miscarriage and second trimester pregnancy loss. These patients are already deeply grieving and are undeserving of additional arbitrary barriers to care during these distressing situations.

Misoprostol is another *very* safe medication, and it is used not only for abortion, but also for treatment of miscarriage and stomach ulcers. It is further used in the practice of gynecology to prepare for procedures related to treatment of abnormal bleeding, fibroids, and contraception (access to which has been shown to reduce abortion numbers). As such, its use is clearly NOT a patient safety issue and, in fact, this proposal would place an unreasonable barrier between patients and their healthcare. Furthermore, determining the timing of administration of misoprostol for management of miscarriage or abortion should only be determined based on clinical circumstances, and should NOT be defined arbitrarily by a politician or anyone not directly involved with each patient's care.

The state of South Dakota should not be in the business of restricting prescription of medication beyond that determined by the FDA. This rule sets a highly concerning precedent in disregarding the clinical judgment of highly educated, board-certified physicians and the rights of patients they serve to receive timely care without unnecessary barriers. As residents of South Dakota, and as future physicians, this type of restrictive legislation dissuades us from returning here to practice medicine. We strongly urge you to block this proposal and maintain the sanctity of the physician-patient relationship.

We are happy to answer any questions you may have.

Sincerely,

South Dakota Medical Students:

Anja Cucak
Kjerstin Hensley
Shelley Feng
Morgan Grosdidier
San Chandra
Morgan Schriever
Amrita Bhagia
Sophie Richardson
Riley Paulsen
Avery Franzen
Sena Uzunlar
Alexandra Kracht
Rachel Van Gorp
Tiffany Johnson
Helean Barwari
Nathan Stadem
J. Samuel Vassar
Narysse Nicolet
Kyra Beckman
Matt Billion
Emily Petersen
Joshua Lambert
Trae Olson
Andrew Nerland
Joshua Mohs
Jillian Stamp
Kyle Siemers
Omar Zineldine
Raina Grimsley
Keely Walker
Bailee Lichter
Michaela Derby

Americans United for Life

December 16, 2021

Governor Noem and the South Dakota Department of Health:

My name is Katie Glenn, and I serve as Government Affairs Counsel of Americans United for Life (AUL).[1] Established in 1971, AUL is a national law and policy nonprofit legal organization with a specialization in abortion, end-of-life issues, and bioethics law. In my role, I travel around the United States testifying on state legislation and advising lawmakers as they enact constitutionally sound, life-affirming policies Our vision at AUL is a world where every member of the human family is welcomed in life and protected in law.

Thank you for the opportunity to weigh in on the Department of Health's rulemaking process. South Dakota has a compelling interest in addressing the unique safety and public health concerns related to drug-induced, or chemical, abortion. This rulemaking process, as well as the executive order that preceded it, and the anticipated legislative action next session, are critical to protecting the welfare of South Dakota women and girls.

South Dakota Can No Longer Rely on Federal Rules to Protect Women and Girls.

In the initial phases of the COVID-19 Pandemic, most medical facilities were closed for all but essential procedures, a term that states defined with varying degrees of specificity. In some states, abortion clinics remained open as essential facilities, while in others they were temporarily closed as non-essential. Abortion providers capitalized on this confusion and took steps towards invalidating the "Risk Evaluation Mitigation Strategies (REMS)" required by the U.S. Food & Drug Administration (FDA) on medication abortion.[2]

While the U.S. Supreme Court upheld the FDA guidelines,[3] the FDA is actively evaluating the regulations while refusing to enforce the in-person dispensing requirement. The Biden

[1] I recently published an article titled "At-home abortion is a poison pill" on the harms of abortion-inducing drugs that can be accessed at AUL.org/unsafe.
[2] *Mifeprex (Mifepristone) Information.* U.S. Food and Drug Administration, (Feb. 5, 2018), www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.
[3] *U.S. Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists*, 592 U.S. ____ (2021).

administration has proven itself hostile to pro-life concerns,[4] and leading pro-abortion activists are calling on emergency room doctors to omit information from patient records to hide the fact that the patient is being treated for complications following a chemical abortion.[5]

Should the abortion industry be successful in their endeavor and rescind all FDA regulations on Mifeprex, states will be faced with the task of protecting women's health and safety without the backstop of the long-standing federal rules. It is against this backdrop that Governor Noem signed Executive Order 2021-12, "Serious Health Complications from Abortion-Inducing Drugs."[6]

Codifying the In-Person Dispensing Requirement is Necessary to Ensure South Dakotans Get the Care They Deserve.

