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Comments of Ingrid Skop, M.D. on behalf of Charlotte Lozier Institute re: TRD-202401262, Proposed Rules concerning Exception to Abortion Ban, Abortion Ban Exception Performance and Documentation, and Complaints Regarding Abortions Performed (TAC 22 § 165.7-9)

Date: April 30, 2024 [Via Electronic Submission]

To: Texas Medical Board
1801 Congress Avenue, Suite 9.200
Austin, TX 78701

To Whom It May Concern:

I, Ingrid Skop, M.D., [OB/GYN hospitalist in Texas and Vice President and Director of Medical Affairs for Charlotte Lozier Institute (CLI)], respectfully submit the following comments on behalf of CLI in response to the Texas Medical Board's (the Board) proposed rules concerning Exceptions to Abortion Ban (§165.7), Abortion Ban Exception Performance and Documentation (§ 165.8), and Complaints Regarding Abortions Performed (§ 165.9). In these comments, I request that the Board make certain clarifying changes to the proposed regulations and/or that additional direction is provided through supporting guidance (*e.g.*, "frequently asked questions," or FAQs) provided by the Board to physicians.

I am a board-certified obstetrician and gynecologist in San Antonio, Texas, where I have practiced for over 30 years. I can personally attest to confusion among physicians when treating potentially life-threatening pregnancy complications since the *Dobbs* decision which did not exist prior to that time. Guidance from the hospital system has been important in dispelling physician confusion. The Methodist Healthcare system in San Antonio sent a notification to their providers in August 2022, reminding them of their therapeutic abortion protocol, and I have seen

little confusion among physicians in that system. The Baptist Health System in San Antonio, conversely, has not provided guidance for physicians, even though their therapeutic abortion protocol also remained unchanged. I have seen several physicians in the Baptist Health System who remained inactive in situations where they previously would have intervened. These protocols address the need for a second opinion under hospital policy (thus documenting "reasonable medical judgment" by demonstrating that another reasonable physician agreed with the action), as well as instructions for appropriate documentation of the decision-making process. Doctors need to feel supported by their medical organizations when pursuing actions that may have legal consequences.

§ 165.7. Definitions.

1. "Abortion"

The proposed definition of "abortion" implicitly provides that for a procedure to be considered an abortion, the intent of the procedure must be to end an unborn child's life. In contrast, a medically indicated separation performed to save a mother's life, such as labor induction for previable premature rupture of membranes (PPROM) with maternal infection, even if, regrettably, the child does not survive, is not an abortion under Texas law because the intent was for the mother's good, not the child's death. Please explain to physicians in greater detail the distinction between a medically indicated separation and an abortion, to reinforce doctors' ability to act within the exceptions in the law.

Also, please emphasize that miscarriage and stillbirth management are specifically allowed by Texas law. While the procedures used for induced abortion and spontaneous abortion management are often the same, miscarriage and stillbirth management are part of quality care intended to protect the mother's health after the spontaneous death of her unborn child. Media

reports of physician refusal to provide miscarriage care for women due to misunderstanding of the law reflects poor quality medical care that should not be tolerated in Texas.

2. "Ectopic pregnancy"

The law, as written, describes an ectopic pregnancy as one implanted "outside" the uterus. More accurately, an ectopic pregnancy is implantation outside of the "normal" location in the uterus. Please inform physicians by modifying the definition in the rule or through supporting documentation that this also includes cervical, cornual or cesarean scar ectopic pregnancies, even though they are technically "inside" the uterus. Importantly, even without a modified definition or additional guidance, the law allows intervention for these potentially life-threatening situations at the time of diagnosis.

3. "Medical Emergency"

Please emphasize to physicians that Texas law does NOT require that a mother's risk of death or "serious risk of substantial impairment of a major bodily function" be immediate. Recently, the Supreme Court of Texas held that Texas' abortion limit "does not require 'imminence' or … that a patient be 'about to die before a doctor can rely on the exception'" (*In re State of Texas*, No. 23-0994, Per Curiam (Dec. 11, 2023), https://casetext.com/case/in-re-state-322203). Physicians understand that it is difficult to predict with certainty whether a situation will cause a woman to become seriously ill or die, but all physicians know what situations could lead to these serious outcomes. At the time of diagnosis of a potentially life-threatening pregnancy complication, a physician must be reassured that the law allows intervention.

4. "Reasonable medical judgment"

Doctors need an explanation about what qualifies as reasonable medical judgment. In guidance provided to physicians, please emphasize that the exercise of reasonable medical

judgment means that the physician is following the standard of care, but that it is not necessary for every doctor to agree. As the Supreme Court of Texas stated, "[T]he exception is predicated on a doctor's acting within the zone of reasonable medical judgment, which is what doctors do every day. An exercise of reasonable medical judgment does not mean that every doctor would reach the same conclusion" (*In re State of Texas*).

165.8. Abortion Ban Exception Performance and Documentation.

5. § 165.8.(a)

The Board should provide to physicians all the applicable sections from the Texas Health and Safety Code Chapters 170, 170A, and 171. Physicians have limited time or willingness to research these laws on their own. This is evidenced by reported failures to treat ectopic pregnancies and miscarriages when such treatment is explicitly permitted under the law.

6. § 165.8.(b)(1)

Again, it is critical that physicians understand that the risk to a mother does not need to be immediate. It would be helpful to amend this section to state: "(1) that the abortion is performed in response to a medical emergency based on a physician's reasonable medical judgment."

