

May 4, 2024

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

Via email: Rule.165@tmb.state.tx.us

Re: Comments on Proposed Rule Changes, 22 Tex. Admin. Code §§ 165.7 – 165.9, 49 TexReg 2164 (Apr. 5, 2024)

To Whom It May Concern:

The Texas Medical Association ("TMA") appreciates the opportunity to provide comments to the Texas Medical Board ("TMB") on proposed §§ 165.7, 165.8, and 165.9, regarding the medical exceptions relating to abortions.

TMA is a private, voluntary, non-profit association of more than 57,000 physician and medical student members. It was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health.

TMA is dedicated to improving the health of all Texans and empowering Texas physicians in the practice of medicine. TMA supports efforts to protect physicians providing medically appropriate care to pregnant women and to clarify the existing medical exceptions, so that pregnant patients can access the critical care necessary to safeguard their own health and future ability to have children.

TMA notes that the TMB has announced a stakeholder meeting to be held on May 20, 2024 from 9 a.m. - 2 p.m. TMA respectfully requests to participate in the stakeholder meeting. Additionally, TMA reserves the right to modify, amend, and/or supplement its comments as the rulemaking process moves forward.

COMMENTS AND RECOMMENDATIONS

General Comments

First, TMA appreciates the TMB's efforts to engage in rulemaking on this important topic. Clarity surrounding the medical exception language is vital for both patients and physicians in Texas. However, TMA has overarching concerns that the proposal, as currently drafted: (1) does not

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provide needed clarity in this area and (2) may only serve to increase the administrative burdens imposed on physicians who are attempting to provide appropriate care in a timely manner to their patients in accordance with the medical exceptions under the law. The proposed rule, as currently drafted, dedicates much of its verbiage to repeating existing statutory language (without additional context or clarification). Then, the proposal adds a lengthy list of new *mandatory* documentation requirements that exceed the current requirements under the law (i.e., that go beyond those listed in Section 171.008, Texas Health and Safety Code).

TMA does not believe the rule language, as currently proposed, meaningfully addresses the concerns expressed by multiple stakeholders at the TMB's March 22, 2024 meeting regarding the ongoing confusion (among both patients and physicians) in this area. Moreover, TMA is concerned that the rules may: (1) work at cross purposes with their intended goal, (2) result in delays in patient care, (3) negatively impact patient care, and (4) create additional confusion (as physicians navigate a complicated array of laws in this area). TMA, therefore, *opposes* the proposed rule as currently drafted.

TMA's comments on specific sections of the rule proposal are included, below.

Proposed §165.7(2), *definition of ectopic pregnancy*

In Subpart (2) of proposed §165.7, "ectopic pregnancy" is defined as "the implantation of a fertilized egg or embryo outside of the uterus."¹ This definition tracks the language of Section 245.002 of the Texas Health and Safety Code. TMA notes, though, that recent legislation has sought to ensure medical treatment of ectopic pregnancies within the uterus too. In H.B. 3058, passed in 2023 during the 88th Regular Session, the Legislature provided additional liability defense for physicians that provide medical treatment in response to "an ectopic pregnancy at any location."² This language would include intra-uterine ectopic conditions, such as cornual, cesarean scar, or cervical ectopic pregnancies. TMA recommends that TMB broaden the proposed definition of ectopic pregnancy under the rule to include these conditions.³ Draft language to that effect is set forth below for TMB's consideration:

(2) "Ectopic pregnancy" means

(A) the implantation of a fertilized egg or embryo outside of the uterus[-and removing an ectopic pregnancy is not an abortion]. This definition is found at Chapter 245, Section 245.002(4-a) of the Texas Health and Safety Code[-]; or

(B) a fertilized egg or embryo attaching to an abnormal or scarred portion of the uterus, such as cornual, cesarean scar, or cervical ectopic

¹ 49 TexReg 2165 (Apr. 5, 2024).

² Acts 2023, 88th Leg., ch. 913 (H.B. 3058), § 1, eff. Sept. 1, 2023 (Tex. Civ. Prac. & Rem. Code Ann. §74.552).