Proposed Rule 44:67:04:13 codifies important health and safety protections, and helps a woman make a fully informed decision. For over twenty years, the FDA has required that the two-step chemical abortion drug regimen be prescribed by a certified provider—a physician who's proved that they are competent to manage drug use and registered with the FDA—and administered in person. This rule should continue that practice regardless of the FDA's actions, ensuring that South Dakota women and girls see a doctor before obtaining a drug-induced abortion, and that he or she be qualified and competent to provide medical care associated with the abortion procedure.

To be competent, the doctor must be able to diagnose contraindications to Mifeprex such as ectopic pregnancy and gestational age and administer RhoGAM for women with an Rh-negative blood type. They must be able to treat the patient for adverse events and transfer her to the emergency room if needed. None of this can be done virtually, but if the FDA regulations are rescinded, there are abortionists who are willing to hand out abortion pills without ever seeing the patient in person or even on video.[7] The rule must prevent at-home, pill-by-mail, DIY abortions that leave women to fend for themselves if medical complications arise.

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[4] Statement from President Biden and Vice President Harris on the 48th Anniversary of *Roe v. Wade*, WhiteHouse.Gov (Jan. 22, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/22/statement-from-president-biden-and-vice-president-harris-on-the-48th-anniversary-of-roe-v-wade/.

[5] Carole Novielli, *ER Doctors Should Falsify Records to Hide Abortion Pill Complications in a Post-*Roe *Era, Suggests Media's Favorite Abortionist*, LiveAction (Dec. 15, 2021), https://www.liveaction.org/news/grossman-er-hide-abortion-pill-complications-roe/

[6] Exec. Order No. 2021-12, https://sdsos.gov/general-information/executive-actions/executive-orders/assets/2021-12.PDF.

[7] Leah Hickman, *The Pill and the Pandemic*, WORLD Magazine (Jan. 30, 2021), https://world.wng.org/2021/01/the_pill_and_the_pandemic.

South Dakota has a legitimate interest in preventing unscrupulous abortionists—some of whom are not even licensed in the United States[8], let alone this state—from mailing abortion-inducing drugs into the state and leaving South Dakota's doctors to pick up the pieces. By mandating that abortions may only be done in clinics licensed by the state, South Dakota public health officials can identify and investigate any locations with high complaint or complication rates.

Before an abortion, the woman needs to be screened to determine that she is even a proper candidate for the drugs. If she has an IUD or an ectopic pregnancy, she cannot take these drugs. If she has a negative blood type, she needs a RhoGAM injection or she may face infertility in future pregnancies. She needs to be screened for coercion or abuse from a parent, partner, or trafficker. The physician needs to ensure that she is not seeking the drugs for someone else.

Women deserve information about their options. This rule helps to make sure every woman is told that if she changes her mind, abortion pill reversal is possible. As the Department implements HB 1130,[9] it should make efforts to partner with South Dakota pregnancy centers and physicians who hold themselves out as able to assist with abortion pill reversal. These forms and online resources should be made available in English, Spanish, and any other language deemed needed by public health officials.

As a Rural State, South Dakota Has a Special Interest in Mitigating Abortion Complication Harms.

Current best estimates suggest that around 27,000 American women find themselves in the emergency room suffering from chemical abortion-related complications each year.[10] It's a safe assumption that number would increase if chemical abortion is further deregulated and allowed to take place at home without any of the basic safeguards that currently exist.

In European countries that actively track complications, the numbers tell a troubling story. One Finnish study found that the complication rate for chemical abortion was four times higher than that of surgical abortion.[11] In the U.S. states that collect and publish data, the numbers are similar. A recent peer-reviewed study of Medicaid claims data demonstrates that emergency room visits following a chemical abortion are on the rise and occur as frequently as 35 ER visits per 100

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[8] *Warning Letter, Aidaccess.org.*, U.S. Food and Drug Administration, (Mar. 8, 2019), www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019.
[9] S. D. HB 1130 (2021).
[10] Donna J. Harrison, *Pushing the Envelope or Pushing the Coat Hanger?* (May 7, 2020), https://krla.org/files/special/aaplog-warns.htm.
[11] Maarit Niinimäki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology, 795 (Oct. 2009).

abortions.[12] They are often miscoded as spontaneous miscarriage, meaning these complications are never reported to public health officials being tied to an abortion, and may even inflate data on miscarriages.[13]

If you're like me and live 1.4 miles (10 minutes in traffic) from the nearest emergency room, this may not be a big concern. However, for people who live in rural areas further from medical care, that extra time can be the difference between life and death, minor treatment or major surgery. Chemical abortion drugs can lead to serious, life-altering complications, including hemorrhage, infection, and loss of fertility.

