TMB Releases Emergency Rules on Non-urgent Surgeries and Procedures

TMA Office of the General Counsel

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*Disclaimer: The information relating to COVID-19 is continually evolving and the information provided here is subject to change at any time. Please contact the TMA Knowledge Center (contact information provided at the end) or view the appropriate agency's website for the most up-to-date information.

On March 24, the Texas Medical Board (TMB) <u>released</u> emergency rules on the provision of non-urgent, elective surgeries and procedures in all licensed inpatient and outpatient facility and medical settings following Governor Abbott's <u>Executive Order GA-09</u>. TMB also released FAQs to provide guidance on its rules and the governor's order. TMB most recently <u>updated</u> its FAQs on March 29, 2020. The most recent version of the FAQs are discussed herein.

Importantly, please note that TMB's new updated FAQs provide a different interpretation of the governor's order and its own rules than the older version of FAQs. The prior FAQ interpreted the governor's order, as well as the board's own emergency rule 22 T.A.C. 187.57, relating to permitted procedures that do not deplete hospital capacity or personal protective equipment (PPE), more narrowly than the language in the order and rule themselves. The older, narrower version appeared to be based on a news release from the Office of the Attorney General. Now, the updated FAQs appear to align with the express language of the governor's order and the board's rules.

More on the board's rules and recently updated FAQs are discussed below.

I. Background

The executive order, issued March 22, directed all licensed health care providers to postpone all surgeries and procedures that "are not immediately necessary to correct a serious medical condition of, or to preserve the life of, a patient who without immediate performance of the surgery or procedure would be at risk for serious adverse medical consequences or death, as determined by the patient's physician." Failure to comply may result in the attorney general assessing penalties of up to \$1,000 or up to 180 days of jail time. The order is effective until April 21, 2020 and may be extended by the governor.

The purpose of the order is to preserve the availability of health care personnel, PPE, and additional hospital space to care for patients affected by the coronavirus (COVID-19). Accordingly, the governor caveated his directive, stating that "this prohibition shall not apply to any procedure that, if performed in accordance with the commonly accepted standard of clinical practice, would not deplete the hospital capacity or the personal protective equipment needed to cope with the COVID-19 disaster."

Attorney General Ken Paxton <u>stated</u> further that the order "applies throughout the State and to all surgeries and procedures that are not immediately medically necessary, including routine dermatological, ophthalmological, and dental procedures, as well as most scheduled healthcare

procedures that are not immediately medically necessary such as orthopedic surgeries or any type of abortion that is not medically necessary to preserve the life or health of the mother."

II. TMB Emergency Rules

TMB issued emergency rules (linked above) incorporating the language from the governor's order prohibiting non-urgent, elective surgeries or procedures and providing the enforcement measures it will take to support the governor's order in licensed inpatient and outpatient facility and medical settings. The two major enforcement changes are:

- 1. An <u>immediate, mandatory reporting</u> requirement for "any peer review committee, licensee, and other group, entity, or person" named in sections <u>160.003</u>, <u>204.208</u>, <u>205.304</u>, and <u>206.159</u> of the Occupations Code. These named individuals and entities must immediately report any physician "scheduling to perform, preparing to perform, performing, or who has performed a non-urgent elective surgery or procedure" to the board. The mandatory duty to report applies regardless of any other statute, rule, or provision concerning reporting timing to the board and regardless of whether "any type of proceeding, inquiry, investigation, or action of any kind is being considered, has been initiated, or is ongoing at a hospital, ambulatory surgical center, or any other facility or medical setting." See <u>22 T.A.C.</u> § <u>178.4(d)</u>.
- 2. Performance of a "non-urgent elective surgery or procedure" is now considered a "continuing threat to the public welfare," and the board's disciplinary panel may hold a temporary suspension hearing with or without notice for an alleged violation. The panel may also temporarily restrict or suspend a physician's license if the panel determines a physician's action violated this section. See 22 T.A.C. § 187.57. Note further that if a restriction or suspension occurs, even if temporary, the board will report it to the National Practitioner Data Bank. Keep in mind though, the board can only act on a valid complaint. And the action the board takes depends on the "level of urgency to address the alleged violation." See TMB FAQ No. 16. For more information on the enforcement process, please look to the board's FAQs or TMB's rules. Also to be clear, TMB does not have the authority to assess the penalties described in the governor's order or to order jail time. The TMB retains its regular enforcement authority.

