**SOUTH DAKOTA BOARD OF CERTIFIED PROFESSIONAL MIDWIVES**
**PUBLIC HEARING**

South Dakota Board of Certified Professional Midwives Office **and** via teleconference
27705 460th Ave. Chancellor SD
Public Hearing
South Dakota Board of Certified Professional Midwives(CPM)
Thursday, April 21, 2021 1:30pm (Central Standard Time)

Steven Blair, Assistant Attorney for the SD Attorney General and Legal Counsel for the SD Board of CPM, called the public hearing to order at 1:30 p.m. on Thursday, April 21 2022 by telecommunication. He noted this hearing is being held at SD Board of CPM office at 27705 460th Ave. Chancellor SD and telephonically. Publication of this time and date has been set and published pursuant to SDCL 1-26-4 and SDCL 1-26-4.1. Members of the public were invited to join the Public Hearing at the SD Board of CPM Office or telephonically. Blair noted that this is the time and place for the Board of Certified Professional Midwives Public Hearing to consider changes to the administrative rules:

**§ Chapter 20:86:02:03. Duration of license.**
**§ Chapter 20:86:04:02 Biennial renewal**
**§Chapter 20:86:03 Appendix A THE FORMULARY**

**Hearing Officer**: Steven Blair, Assistant Attorney for the SD Attorney General and Legal Counsel for the SD Board of CPM Rapid City

**Members of the Board in attendance via teleconference**: President Debbie Pease, Vice President Susan Rooks CNM, Kimberley McKay OB/GYN, and Jackie Lopez CPM. Secretary Autumn Cavender-Wilson CPM joined after the meeting was in progress.

**In attendance in person:** Board Executive Secretary Tammy Weis

**Guests in attendance by telecommunication:** Eudine Stevens CPM, Debbie Eaks CPM, Alaina Kerkhove CPM, Evie DeWitt Midwive's Assistant and Doula, Justin Bell, Legal Counsel for South Dakota State Medical Association (SDSMA) and Dr. Keith Hanson OB/GYN speaking on behalf the of SDSMA

Blair stated that those in attendance and statements made during the hearing were being recorded in the minutes and that a quorum of the board was present. Before beginning with any comments, and for the public record, he verified that the following information was in the CPM Board's file for the record:

- Copy of proposed rules were submitted to Dept. of Health: 3/14/2022
- Sec. has given authorization to proceed: 3/14/2022
- Notice of Hearing prepared: 3/17/2022
- Notice publ. 3 papers gen. circulation
    - Rapid City Journal 3/19/2022
    - Brookings Register 3/ 21/2022
    - Aberdeen News 3/19/2022
- Affidavits of Publication from the papers received 4/1/2022
- Fiscal Note prepared by Tammy Weis 3/14/2022
- Small Business impact statement prepared 3/15/2022
- Dir./LRC was served at least 20 days prior hrg. 3/16/2022

**SOUTH DAKOTA BOARD OF CERTIFIED PROFESSIONAL MIDWIVES**
**PUBLIC HEARING**

South Dakota Board of Certified Professional Midwives Office **and** via teleconference
27705 460th Ave. Chancellor SD

- w/ Proposed rules, Notice Hearing, Fiscal Note & Small Business impact statement

- Comm/BFM served at least 20 days prior hearing. 3/20/2022
  - Same materials as LRC
- Mail to interested parties none requested

**Written Testimony:**

- LRC Style & Form comments
- Letter from SD Birth Matters
- Letter from Eudine Stevens CPM
- Letter from American College of Obstetricians and Gynecologists
  Mark Ballard, MD Ob/Gyn, FACOG SD ACOG Section Chair

The rules were presented by Tammy Weis Board Secretary. §Chapter 20:86:03 Appendix A and § Chapter 20:86:02:03.

Statute 36-9C-13 (SD Codified Laws, 2021) refers to prescription drugs that a licensed CPM may administer. These are as follows:

Vitamin K
Post-partum anti-hemorrhagic medication
Local anesthetic
IV antibiotics for treatment of Group B Strep
Oxygen
Eye prophylaxis
RhoGAMn

This rule change would add IV fluid and Tranexamic Acid (TXA) to the Post-partum anti-hemorrhagic medication in an emergency situations. It will also include follow-up emergency treatment for allergic reactions that might arise from the use of the medications listed above. The final change will make the renewal of licenses more expedient, equitable, and in compliance with SDCL 36-9C-16.
The reason for adopting the proposed rules is to provide a greater protection for public safety.

The board then heard public testimony from one opponent and five proponents.

**Oral Testimony:**

**Opponent:**

Dr Keith Hanson Ob/GYN from Sioux Falls, SD on behalf of the SDSMA, spoke first by prior arrangement.