The rule addresses the state's interest in a woman having continuous medical care throughout the procedure as she would during an in-clinic surgical abortion. While other states have not established a similar safeguard, emerging complications data show that the problem is much greater than the Biden administration and the abortion industry are willing to admit. Historically, some European countries treated chemical abortion as an in-patient procedure, even admitting the woman overnight. However, these countries abandoned the practice because delivering the early pregnancy can happen over several days, and ensuring that the woman came back for a follow up appointment within two weeks of taking the second drug was more important.

After an abortion, the woman must confirm that there is no retained fetal tissue or other complication. In fact, the Mayo Clinic states on its website that "medical abortion isn't an option if you . . . **can't make follow-up visits to your doctor** or don't have access to emergency care" [emphasis in original].[14] This rule requires that the licensed facility schedule a follow up appointment and express the importance of that visit.

South Dakota lawmakers and public officials know best what is needed to ensure the health and safety of their citizens, and I encourage you to craft rules that align with similarly serious procedures to make sure that no woman is abandoned, left to decide on her own how much blood is too much blood as she delivers her early pregnancy.

South Dakota Public Officials Have a Legitimate Interest in Regulating Abortion-Inducing Drugs to Ensure Women's Health and Safety.

From its inception in *Roe v. Wade*, the abortion "right" has been explicitly qualified. In *Roe*, while the Court established a constitutional "right" to abortion, it simultaneously expressed

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[12] *Public Health Threat: Chemical Abortion Leads to Significantly Higher Rate of ER Visits*, Charlotte Lozier Institute (Nov 16, 2021), https://lozierinstitute.org/public-health-threat-chemical-abortion-leads-to-significantly-higher-rate-of-er-visits/.

[13] *Id.*

[14] *Medical Abortion*, Mayo Clinic, (May 14, 2020), https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687.

that "[t]he State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that [ensure] maximum safety for the patient."[15] Affirming what is considered the essential holding of *Roe*, the U.S. Supreme Court in *Planned Parenthood v. Casey* asserted that "it is a constitutional liberty of the woman to have some freedom to terminate her pregnancy. . . . The woman's liberty is not so unlimited, however, that from the outset [of pregnancy] the State cannot show its concern."[16] In both *Casey* and *Gonzales v. Carhart*, the Court affirmed *Roe*'s "essential holding" that states have "legitimate interests from the outset of the pregnancy in protecting the health of the woman."[17] This means the states can enact regulations aimed at protecting the health of the mother from the earliest stages of pregnancy.

Earlier this month, the United State Supreme Court heard oral arguments in *Dobbs v. Jackson Women's Health Organization,* a case challenging abortion doctrine in which the state of Mississippi argued that the question of how to regulate abortions should be returned to the states. In that case, 231 Members of Congress, including the South Dakota delegation, signed amicus briefs in support of the states' compelling interest in appropriately legislating this area of the law and calling for the overturn of *Roe* and *Casey*.[18] We anticipate a favorable decision that strengthens state lawmaking authority, perhaps to a greater degree than they have had under this jurisprudence for five decades. This includes applying basic health and safety regulations to the prescribing and administration of abortion-inducing drugs, which courts have inconsistently permitted under shifting standards of review. Complication data demonstrates that the problem is real, and states have a compelling interest in enforcing health regulations that improve medical outcomes for their residents.

I strongly encourage South Dakota to protect women's health and affirm life by enacting comprehensive, defensible rules that can be supplemented by legislation during the 2022 session.

Respectfully Submitted,

Katie Glenn, Government Affairs Counsel
Americans United for Life

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[15] *Roe v. Wade*, 410 U.S. 113, 150 (1973).
[16] *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 869 (1992).
[17] *Id.* at 846; *see also Gonzales v. Carhart*, 550 U.S. 124, 145 (2007).
[18] Brief *Amici Curiae* of 228 Members of Congress in Support of Petitioners, *Dobbs v. Jackson Women's Health Org.*, No. 19-1392 (2021), https://www.supremecourt.gov/DocketPDF/19/19-1392/185247/20210729122803733_19-1392%20Amicus%20Brief%20of%20228%20Members%20of%20Congress.pdf

#5

From: Admin and Rules <DOHAdminRules@state.sd.us>
Sent: Monday, December 13, 2021 7:00 AM
To: DOH Admin Rules <DOHAdminRules@state.sd.us>
Subject: Comment on : South Dakota Department of Health

Name: SD ACOG

Address:

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Comment: Dec 13, 2021 Via email dohcomments@state.sd.us and First Class Mail The Honorable Kim Malsam-Rysdon Secretary, SD Department of Health 600E Capital Avenue Pierre, SD 57501 As the leading experts in women's health in the state of South Dakota, the South Dakota section of the American College of Obstetricians and Gynecologists (SD ACOG) wishes to comment and suggest amendments to the proposed rule 44:67:04:13. Regarding Mifepristone Administration Under 44:67:01:01. Definitions. Change statement to "medical abortion" shall mean a procedure that uses medication to end an ongoing pregnancy. For the purposes of this document, it does NOT refer to medical management of miscarriage.. Reasoning: • Mifepristone is used both for medication abortion and for medical management of miscarriage. It is also used in cervical preparation for surgical management of second trimester miscarriages. Approximately 10% of clinically recognized pregnancies and an estimated 20-25% of all pregnancies result in miscarriage. An exception needs to be made in this policy for management of miscarriage. 44:67:04:13. Mifepristone Administration Below I have listed our concerns with this paragraph. Concerns regarding restrictions on Misoprostol Use. The broad impact of the requirement that "Neither medication may be dispensed in any manner contrary to this section" is extremely concerning to us. That is because Misoprostol is used for multiple other indications outside of abortion and miscarriage management. Misoprostol does not currently require or necessitate in-person dispensing. This rule goes beyond enforcing current FDA restrictions and requiring in person dispensing would complicate many aspects of medical care without improving safety. Misoprostol's primary indication is for the treatment of stomach ulcers. It used in cervical preparation for diagnosis and treatment of endometrial and cervical cancer via endometrial biopsy, endocervical curettage, and gynecologic D&C. It is also used for cervical preparation for IUD placement and removal as well as labor inductions. Concerns about Safety are not based in evidence Mifepristone has been used by over 3 million women in the United States since FDA approval in 2000 and robust evidence exists regarding the safety of mifepristone for medication-induced abortion. Research conducted during the COVID-19 pandemic, when enforcement of the in-person dispensing requirement for mifepristone was suspended, has further confirmed the safety of providing abortion in this manner. Proposed rules run counter to ACOG's evidence-based recommendations: • The timing in the proposed rule dictating administration of misoprostol does not reflect evidence-based care. For medical management of both miscarriage and abortion, misoprostol is most often prescribed to be taken 24-48 hours after mifepristone. Evidence shows that the initial dose can be given 0-72 hours after mifepristone. Repeat dosing of misoprostol can also be given as needed and should not require in-person dispensing. This rule states that it must be given at 36-48 hours after mifepristone. 36 hours is impractical, as a patient who received mifepristone at 2pm would need to return the following night at 2am for their misoprostol. • This rule would necessitate a third in-person appointment for the patient. Current SD law mandates a medically unnecessary initial consultation and a 72-hour waiting period before taking mifepristone for abortion, including medically indicated abortion. Adding another in-person appointment within the impractical time frame, would add unnecessary burdens for patients and practices, potentially requiring after-hours staffing with the physician, as well as requiring the patient to take additional time off work and find transportation and childcare. • The

possible hemorrhage risk associated with mifepristone occurs when patients do NOT take the misoprostol. Requiring in-person dispensing puts another barrier in front of the patient and will likely result in aggravating rather than decreasing this risk. • Patients who miscarry are counseled regarding options and often go home to consider how they wish to proceed. It is unnecessary and inhumane to require them to return to the clinic for in-person dispensing of mifepristone and misoprostol, particularly as the safety data show that it is unnecessary. It is particularly burdensome on weekends and holidays, when miscarriages still happen, as most acute care settings do not manage mifepristone due to the onerous regulations in place. • The proposed rule inappropriately conflates medical follow up with "complications" • The proposed rule arbitrarily requires that the patient "return to the abortion facility on the 14th day after taking the medication." Routine in-person follow-up is not always necessary after medication abortion. Further, such prescriptive timing is unworkable for both physicians and patients. Regulations predicated on speculations about FDA action are ill-advised • ACOG is hopeful that the FDA will thoroughly review the available evidence and make an evidence-based determination to remove medically unnecessary restrictions that hinder access to mifepristone. • We are concerned that the proposed rule promulgates policy in speculation about a federal agency's actions, making assumptions regarding the outcome without reviewing the decision and the evidence cited to undergird the decision. • In fact, the proposed rule goes further than the FDA's current restrictions. For example, the proposed rule requires that misoprostol be administered in a clinic, dictates the gestational age that mifepristone must be administered, limits the qualified clinicians that may administer mifepristone, and mandates follow-up care. • Regardless of FDA action, ACOG has overarching concerns with state regulatory or legislative action that enshrines FDA labelling or otherwise dictates the practice of medicine, because medical knowledge is not static. Even if the law or regulation is generally consistent with the clinical standard of care, medical treatment protocols written into law are problematic. As knowledge advances, these protocols, tests, and procedures can become outdated. The state government should not be in the business of restricting prescription of medication beyond that determined by the FDA. This rule sets a highly concerning precedent in disregarding the clinical judgment of qualified physicians and the right of patients to receive timely care without unnecessary barriers. We welcome any questions you may have pertaining to this recommendation. Respectfully submitted, South Dakota ACOG Mark Ballard, MD FACOG, Chair Amy Kelley, MD FACOG, Vice Chair Erica Schipper, MD FACOG, Immediate Past Chair Elizabeth Hultgren, MD, Secretary Sources: Creinin, Mitchell D. et al. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol 2020; 135(1):158-165. CDC Maternal Mortality Surveillance: https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm Early Pregnancy Loss, ACOG Practice Bulletin, Nov 2018. Number 200 (Replaces Practice Bulletin Number 150, May 2015. Reaffirmed 2021) Medical Abortion up to 70 days gestation. ACOG Practice Bulletin, Oct 2020 (Number 200 (Replaces Practice Bulletin Number 150, May 2015. Reaffirmed 2021 Chong E, Shochet T, Raymond E, Platais I, Anger H, Raidoo S, et al. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception 2021. Kerestes C, Murayama S, Tyson J, Natavio M, Seamon E, Raidoo S, et al. Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models. Contraception 2021. Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship, ACOG Statement of Policy. (Amended and Reaffirmed August 2021)

