April 18, 2022

SD Board of Certified Professional Midwives
27705 460th Ave
Chancellor SD, 57015

RE: Comment on Proposed Rules (hearing date 4/21/22)

Dear Board Members:

It has come to the attention of the American College of Obstetricians and Gynecologists (“ACOG”) that there is a proposed change to the formulary, granting access for Certified Professional Midwives (“CPM”) to use medications on patients being cared for outside of medical centers (i.e., homes, motels, etc.) during a patient’s labor and delivery.

Deliveries outside of medical centers that CPMs are authorized to attend are limited to those which are “low risk”, which is defined as one that is “anticipated to be problem free.” Once those deliveries are elevated in risk, they should, both for ethical and patient safety reasons, be transferred to a medical facility that can accommodate the needs of the patient and her fetus/newborn. The proposed rules appear to us to be an effort to authorize care for higher risk patients outside of an appropriate setting and have significant potential to increase the risk for maternal and/or neonatal morbidity or mortality.

We oppose the proposed changes to the formulary for the following reasons:

**Epinephrine HCL**

Epinephrine is not supportable in the out of hospital setting. This is a medication only indicated in the setting of circulatory collapse. **In my 29 years practicing as an Ob/Gyn, I have never used epinephrine outside of a cardiac resuscitation for mother or neonate.** Training for licensed midwives is not adequate to treat either women or neonates who are in cardiac arrest. If the provider did have ACLS or NRP certification, attempting a code resuscitation without support would be highly unlikely to benefit the mother or infant. In these circumstances, CPMs should activate EMS and emergently transfer the patient to the hospital. If a licensed midwife is doing an appropriate job with monitoring fetal heart tones and maternal vital signs during labor, transfer to a hospital should be accomplished long before any situation requiring epinephrine evolves.

**Tranexamic Acid (TXA)**

We believe authorization for the use of this medication is potentially dangerous and thus inappropriate. Oxytocin, on the other hand, is an excellent first-line drug to control hemorrhage; it can easily be given via intramuscular injection, and it will serve well to stabilize women while transportation to a hospital can be arranged.

**Intravenous Liquids**

Intravenous fluids like lactated ringers or normal saline are not supportable in the outpatient setting. There is no reason that a healthy normally laboring patient would need intravenous fluids during labor in the out of hospital setting where she is typically still allowed to consume liquids by mouth during her labor course.
In addition, although not a part of the proposed amendments to the formulary, we offer the following comments on other medications listed in the formulary as it exists today.

**Injected Lidocaine**

Injected lidocaine is not supportable in out of hospital settings. Intravascular Lidocaine can cause life threatening hypotension, cardiac arrhythmias and sudden cardiac arrest leading to maternal death. While the use of topical Lidocaine may be supportable in the out of hospital setting, injection of Lidocaine is risky and should not be required in the setting of a normal, uncomplicated birth. The only reason injected lidocaine would be required is if women have complex perineal lacerations. For those complex lacerations, patients requiring repair should be transferred to the hospital for surgical evaluation and management.

**Penicillin or Other Antibiotics.**

Penicillin and other antibiotics are not supportable in the out of hospital setting. It is no longer a normal uncomplicated pregnancy if a patient requires antibiotics. There are risks of anaphylaxis (severe allergic reaction) with administration of intravenous antibiotics which could be life threatening in the out of hospital setting.

If a patient is GBS positive and requires prophylactic antibiotics, this is an indication for an in-hospital delivery due to the risk for early or late onset neonatal sepsis (overwhelming infection). These infants benefit from additional time for pediatric observation and monitoring of vital signs after birth which is not permitted in the out of hospital setting in which midwives typically do not monitor longer than 2-4 hours.

We are extremely passionate about South Dakota's women receiving quality care during pregnancy, and during their labor and delivery. Healthy moms and healthy babies are goals for South Dakota ACOG. This includes all South Dakotans, even those that deliver outside of a medical facility. If you have any furthers questions or concerns, please feel free to contact me at 605 390-5635.

Sincerely,

Mark Ballard, MD
Ob/Gyn, FACOG
SD ACOG Section Chair