III. TMB FAQs

TMB also published FAQs,¹ updated most recently on March 29, to assist physicians in determining what is considered an elective, non-urgent procedure or surgery and when such procedure or surgery can be performed in inpatient and outpatient facility and medical settings while the executive order is effective. The board's FAQs provide a four-step analysis to assist physicians in making these decisions. However, before moving to the analysis, it is important to note four items:

¹ Please continue to check the board's <u>website</u> for the most up-to-date information as information is constantly changing to address the impact of the coronavirus.

First, the board describes non-urgent, elective surgeries or procedures as the following:

Non-urgent elective cases are being defined as instances where **there is no anticipated short-term nor long-term negative impact** on the patient because of delaying a procedure or surgery. Examples include screening for a *non-life-threatening*, chronic condition and most cosmetic procedures.

(Emphasis added).

Second, the board exempts certain medical acts from the term "procedures" for the purpose of enforcing the order—the board expressly states in its FAQs that a "procedure" does *not* include physical examinations, noninvasive diagnostic tests, the performing of lab tests, or obtaining specimens to perform laboratory tests.

Third, the governor's order provides two categories of surgeries or procedures that may be performed: (1) a surgery or procedure that is immediately necessary to correct a serious medical condition of, or to preserve the life of, a patient who would be at risk for serious adverse medical consequences or death if the procedure or surgery did not immediately occur, as determined by the physician; or (2) a procedure, performed in accordance with the applicable standard of care, that will not deplete hospital capacity or PPE needed to fight COVID-19. TMB's rules and FAQs reflect the same. See 22 T.A.C. § 187.57(c); TMB FAQs Nos. 2, 5.

Fourth, TMB expressly recognizes that a physician's judgment in this matter is important. Indeed, it states that both the governor's order and its emergency rules allow physicians "to use their own judgment in determining whether a surgery or procedure will prevent serious adverse medical consequences or death.

A. TMB's Four-Step Analysis

The board provides a four-step analysis to assist physicians in determining if a surgery or procedure is permissible under the order and the board's rules. *See* TMB FAQ No. 19.

- 1. First, does the prohibition apply to the physician or the physician's practice?
 - a. The order applies to all licensed health care providers and their delegates, as well as all licensed health care facilities, including hospitals, medical spas, and ambulatory surgical centers. This also includes a physician's office if a surgery or procedure is being performed in violation of the order and the board's rules.
 - b. If a physician answers yes to this question, then the physician should proceed to question two.
- 2. Second, is the medical act a surgery or "procedure"?
 - a. The board expressly states in its FAQs that a "procedure" does *not* include the following: physical examinations, noninvasive diagnostic tests, the performing of lab tests, or obtaining specimens to perform laboratory tests. Thus, these medical acts are outside the scope of the governor's order. If a physician is performing one of these carved-out acts, the analysis ends, and the physician may perform the medical act.

- b. Otherwise, if the answer is yes, the physician should proceed to question three.
- 3. Third, is the surgery or procedure, in the physician's judgment, "immediately medically necessary":
 - a. Is this immediately medically necessary to correct a serious medical condition or to preserve the life of a patient? If yes, the physician moves to the second part below.
 - b. Part Two: Would this patient, without immediate performance of the surgery or procedure, be at risk for serious adverse medical consequences or death?
 - c. **TMB recognizes that the physician's judgment is important for this element. TMB FAQs No. 13, 20. Indeed, its FAQ No. 20 expressly states that the governor's order and the board's rules allow physicians to "use their judgment in determining whether a surgery or procedure will prevent serious adverse consequences or death."