#6

From: Admin and Rules <DOHAdminRules@state.sd.us>
Sent: Thursday, December 9, 2021 7:00 AM
To: DOH Admin Rules <DOHAdminRules@state.sd.us>
Subject: Comment on : South Dakota Department of Health

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Comment: To Whom It May Concern: As an obstetrician-gynecologist in the state of South Dakota, I have grave concerns regarding the proposed rule relating to Article 44:67:04:13, apparently requiring patients to receive mifepristone and misoprostol via in-person dispensing from a clinic and prohibiting pharmacy dispensing of these medications, as well as mandating specific timing of the administration of misoprostol. The state government would be egregiously overstepping its bounds in requiring in-person dispensing of these medications for any indication. At this time, mifepristone requires in-person administration due to FDA requirements. I firmly believe the FDA and physicians are the most qualified to determine what medications should be available by prescription at a pharmacy, and which should require in-person dispensing. Mifepristone has been used by over 3 million women in the US since FDA approval in 2000, and robust evidence supports its safety. It is not only used in abortion, but also in management of miscarriage and second trimester pregnancy loss. It is further utilized outside of gynecologic care in the treatment of endocrine disorders such as Cushing's disease. Misoprostol is a very safe medication, and it is used not only for abortion, but also for miscarriage and for treatment of stomach ulcers. It is further used in gynecology to help prepare for procedures for abnormal bleeding, treatment of fibroids, and placement of long-acting reversible contraception (access to which has been shown to reduce abortion numbers). As such, this is clearly NOT a patient safety issue and, in fact, places an unreasonable barrier between patients and their care. Further, determining the timing of administration of misoprostol for management of miscarriage or abortion should be determined based on clinical circumstances, and should NOT be assigned arbitrarily by government officials not directly involved in patient care. The state of South Dakota should not be in the business of restricting prescription of medications beyond that determined by the FDA for any indication. This rule sets a highly concerning precedent in disregarding the clinical judgment of qualified physicians and the rights of patients to receive timely care without unnecessary barriers. I am happy to answer any questions you may have. Sincerely, Erica Schipper, MD, FACOG Sioux Falls, SD

From: Admin and Rules <DOHAdminRules@state.sd.us>
Sent: Monday, December 6, 2021 7:00 AM
To: DOH Admin Rules <DOHAdminRules@state.sd.us>
Subject: Comment on : South Dakota Department of Health
Name: Anonymous
Address:
City: Chicago
State: IL
Zip: 60622
Email: Nergui247365@gmail.com
Phone:
Comment: This state-sponsored rule is attacking citizens of its very state who are seeking medical care in a difficult and
time-sensitive situation. Imposing unnecessary rules on medications that are known to be safe and observation time
periods does nothing but delay care and lead to later gestation abortions. Efforts should be made to ease restrictions
and enable access to such medications and care that abortions can be done early and safely. Until South Dakota no
longer has problems with rates of substance abuse, opioid related deaths, mental healthcare shortages, school
shootings, the state should prioritize addressing actual problems that affect large number of its population rather than
singling out a small issue to appease the religious sector.