[redacted]

From: SD ACOG <sdacog@gmail.com>
Sent: Tuesday, January 4, 2022 10:24 AM
To: dohcomments@state.sd.us; [redacted]
Subject: [EXT]: Re: Written Comments from ACOG on proposed rule 44:67:04:13. Hearing 1/6 at 2pm

On Tue, Jan 4, 2022 at 10:14 AM SD ACOG <sdacog@gmail.com> wrote:

Jan 4, 2022

Rules Review Committee

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 further on the proposed rule **44:67:04:13. Regarding Mifepristone Administration**

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 is and has been used without this requirement for years. It is used 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.

There is NO medical reason that this needs to be given in person and we have grave concerns about the state government overriding the FDA without a scientifically valid reason. This is particularly true when it would be in opposition to national standards of care.

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.

Medical Treatment for miscarriage

- Additionally, 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.

- The current wording can still be misinterpreted as meaning to end a nonviable pregnancy (ie miscarriage)

- 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.

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 24-72 hours after mifepristone.

- 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.

- 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.

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. There is no medical reason either of this medications need to be given in person, no matter what the indication. 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:

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