³ TMA notes, though, that even if not included in the definition of ectopic pregnancy, these conditions would generally still fall within the definition of a "medical emergency."

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pregnancy. Providing medical treatment to pregnant woman in response to an ectopic pregnancy within the uterus is supported by Texas Civil Practice and Remedies Code §74.552.

Removing an ectopic pregnancy is not an abortion.⁴

Proposed §165.7(3), defining a "major bodily function"

Next, in proposed §165.7(3), the proposed rules state that a "major bodily function":

includes but is not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory circulatory, endocrine, and reproductive functions. *This definition is found at Chapter 21, Section 21.002(11-a) of the Texas Labor Code*.[1]

While TMA does not have major concerns with the substantive language in this proposed definition at this time (i.e., the first sentence of the proposed language), we respectfully request additional information concerning the TMB's rationale for and the intended effect of including the specific citation to the Texas Labor Code (i.e., the second sentence of the definition). Additional background on this would inform any future comments TMA makes on this proposed language in supplemental comments.

Proposed §165.8(a), Abortion Ban Exception

Next, in proposed §165.8, subsection (a) includes the following abortion prohibition language:

(a) An abortion shall not be performed in this state unless it is performed in compliance with all provisions of Texas Health and Safety Code Chapters 170, 170A, and 171, in addition to any other applicable federal and statute statutes, rules, and court opinions.⁵

It is unclear what the goal is with this proposed language as it does not provide any additional guidance to physicians or patients. Rather, it adds to the existing confusion regarding the interplay of various Texas abortion laws by adding an additional overlay of other laws, rules and (in a highly unusual fashion) court opinions.

TMA first queries: is the intent of this language to broaden the prohibition or to make a technical violation of another law or rule that does not restrict the performance of an abortion but is related to its performance (e.g., a complication reporting violation) an improper abortion? TMA notes that this is how the language as currently drafted reads. Clearly, such an extension would not be consistent with the Texas Supreme Court's statement in *In Re State of Texas* that "If a doctor, using her 'reasonable medical judgment' decides that a pregnant woman has such a condition [i.e., a condition falling within the medical exception language], then the exception applies and

⁴ The proposed rule language is shown without TMB's original underlining, so that the editing marks reflect TMA's recommended revisions.

⁵ 49 TexReg 2165.

Texas law does not prohibit the abortion."⁶ Given the potential broadened application here, TMA **opposes** this proposed language. The heading of the section could also be misleading as the title refers to the abortion ban exception and the body of the proposed rule refers to all laws, rules, etc. related to the performance of any abortion (many of which are not related to the exception).

Next, TMA is very concerned that this proposed language also includes an express requirement for physicians to comply with applicable court opinions. Mandating compliance with applicable court opinions (particularly in an area as challenging as abortion litigation) is both an unreasonable and unusual burden to place on physicians in rulemaking (as physicians are clinicians, not lawyers). Even health lawyers would find this requirement exceedingly challenging to satisfy. It's also unclear what the TMB would consider to be an "applicable" court opinion (e.g., is this supposed to be jurisdiction based, directly applicable to the physician as a named party, subject to a stay pending appeal?). And how soon would a physician need to be aware of a court's decision? Are physicians supposed to be conducting a survey of each day's court decisions prior to starting their workday or prior to the performance of each procedure itself delaying care in a medical emergency?). Physicians should not face this kind of uncertainty when providing care to women needing treatment in the face of life-threatening conditions.

If the TMB were to move forward with this language as proposed, physicians would have an even greater need for legal assistance/judgment in addition to medical judgment to properly navigate Texas abortion law and this TMB rule. The Texas Supreme Court underscored in *In re State*, 682 S.W.3d 890 (Tex. 2023)⁷ that "… [The Texas Legislature] has delegated to the medical—rather than the legal—profession the decision about when a woman's medical circumstances warrant this exception." Thus, this rule language is moving in the wrong direction. For all the foregoing reasons, TMA **opposes** the language in subsection (a) in its entirety and recommends striking it in its entirety.