7. § 165.8.(b)(3)

The Board should add the word "complication," so that the amended provision states: "what complication placed the woman in danger of death…"

8. § 165.8.(b)(7)

The Board should emphasize that transferring a patient who is facing a risk of death or serious risk of substantial impairment of a major bodily function out of state is poor quality care

and not required by law. If such threats exist, intervention can occur in Texas whether or not a fetal anomaly exists.

In the absence of a maternal risk allowing an exception by law, however, performing an abortion due to a "life-limiting" fetal condition is not permitted by Texas law. The Board should also provide information about perinatal palliative care that physicians can provide to mothers facing life-limiting prognoses for their unborn children. This information should inform parents that when babies who are diagnosed prenatally with life-limiting conditions are provided treatment, their chance of survival and length of life increase. For instance, one study showed that 20% of babies with Trisomy 13 (T13) and 13% of babies with Trisomy 18 (T18) lived at least one year, and in the U.S., babies with T13 or T18 who underwent surgery to repair heart problems had a median survival of 15 or 16 years. (*See*, "Five Facts about 'Life-Limiting' Fetal Conditions," https://lozierinstitute.org/five-facts-about-life-limiting-fetal-conditions/).

9. § 165.8.(b)

The Board should provide more guidance on what the exercise of reasonable medical judgment and the accompanying documentation look like in practice. For example, stories abound of physicians refusing to intervene for previable premature rupture of membranes (PPROM), a tragic situation where the prognosis for the fetus is very poor, and the risk to the mother from infection is high. The American College of Obstetricians & Gynecologists (ACOG) addresses this situation in their 2020 practice bulletin Prelabor Rupture of Membranes:

> Women presenting with PROM before neonatal viability should be counseled regarding the risks and benefits of expectant management versus immediate delivery. Counseling should include a realistic appraisal of neonatal outcomes [which ACOG documents elsewhere are uniformly poor]. Immediate delivery (termination of pregnancy by induction of labor or dilation and evacuation) and expectant management should be offered. (ACOG Practice Bulletin 217: Prelabor Rupture of Membranes. Obstet Gynecol 2020;135(3):80-97).

If a physician believes, in his reasonable medical judgment, that an abortion in this circumstance is necessary, he may document that his judgment meets the standard of care by referencing ACOG's guidelines. Other life-threatening diagnoses and recommendations for abortion may be documented in a similar way, by referencing guidance from ACOG or other professional association guidance or the peer-reviewed literature. In a rare situation that is not sufficiently addressed in the literature (e.g., the mother has a rare malignancy), the convening of a multidisciplinary hospital quality committee may document recommendations based on their knowledge of a specific woman's medical condition.

§ 165.9. Complaints Regarding Abortions Performed.

10. § 165.9 (b)

The Board should emphasize that disciplinary determinations will be based on whether a physician who performed an abortion exercised reasonable medical judgment (*i.e.,* followed the "standard of care" based on professional association guidance, peer-reviewed literature, and/or a multidisciplinary hospital quality committee recommendation). The Board should provide examples or detailed instructions on how reasonable medical judgment should be documented and will be evaluated by the Board.

11. § 165.9 (c)

Title 2, Subtitle B § 164.005 of the Occupations Code, which became law on September 1, 2023, states, "the (Texas Medical) Board may not take disciplinary action against a physician who exercised reasonable medical judgment in providing medical treatment to a pregnant woman as described…" (Acts 2023, 88th Leg., R.S., Ch. 913 (H.B. 3058), Sec. 1, eff. September 1, 2023). The Board should further explain this law to reassure its members that they will not lose

their licenses for treating women who are suffering from ectopic pregnancy, PPROM, or other life-threatening pregnancy complications while following the standard of care.

The Board proposes that "[a]ny decision by the Board, to either dismiss the complaint or discipline the physician who is the subject of a complaint, is separate and independent of any other possible criminal or civil action under the law. If the Board is aware the licensee is subject to a pending criminal or civil action, then the Board may defer or delay action. Depending on the outcome of criminal or civil action, the Board retains authority to investigate and potentially take disciplinary action."

If possible, the Board should act concurrently with the adjudication of any criminal or civil action. Demonstration that the physician did use reasonable medical judgment and that his actions followed the standard of care may cause a hastily charged criminal or civil complaint to be dismissed. Likewise, a determination by the Board that a physician acted outside the scope of reasonableness would be relevant to pending litigation, as evaluating the physician's actions is key to determining whether Texas laws were followed or broken. The physician and his or her patients, colleagues, and employer all benefit from a shorter timeline to understand whether disciplinary action will be taken against a practitioner's license or certifications.

Although not specifically in the Board's purview, the Board should encourage professional hospital associations and individual hospital systems to create or update existing "Therapeutic Abortion Protocols" for their physicians in consultation with their legal departments, noting that "therapeutic abortions" should be limited to those meeting the medical emergency exception in the law. Every hospital has a multidisciplinary medical quality committee as mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). If an emergency arises in which appropriate treatment is uncertain, this committee should conduct an urgent

meeting to help the treating physician make a decision that treats his pregnant patient appropriately within the law.

The Board should also recommend guidance from professional pharmacy associations regarding the appropriate use and documentation of medications that can be used to induce abortions but also have other indications, such as for miscarriage management and other gynecologic indications (mifepristone and misoprostol) and for ectopic treatment (methotrexate).

Respectfully submitted,

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