If the physician answers "yes" to these two questions, then the physician may proceed with the surgery or procedure.

If the physician answers "no," and the medical act is a <u>surgery</u>, the surgery is prohibited according to the board's FAQs.

If the physician answers "no," and the medical act is <u>a procedure</u>, then the physician should proceed to question four.

- 4. Fourth, if it is a *procedure*, does it deplete PPE or hospital bed capacity needed to cope with COVID-19 disaster when performed in accordance with the commonly accepted standard of clinical practice?
 - a. If the answer is no, then the physician may perform the procedure.
 - b. If the answer is yes, then the physician may not perform the procedure under the board's FAQs.

In making these determinations using the board's analysis, TMB also suggests reviewing FAQ 13, which describes what facilities generally consider "elective, non-urgent," "urgent or elective urgent," and "emergent." For convenience, those descriptions are provided here:

- 1. "<u>Elective, non-urgent</u>" cases are defined as cases where there is no anticipated short term nor long-term negative impact as a result of delaying a procedure or surgery. Examples are screening for a nonlife-threatening chronic condition or most cosmetic procedures.
- 2. "<u>Urgent or Elective Urgent</u>" means a surgery or procedure is scheduled where there is a risk of patient deterioration or disease progression that is likely to occur if the procedure or surgery is not undertaken immediately and/or the surgery or procedure is significantly delayed. The resulting decline in the patient's health could make them more vulnerable to COVID-19 and other issues.
- 3. "**Emergent**" means a life-threatening condition in which the surgery or procedure must be undertaken and/or cannot be safely delayed for any significant period of time.

B. Documentation

The board stresses that in these fact-specific cases, documentation is "key." Specifically, the board's FAQs state:

It is very important that the medical record clearly reflects why the elective surgery or procedure was necessary to prevent serious adverse medical consequences or death. This documentation could include information on the patient's medical history, prescriptions, lab results, imaging, or other relevant factors used to help make the determination of the necessity of the surgery or procedure.

TMB will determine if a surgery or procedure was medically necessary (or if not, does not deplete PPE or hospital bed capacity) by, among other things, reviewing the patient's medical records. Documentation should include information describing the factors that, in the physician's judgment, made the procedure or surgery immediately necessary to prevent serious adverse medical consequences or death. Boilerplate language or rubber stamping a patient's file is likely insufficient.

It is also particularly important for a physician being delegated tasks to document the information communicated if the delegate agrees the surgery or procedure is immediately medically necessary (or if the delegate does not believe it is and is not going to perform the delegated task). And of course, if a physician feels a prohibited procedure or surgery is being planned, is being performed, or was performed, the physician should comply with the board's mandatory reporting requirement. Reporting under the emergency rule is immune from civil liability under Section 160.010 of the Texas Medical Practice Act, and the prohibitions on discipline and discrimination under Section 160.012 of the act also protect reporters.

Also it may be helpful, given the uncertainty at this time, to document a physician's decision to delay a procedure or surgery. For example, a physician might include the factors for his or her decision and cite to the executive order and board's emergency rules, as well as any specific board FAQ the physician may be relying on for the delay. Proper documentation may provide the physician support in the event a patient suffers an unanticipated negative consequence due to the delay mandated by the governor's order and the board's emergency rules.

The board may continue to update its FAQs or release other guidance as it obtains new information. It is good risk management practice to retain a copy of each FAQ or other guidance. Each FAQ and other guidance is generally dated. This is important, because a physician may have made a decision on a date an earlier FAQ was in place that may or may not be permissible under a new FAQ. Maintaining a copy of each update, as well as a copy of the executive order and the news release by the Office of the Attorney General (linked above) is a good risk management practice during this confusing and ever-changing time period.

