AAPLOG

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Representative John Hansen, Chair
Senator Jean Hunhoff, Vice Chair
Interim Rules Review Committee
500 E. Capitol Ave
Pierre, South Dakota 57501

Chair and Members of this Committee,

Thank you for allowing me to address this committee as a proponent of the Department of Health's proposed rule 44:67:04:13, Mifepristone and Misoprostol administration for medical abortions.

I am Dr. Donna Harrison, Board Certified obstetrician and gynecologist and the CEO of the American Association of Pro-Life Obstetricians and Gynecologists. AAPLOG represents over 6000 reproductive health professionals, 10 of which are in South Dakota. We defend the lives and health of both our pregnant patients and their preborn children.

The reckless push for demedicalization of the process of chemical abortion has resulted in essentially medical abandonment of our pregnant patients during a procedure fraught with immediate and long-term complications.[1] [2] These complications include massive hemorrhage, tissue left inside the woman, infection, and failed abortion. The risk of these complications increases with increasing gestational age.[3]

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[1] Niinimäki M, Pouta A, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009 Oct;114(4):795-804. doi: 10.1097/AOG.0b013e3181b5ccf9. PMID: 19888037.

[2] American Association of Pro-Life Obstetricians and Gynecologists PB * Medical Management of Elective Induced Abortion 2020. Available at https://aaplog.org/wp-content/uploads/2020/03/FINAL-PB-8-Medical-Management-of-Elective-Induced-Abortion.pdf

[3] Mentula MJ, Niinimäki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Hum Reprod. 2011 Apr;26(4):927-32. doi: 10.1093/humrep/der016. Epub 2011 Feb 11. PMID: 21317416.

It is my understanding that South Dakota requires an abortion patient to have an informed consent visit with the physician before scheduling the actual abortion, with a 72-hour waiting period. At the patient's second visit, the abortion drug mifeprex is administered. At the third actual visit to the office, she would be given misoprostol, the second drug.

The purpose of FDA's original requirement for two in person visits was to minimize these complications associated with the chemical abortion drug regimen.

The purpose of the in person visits prior to administration of mifeprex is to:

1. Determine the exact gestational age of the patient so that the patient can be given her specific risks based on exactly what gestational age she is. This requires an in person visit for an ultrasound. In decades of studies, it has been shown that only half of women can accurately determine how far along they are in pregnancy from their last menstrual period. So, without an ultrasound a woman cannot know if she is really further along in pregnancy than she thinks she is. And that is important for informed consent, because a woman's risk for complications from chemical abortion dramatically increases as the gestational age of the pregnancy increases.[4]
2. Determine that the preborn child is actually located inside her uterus, and not inside her tubes (i.e., ectopic pregnancy). Approximately 3% of women, (i.e., 1 out of 30 women) have an ectopic pregnancy. Mifeprex chemical abortion does not treat ectopic pregnancy. Instead, the symptoms of a mifeprex abortion (extreme pain and bleeding) are exactly the same symptoms that a woman would experience if she has a rupturing ectopic pregnancy. According to the adverse event reports submitted to the FDA, woman have died from ruptured ectopic pregnancy, when they were told over the phone to simply lie down and take pain medicine.
3. Determine whether or not she has a blood type which is Rh negative. If a woman has Rh negative blood type, she must receive a medication called Rhogam in order to prevent her from miscarrying in future pregnancies. If she does not receive this, she is at great risk of future miscarriages and also stillbirths in subsequent pregnancies.[5]
4. Perform a physical examination to identify any physical problems or reason why mifeprex should not be given (i.e., contraindications) such as severe anemia which could be life threatening if she hemorrhages.
5. Screen for coercion to abort (which is illegal in all 50 states) as well as screen for domestic violence and sex trafficking and abuse. There is no possible way to do an adequate screening for sex trafficking and abuse via a telemedicine visit, because there is no possible way of controlling for who is present in the room with the patient during a telemedicine visit.

The purpose of a separate subsequent in person visit for the administration of misoprostol is for the safety and benefit of the patient. In the original FDA approval, the assumption was that women would be observed in clinic for 6 hours, as most women abort sometime within 6 hours of administration of misoprostol. Taking misoprostol with subsequent observation was meant to allow the woman to receive adequate pain control in a medical setting during the worst and most painful part of the abortion process.

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[4] Mentula MJ, Niinimäki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Hum Reprod. 2011 Apr;26(4):927-32. doi: 10.1093/humrep/der016. Epub 2011 Feb 11. PMID: 21317416.

[5] American College of Obstetricians and Gynecologists. Prevention of Rh D Alloimunization. https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/08/prevention-of-rh-d-alloimmunization

Although FDA does not require such observation currently, there is still the need for a medical professional to see the woman prior to the misoprostol administration in order to:

1. Determine whether or not she has already aborted as a result of just taking the mifepristone alone. 1 out of 20 (approximately 5%) of women will abort without taking the second drug misoprostol. This is critically important information, because not only can mifepristone suppress a woman's immune system, but also misoprostol can additionally suppress a woman's immune system and make her even more susceptible to a deadly infection called Clostridium sordellii. Over 10 healthy young women have died from this overwhelming infection after using mifepristone and misoprostol. If she has already aborted, she doesn't need to expose herself to the second drug with all of its complications.
2. Determine if she has complications such as anemia from hemorrhaging, infection and other complications which might necessitate a surgical completion of the abortion.
3. Assess her need for pain control and other needs during the arduous process of chemical abortion.

It is reasonable and prudent for the State to require a separate subsequent in person visit for administration of misoprostol, the second drug in the chemical abortion regimen, in order to minimize the risks for women from the chemical abortion procedure.

Respectfully submitted,

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