- Post-partum ~~anti-~~hemorrhage used to be a primary cause of maternal death but is now a rare occurrence because of good medical interventions now available
- There are three primary causes of postpartum hemorrhage
  - Uterine atony
  - Retained placental tissue
  - Lacerations or trauma to cervical, *vaginal or perineal* tissues
  - Rare ~~etiologies~~ *coagulopathies*
- All three (four) would require transfer to the hospital for medical treatment

- Tranexamic Acid (TXA) side effects include blood clotting issues that must be addressed in a hospital setting
- IV side effects can include Pulmonary Edema from too much fluid too fast
- IV starts on bleeding patients are difficult
- Epinephrine HCL has a history of dosage mistakes (even) in the hospital setting

**Primary Concerns of SDMA**

- Adding medication options may delay transfer to the hospital
- Dosage mistakes could be deadly
- Treatments for the noted side effects are unavailable outside of the hospital setting.

**Proponents:**

Eudine Stevens CPM from Conde, SD testified from Walla Walla, WA

- In rural areas it can take from 5-30 minutes for EMS to arrive.
- She has been present for over 200 out of hospital births and never had to use TXA but has worked with midwives who did have to use it.
- When bleeding is due to trauma, it can be very heavy with few direct pressure options
- 15 minutes while waiting for transfer can be life or death.
- Replacing fluid volume while waiting for transfer allows the hospital to receive the woman in better condition.

Alaina Kerkhove CPM from Colman,SD testified next

- She has lived in a rural South Dakota area for 27 years.
- Her local EMT is staffed by volunteers 25 miles away.
- They are EMT and not paramedics/ Many rural EMT crews cannot start IVs
- The closest hospital that has the capacity to manage obstetrical emergencies is further away than the local hospital.
- Preloaded ~~Epi Pens~~ EpiPens® have no dosage risks for adults.

Evie DeWitt Midwive's Assistant and Doula, Mitchell,SD

- Supports all four changes
- Agrees with all of the other proponent testimony
- Thanks the board for making birth safer for those who choose out of hospital birth

Debbie Eaks CPM- Montevideo, MN

- Thanked the board for taking up these issues for emergency situations
- Supports the changes and agrees with other proponent testimony

Blair **closed the testimony period of the hearing at 1:55pm** after hearing no more requests to testify.

The board began discussion and deliberation with the change in the renewal of licenses, **§ Chapter 20:86:02:03. Duration of license** and **§ Chapter 20:86:04:02 Biennial renewal.** LRC recommended corrections and changes were made. Pease suggested a change in the language to add "for" between "valid" and "two year" to clarify the beginning of the licensure period. Discussion: changing rule 20;86;02;03 made the first sentence in rule 20:86:04:02 unnecessary**.** Pease moved to adopt both rules as amended, Rooks Second. The voice vote was **unanimous. Motion passed**.

Final adopted rules:

**20:86:02:03. ~~Issuance of license.~~** ~~Licenses will be renewed biennially on October 30th~~.

**Duration of license.** A license is valid for two years from the date that it was issued by the board.

**Source:** 45 SDR 31, effective September 10, 2018.

**General Authority:** SDCL 36-9C-32(1).

**SOUTH DAKOTA BOARD OF CERTIFIED PROFESSIONAL MIDWIVES**
**PUBLIC HEARING**

South Dakota Board of Certified Professional Midwives Office **and** via teleconference
27705 460th Ave. Chancellor SD

**Law Implemented:** SDCL ~~36-9C-11~~. 36-9C-15

**20:86:04:02. Biennial renewal.** ~~Each person licensed to practice within this state shall renew the license biennially on October 31st.~~ The renewal fee is $1,500. Failure to secure a renewal certificate shall result in a lapsed license. A lapsed license may be reinstated as provided in § 20:86:02:06.

**Source:** 45 SDR 31, effective September 10, 2018.
**General Authority:** SDCL 36-9C-32(4).
**Law Implemented:** SDCL 36-9C-19(2).

**FORMULARY CHANGE #1**

Next the board discussed **the expansion of the use of IV fluids from prophylactic antibiotic use only to use for postpartum hemorrhage as well.** McKay addressed the concerns of the medical association, including the difficulty of IV starts when a woman is bleeding, and the possibility of delayed hospital transfer. The board was reminded that the initial concern that prompted the change to the rules was the question of:

1. If the CPM has the equipment to start an IV
2. If the CPM has the education and experience to start an IV
3. If the CPM **doesn't** start an IV in the event of a postpartum hemorrhage **because the rules do not specifically give authority to do so**, will the CPM be considered negligent. (Especially in the case of a ~~bad outcome~~ *an adverse event*).
4. If the CPM **does** start and IV in the event of a postpartum hemorrhage and **because the rules do not specifically give authority to do so**, ~~will they~~ *this action could* be considered outside their scope of practice.