TMA also notes that the inclusion of an express requirement for physicians to comply with court opinions in proposed subsection (a) while simultaneously declining to include *any* of the critical guidance from the Texas Supreme Court decision (*In Re State of Texas*) in the proposed rulemaking (which is concrete court guidance that physicians currently have) is puzzling. The Texas Supreme Court decision expressly states that:

The points we have made ... provide some clarity about the legal standards and framework for this sensitive area of Texas law. The courts cannot go further by entering into the medical-judgment arena. The Texas Medical Board, however, can

⁶ In re State of Texas, 682 S.W.3d 890, 892 (Tex. 2023).

⁷ Agencies may incorporate court precedent into agency rulemaking. See 7 Tex. Admin. Code § 3.111 (citing *Stewart v. McCain*, 575 S.W.2d 509 (Tex. 1978)); 7 Tex. Admin. Code § 21.92 (citing *Spector v. L Q Motor Inns, Inc.*, 517 F.2d 278 (5th Cir. 1975)); 7 Tex. Admin. Code § 25.19 (citing *Sexton v. Mount Olivet Cemetery Association*, 720 S.W. 2d 129 (Tex. App.-Austin 1986, no writ)); 16 Tex. Admin. Code § 3.29 (citing *Hyde Corp. v. Huffines*, 314 S.W.2d 763 (Tex. 1958)); 30 Tex. Admin. Code § 297.1 (citing *State of Texas v. Hidalgo County Water Control and Improvement District No. 18*, 443 S.W.2d 728 (Texas Civil Appeals - Corpus Christi 1969, writ ref. n.r.e.)).

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do more to provide guidance in response to any confusion that currently prevails.⁸

We respectfully ask the TMB to do more and add the Texas Supreme Court's guidance from In Re State of Texas (quoted below) into the rulemaking (which is also reflected in our comments to proposed §165.10, below):

Though courts may not expand the statute beyond the Legislature's remit, limiting a physician's judgment by construing the exception more narrowly than the statute provides would likewise be error. For example, the statute does not require "imminence" or, [] that a patient be "about to die before a doctor can rely on the exception." The exception does not hold a doctor to medical certainty, nor does it cover only adverse results that will happen immediately absent an abortion, nor does it ask the doctor to wait until the mother is within an inch of death or her bodily impairment is fully manifest or practically irreversible. The exception does not mandate that a doctor in a true emergency await consultation with other doctors who may not be available. Rather, the 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.

A pregnant woman does not need a court order to have a life-saving abortion in Texas.⁹

Proposed §165.8, Documentation Requirements

Next, in proposed §165.8, Subsection (b) would require a physician who performs an abortion in response to a medical emergency to "specifically document" certain information in the patient's medical record.¹⁰ This information includes numerous elements such as descriptions of the patient's condition, how the risk to the patient was determined, the decision-making to proceed with an abortion, additional information or sources that were consulted, and whether it was possible to transfer the patient.¹¹

TMA *opposes* the documentation requirements as currently proposed. TMA appreciates that TMB's intent underlying these requirements, as noted during TMB's March 22 meeting, is to provide a guiding framework for physicians addressing medically indicated abortions. TMA has serious concerns, though, that these documentation requirements may limit physicians' ability to exercise reasonable medical judgment in a medical emergency situation.

Specifying certain steps and considerations that must be documented could result in a "checklist" approach to care that may not be applicable or appropriate for all patients or treatment situations. And, although the TMB indicated at the March 22, 2024 meeting that it would not expect all of

⁸ In re State of Texas, 682 S.W.3d 890, 894 (Tex. 2023).

⁹ Id.

¹⁰ 49 TexReg 2165.

¹¹ 49 TexReg 2165.

these elements to be documented in the medical record *before* care is provided in a medical emergency situation, there is still a risk that this proposed language may result in a delay to patient care as physicians attempt to navigate the litany of specific considerations set forth in proposed § 165.8 (whether medically relevant to the patient presenting or not).