C. Medical Acts that are Generally Prohibited or Permitted

The board's FAQs identify the following surgeries or procedures that are generally prohibited while the order is in effect:

- 1. Screening for a nonlife-threatening chronic condition,
- 2. Most cosmetic procedures,
- 3. Routine dermatological procedures,
- 4. Routine ophthalmological procedures,
- 5. Routine dental procedures,
- 6. Non-emergent orthopedic surgeries,²
- 7. Most cosmetic and plastic surgeries,
- 8. Nonsurgical cosmetic procedures, and
- 9. An abortion not medically necessary to preserve the life or health of the mother.

The board expressly identifies the following medical acts as permissible and outside the governor's order:

- 1. Office-based visits that do not require surgery or procedures (so long as conducted in accordance with standard protocols, including safety measures that prevent the spread of COVID-19),
- 2. Non-procedures (as carved out by the board's definition of "procedures") that involve:
 - a. Physical examinations,
 - b. Noninvasive diagnostic tests,
 - c. The performing of lab tests, or
 - d. Obtaining specimens to perform laboratory tests; and
- 3. Surgeries or procedures immediately medically necessary to correct a serious medical condition of, or to preserve the life of, a patient who without immediate performance of the surgery or procedure would be at risk for serious adverse medical consequences or death, as determined by the patient's physician.

D. TMB's 10 Tips

TMB also provided 10 tips to help physicians navigate the board's new emergency rules:

- 1. The governor's order and TMB's rules allow physicians to use their judgment in determining whether a surgery or procedure will prevent serious adverse medical consequences or death.
- 2. If a physician could or would normally wait a few weeks to provide the surgery or procedure being considered for a specific patient based on the patient's unique circumstances, then that might help the physician decide what to do.

² This appears to be a typo and should instead read "non-urgent." TMA will seek clarification and ask the board to change this to "non-urgent," which is consistent with the board's rules.

- 3. If a physician normally could not or would not wait a few weeks to provide the surgery or procedure being considered for a specific patient based on the patient's unique circumstances, then that might help the physician decide what to do.
- 4. If a physician proceeds with a surgery or procedure during this time, then he or she should clearly document why the decision was made (also revisit TMA's recommendation on documentation for delaying surgeries or procedures in Section III.B above).
- 5. Referencing legitimate literature and guidelines, such as the CDC, CMS, or specialty guidelines will be very helpful.
- 6. TMB cannot put anyone in jail.
- 7. The decision to hold a temporary suspension or restriction hearing will meet the same standard as before the COVID-19 disaster.
- 8. TMB understands the importance of having as many safe licensees available as possible during this time.
- 9. The TMB Board Members include 12 physicians that also must navigate these times, the Executive Order, and the rules while providing safe patient care.
- 10. TMB is and will continue to be understanding that these are unprecedented times.

IV. Additional Information

Please remember that the board's FAQs are intended to provide guidance—the FAQs are not law; however, they reflect the board's view on its enforcement authority and how it intends to apply its rules. Note also that the board's FAQs do not govern how the attorney general will enforce the governor's order. Other than the statement released from the attorney general cited and linked to above, there is no additional information from the Office of the Attorney General at this time on enforcement.

As part of its tips, TMB stated it would be helpful for a physician to refer to "legitimate literature and guidelines, such as CDC, CMS, or specialty guidelines." *See* TMB FAQ No. 20. Accordingly, TMA prepared a <u>document</u> with a compilation of links to resources providing guidance on non-urgent, elective surgeries or procedures, including links to guidance from national medical specialty societies. These resources may be helpful to review. **However, these resources do not bind TMB or the attorney general's interpretation and enforcement of the governor's order. TMA strongly recommends that a physician seek the advice of his or her retained attorney to help navigate the governor's order and the board's rules.**

TMA will continue to update you on developments from TMB regarding its rules and guidance. For a specific fact analysis under the new emergency rules and order, please contact your retained attorney for legal advice. For general questions on the rule and order, please contact the TMA Knowledge Center by email at knowledge@texmed.org or by phone at (800) 880-7955.

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