Discussion was active. All were in agreement that if Pitocin was not immediately effective, additional assessment and an early IV placement (earlier access is much easier) is the best safeguard to be prepared for a transfer if necessary. This is especially important in rural areas where EMTs may not have IV capacity and wait times for EMTs might be long. Final language was added to assure that hospital transfer was not delayed. The time that it takes to infusion the first liter (7-15 minutes) can be used for assessment and treatment**. "With the start of the second liter, transport to hospital is required and local medical support will be notified."** This addresses the medical association's concerns that transport be prioritized and ensures that the woman has replacement fluids during the transport process. LRC changes were previously made.

Cavender-Wilson moved to **adopt the new rule as amended**, Rooks second. The board voted with a **unanimous** voice vote. **Motion passed**

**FORMULARY CHANGE #2**

The next **addition to the Formulary is Tranexamic Acid (TXA) for use for Postpartum Hemorrhage, to be used when initial anti-hemorrhagic therapies fail and with notification of local medical support.** LRC corrections had been previously made. There was little discussion as it was more completely discussed at our previous meeting. Rooks moved to adopt the rule as written (after LRC changes) Cavender-Wilson second. The voice vote was unanimous. **Motion passed**

**FORMULARY CHANGE #3**

**Epinephrine HCL** Is an important medication used for **post-exposure treatment for severe allergic reactions.** The board's discussion of this medication centered around two issues

1. Epinephine HCL has a terrible **history of dosage mistakes** by medical professionals. **The dosages are weight dependent** and a mistake is often deadly**.**

a. The board addressed this issue by removing the dosage component and changed the request to use of an adult metered dose auto-injector also known as an ~~epi-pen~~ *EpiPen®*
b. The pen dosage is set at the pharmacy and cannot be changed.
c. The board added "Maternal" to the indication because infant allergic reactions are extremely rare and will *most* likely ~~never~~ *not* be needed.

2. The SDCL does **not specifically name** Epinephrine HCL.
   a. While it is not specifically named, "The ability for a health care provider to carry and to administer drugs of antibiotics, anti-hemorrhagic, or in the care for the newborn implies that they are also able to carry and administer the antidote in case of an allergic reaction…" Stevens CPM, written testimony.
   b. Severe allergic reactions to medications are rare but have become more prevalent.
   **c.** Many people at risk already carry an ~~epi-pen~~ *EpiPen®*, but **an** allergic ~~R~~reaction~~s~~ can ~~be swift and deadly.~~ *occur suddenly, requiring immediate response*.
   d. The board is **aware the LRC recommended** that we remove this change but requested that the ARSD legislators consider public safety, the implied authority to carry the antidote to any medication that could potentially cause ~~harm~~, *anaphylaxis* and the safety of the ~~epi-pen~~ *EpiPen®* ~~option~~.
   e. The board will work toward changing the verbiage in the statute as soon as possible. For the interim, the board is requesting this addition to take place immediately in order to avoid the rare possibility of an adverse event, should rural EMS be too far away.

Final discussion was CPMs will "Seek medical support immediately after administration of first injection" Activation of the EMS verbiage was rejected because sometimes it is faster to transport to the hospital via private vehicle.

**Rooks moved to adopt the rule as amended, McKay second**. The board voted by unanimous voice vote. **Motion carried**

**Additions to the formulary**

| **Drug** | **Indication** | **Dose** | **Route of Administration** | **Duration of Treatment** |
|---|---|---|---|---|
| Epinephrine HCL | Maternal post-exposure treatment for severe allergic reaction as follow-up to any approved medication | Adult metered dose auto-injector | Intramuscular injection into anterolateral aspect of the thigh via metered dose auto-injector | Seek medical support immediately after administration of first injection. May be given every 5-15 minutes as needed for up to 4 doses |
| Tranexamic Acid (TXA) | Postpartum Hemorrhage<br><br>To be used when initial anti- | 100mg/ml (1 g) | IV at 1 ml per minute | 2nd dose if bleeding continues past 30 min or restarts with 24 hours |

| | | | | |
|---|---|---|---|---|
| | hemorrhagic therapies fail and with notification of local medical support | | | |
| IV Fluids<br>• Lactate Ringers (LR)<br>• .45% Saline<br>• .9% Normal Saline | Postpartum Hemorrhage | Infuse 1 liter at wide-open rate | IV line with 16-18 gauge needle | After first liter, a second liter may be titrated to client's condition.<br>With the start of the second liter, transport to hospital is required and local medical support will be notified. |

The board completed discussion, deliberation and voting to adopt the rules. There being no further business the public hearing was adjourned at 3:20.

Respectfully Submitted

_____

Tammy Weis Exec. Secretary