TMA has particular concerns about and strong objections to proposed subpart (7), which would require a physician to document "whether there was adequate time to transfer the patient, by any means available to a facility or physician with a higher level of care or expertise to avoid performing an abortion."¹² This requirement is problematic for several reasons.

First, this language could be construed as inappropriately imposing a new obligation on physicians to try to effect a transfer. No provisions in Texas Health and Safety Code Chapters 170, 170A, and 171 require a physician to consider transferring a patient experiencing a medical emergency.¹³ For example, in §170A.002, the prohibition against performing an abortion does not apply if "in in the exercise of reasonable medical judgment, the pregnant female on whom the abortion is performed, induced, or attempted has a life-threatening physical condition aggravated by, caused by, or arising from a pregnancy that places the female at risk of death or poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed or induced."¹⁴ Section 170A.002 also requires that the physician "performs, induces, or attempts the abortion in a manner that, in the exercise of reasonable medical judgment, provides the best opportunity for the unborn child to survive unless, in the reasonable medical judgment, that manner would create: (A) a greater risk of the pregnant female's death; or (B) a serious risk of substantial impairment of a major bodily function of the pregnant female.¹⁵

There is no requirement to consider whether those circumstances could change if the patient could be transferred "to a facility or physician with a higher level of care or expertise." Creating such a requirement is unsupported by the statutory framework and would delay initiation of treatment, resulting in worse clinical outcomes for pregnant patients experiencing medical emergencies.

Furthermore, this proposed language (and its new timing element) appears to conflict with the Texas Supreme Court's guidance in *In Re State of Texas*, which clarifies that the risk of death or substantial impairment of a major bodily function is not required to be imminent, fully manifest, or irreversible.

The information required under proposed Subsection (b) also exceeds the documentation required in statute. Section 171.008 of the Texas Health and Safety Code sets forth the documentation requirements for an abortion performed or induced on a pregnant woman because of a medical emergency. As such, TMA recommends that Subsection (b) of proposed §165.8 be amended by deleting the current language and incorporating the statutory documentation requirements of

¹² 49 TexReg 2165

¹³ TMB has not provided any other authorities that would require consideration of a transfer either.

¹⁴ Tex. Health & Safety Code § 170A.002(b)(2).

¹⁵ Tex. Health & Safety Code § 170A.002(b)(3).

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171.008. As TMA also recommends the deletion of subsection (a), Section 165.8 would read as follows:

§165.8.Abortion Ban Exception [Performance and]Documentation.

For an abortion performed or induced on a pregnant woman because of a medical emergency, the physician who performs or induces the abortion shall comply with the documentation requirements set forth in Tex. Health & Safety Code §171.008.

Application of Reasonable Medical Judgment to the Medical Exception

As noted above, TMA appreciates TMB's intent to provide a guiding framework for physicians addressing medically indicated abortions. TMA recommends that instead of prescribing required documentation, TMB create a separate section, §165.10, *Application of Reasonable Medical Judgment to a Medical Emergency*. This section would incorporate guidance from the Texas Supreme Court's decision in *In re State of Texas*, 682 S.W.3d 890 (Tex. 2023).¹⁶ TMA acknowledges the concern stated at TMB's March 22, 2024 meeting regarding incorporating court decisions into agency rulemaking, and that such an approach may require TMB to revisit and revise its rules in light of court decisions. However, such a process would not seem significantly more burdensome to the agency than what is regularly required to address statutory changes. As such, TMA urges TMB to not let this consideration outweigh the agency's potential to provide crucial guidance on this issue critical to the safety of pregnant women in this state. TMA recommends that §165.10 include the Texas Supreme Court's guidance on medical emergencies and medical judgment:

Though courts may not expand the statute beyond the Legislature's remit, limiting a physician's judgment by construing the exception more narrowly than the statute provides would likewise be error. For example, the statute does not require "imminence" or, [] that a patient be "about to die before a doctor can rely on the exception." The exception does not hold a doctor to medical certainty, nor does it cover only adverse results that will happen immediately absent an abortion, nor does it ask the doctor to wait until the mother is within an inch of death or her bodily impairment is fully manifest or practically irreversible. The exception does not mandate that a doctor in a true emergency await consultation with other doctors who may not be available. Rather, the exception is predicated on a

¹⁶ Agencies may incorporate court precedent into agency rulemaking. See 7 Tex. Admin. Code § 3.111 (citing *Stewart v. McCain*, 575 S.W.2d 509 (Tex. 1978)); 7 Tex. Admin. Code § 21.92 (citing *Spector v. L Q Motor Inns, Inc.*, 517 F.2d 278 (5th Cir. 1975)); 7 Tex. Admin. Code § 25.19 (citing *Sexton v. Mount Olivet Cemetery Association*, 720 S.W. 2d 129 (Tex. App.-Austin 1986, no writ)); 16 Tex. Admin. Code § 3.29 (citing *Hyde Corp. v. Huffines*, 314 S.W.2d 763 (Tex. 1958)); 30 Tex. Admin. Code § 297.1 (citing *State of Texas v. Hidalgo County Water Control and Improvement District No. 18*, 443 S.W.2d 728 (Texas Civil Appeals - Corpus Christi 1969, writ ref. n.r.e.)).

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> 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.

A pregnant woman does not need a court order to have a life-saving abortion in Texas.¹⁷

Draft language to incorporate the Court's guidance into this rulemaking is set forth below:

§165.10.Application of Reasonable Medical Judgment to a Medical Emergency.

(a) In determining whether to initiate treatment in response to a medical emergency, a physician may consider the following guidance from *In re State of Texas*, 682 S.W.3d 890 (Tex. 2023):

(1) a woman who meets the medical emergency exception need not have obtained a court order for a physician to provide an abortion;

(2) the risk of death or substantial impairment of a major bodily function is not required to be imminent, fully manifest, or irreversible;

(3) the medical emergency exception is not limited to adverse results that will happen immediately absent an abortion;

(4) A physician's determination that a medical emergency exists is not held to a standard of medical certainty;

(5) when emergency treatment is indicated, a physician need not await consultation with other physicians who may not be available; and

(6) the exercise of reasonable medical judgment does not mean that every physician would reach the same conclusion.

(b) This section does not create a standard of care and shall not be construed to establish additional requirements for determining, treating, and documenting a medical emergency.

Non-Exclusive List of Applicable Conditions

Based upon the TMB's statements at its March 22, 2024 meeting, TMA understands that the TMB is not inclined to adopt a list specifying clinical conditions that would fall within the medical emergency exception (instead noting the importance of determinations made on the basis of each patient and her physician's reasonable medical judgment). TMA supports physicians in exercising their medical judgment as appropriate to treat their patients and understands the challenges

¹⁷ In re State of Texas, 682 S.W.3d 890, 894 (Tex. 2023)

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associated with creating lists, as each patient may present differently (and, depending upon the drafting, there is a risk that one could perceive a condition that is not listed as being excluded). Thus, TMA opposes the inclusion of a list in the rule proposal. However, if TMB were to change its position and consider the adoption of a specific list of conditions, TMA notes that it would be imperative that: (1) such a list be non-exclusive/non-exhaustive (in order to avoid a perception that conditions not listed are not within the medical emergency exception), and (2) TMA be included as a stakeholder when determining any clinical conditions to include on such a list.

CONCLUSION

TMA thanks TMB for the opportunity to comment on this proposed rule and any future engagement on this issue and, again reserves the right to modify, amend, and/or supplement its comments as the rulemaking process moves forward. If you have any questions, please do not hesitate to contact Kelly Walla, Vice President and General Counsel, at <u>kelly.walla@texmed.org</u>, Eamon Reilly, Associate General Counsel, at <u>eamon.reilly@texmed.org</u>, Clayton Stewart, Vice President and Chief Lobbyist, at <u>clayton.stewart@texmed.org</u>, or Caitlin Flanders, Director of Public Affairs at <u>caitlin.flanders@texmed.org</u>.

Sincerely,

Anon m

Richard W. "Rick" Snyder, II, MD President, Texas Medical Association