

The Texas Medical Board (Board) proposes new rule concerning Chapter 173, Office-Based Anesthesia Services, Subchapter B, concerning Parenteral Ketamine Therapy, §§173.6-173.18.

The proposed new sections are as follows:

New §173.6, Definitions, sets forth definitions for ketamine administration and psychotropic ketamine therapy (PKT).

New §173.7, Exception for Licensed Hospice Provider, provides an exception to the application of the rules under the subchapter for patients enrolled in a hospice program licensed by Texas Health and Human Services.

New §173.8, Mandatory Registration, requires registration for practice settings providing psychotropic ketamine therapy and provides exceptions to registration for certain practice settings.

New §173.9, Operation of PKT Clinics, sets forth requirements for operation of clinics providing PKT and limits the administration of psychotropic ketamine therapy to physicians and midlevel providers. The new section further specifies training, certification, patient monitoring, emergency management and consultation and delegation requirements for the provision of psychotropic ketamine therapy. The new section provides that delegating physicians are limited to delegating to no more than six delegates total or delegates at no more than three PKT clinics, whichever is less.

New §173.10, Physician Requirements, sets forth requirements for physicians ordering PKT for psychiatric indications. The requirements include education and training, delegation, Prescription Monitoring Program verifications, maintenance of ASA guidelines for moderate sedation, and pregnancy verification for women of child-bearing age.

New §173.11, Minimum Standards When Administering PKT, sets forth minimum standards related to medical record documentation, patient evaluation, diagnosis, informed consent, time out procedures, continuous monitoring; and equipment standards when providing psychotropic ketamine therapy.

New §173.12, Monitoring Requirements During PKT Administration, sets forth additional requirements for administering or delegating physicians to ensure adequate monitoring during PKT administration, until complete.

New §173.13, Monitoring Requirements After the Completion of PKT Administration, sets forth monitoring requirements for patients upon completion of PKT administration and prior to discharge.

New §173.14, Minimum Equipment Requirements, sets forth on-site equipment requirements for continuous monitoring and in cases of emergency.

New §173.15, Prohibited PKT Administration, provides that the following prohibitions on parenteral PKT apply: the administration of PKT outside of a registered clinic or an exempt setting set forth under Section 173.8 and the prescribing of PKT for home use.

New §173.16, Complaints and Investigations, clarifies that the medical director and physician owner(s) are responsible for the clinic's operations and regulatory compliance.

New §173.17, Renewal of PKT Clinic Registration, sets forth a registration term of two years and registration renewal requirements.

New §173.18, Audits, Inspections, and Investigations, mandates that psychotropic ketamine therapy clinics be subject to audits, inspections and investigations as outlined in Chapter 172 of the Board rules related to pain management clinics.

Mr. Scott Freshour, General Counsel for the Texas Medical Board, has determined that, for each year of the first five years the proposed new rules are in effect, the public benefit anticipated as a result of enforcing these proposed new rules will be to enhance the safety of the public health and welfare through the establishment of minimum standards for the provision of psychotropic ketamine therapy.

Mr. Freshour has also determined that for the first five-year period these proposed new rules are in effect, there will be no fiscal impact or effect on government growth as a result of enforcing the proposed sections.

Mr. Freshour has also determined that for the first five-year period these proposed new sections are in effect there may be a minimal economic cost to individuals required to comply with these proposed sections. Those economic costs will vary and may include the following: 1) new education and training requirements for ketamine clinic providers and staff; 2) possible increased staffing to meet requirements for the evaluation of patients and administering and monitoring of patients receiving PKT; and 3) costs related to purchasing equipment required for monitoring patients receiving PKT treatment. The expenditures described above will be one-time expenditures and may not apply if an individual subject to these rules already meets the requirements.

Pursuant to Texas Government Code §2006.002, the agency provides the following economic impact statement for these proposed new sections and determined that for each year of the first five years these proposed new sections will be in effect there will be no effect on small businesses, micro businesses, or rural communities. The agency has considered alternative methods of achieving the purpose of these proposed new sections and found none.

Pursuant to Texas Government Code §2001.024(a)(4), Mr. Freshour certifies that this proposal has been reviewed, and the agency has determined that for each year of the first five years these proposed new sections are in effect:

(1) TMB is unable to determine how many clinics exist at this time; however, the initial registration function can likely be absorbed with existing resources. The subsequent enforcement, if any, is variable based on the number of complaints received. TMB also has inspection authority which

will be conducted with existing resources in a manner similar to the existing office-based anesthesia inspections. There is no additional estimated cost to the state or to local governments expected as a result of enforcing or administering these proposed new sections; the jurisdiction is exclusive to the Texas Medical Board.

(2) there are no estimated reductions in costs to the state or to local governments as a result of enforcing or administering these proposed new sections;

(3) there is no estimated loss and no increase in revenue to the state or to local governments as a result of enforcing or administering these proposed new sections; and

(4) there are no foreseeable implications relating to cost or revenues of the state or local governments with regard to enforcing or administering these proposed new sections.

Pursuant to Texas Government Code §2001.024(a)(6) and §2001.022, the agency has determined that for each year of the first five years these proposed amendments will be in effect, there will be no effect on local economy and local employment.

Pursuant to Government Code §2001.0221, the agency provides the following Government Growth Impact Statement for these proposed new sections. For each year of the first five years these proposed new sections will be in effect, Mr. Freshour has determined the following:

(1) the proposed rules do not create or eliminate a government program;

(2) implementation of the proposed rules does not require the creation of new employee positions or the elimination of existing employee positions;

(3) implementation of the proposed rules does not require an increase or decrease in future legislative appropriations to the agency;

(4) the proposed rules do not require an increase in fees paid to the agency;

(5) the proposed rules do create a new regulation;

(6) the proposed rules do not expand, limit, or repeal an existing regulation;

(7) the proposed rules do increase the number of individuals subject to the rule's applicability; and

(8) the proposed rules do not positively or adversely affect this state's economy.

Comments on the proposal may be submitted using this link

<https://forms.cloud.microsoft/g/WrgW5yPyKm> or e-mail comments to:

[rules.development@tmb.state.tx.us](mailto:rules.development@tmb.state.tx.us). A public hearing will be held at a later date.

The proposed new rule(s) are proposed pursuant to Texas Occupations Code Section 153.001. No other statutes, articles or codes are affected by this proposal.

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## SUBCHAPTER B PARENTERAL KETAMINE THERAPY

### §173.6. Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

(1) Ketamine Administration--The administration of parenteral ketamine (IV, subcutaneous and IM) is the practice of medicine under Section 157.002 of the Act and is subject to regulation by the Texas Medical Board, including required registration under this Chapter.

(2) Psychotropic Ketamine Therapy (PKT)--The administration of parenteral ketamine in a low-dose for psychiatric indications that have been evaluated and diagnosed by a physician such as PTSD, treatment-resistant depression and suicidal ideation.

### §173.7. Exception for Licensed Hospice Provider

The rules promulgated under this Subchapter do not apply to hospice programs licensed by the Texas Health and Human Services Commission with regard to the administration of ketamine to patients enrolled in such hospice programs.

### §173.8. Mandatory Registration

(a) Any medical practice, clinic or facility providing PKT must be registered with the Board, except the following:

- (1) a medical school or an outpatient clinic associated with a medical school;
- (2) a hospital, including any outpatient facility or clinic of a hospital;
- (3) a facility maintained or operated by this state;
- (4) a medical clinic maintained or operated by the United States; or
- (5) a health organization certified by the board under Section 162.001 of the Act.

(b) Registration requires completion of a board-approved application filed by a physician owner or medical director of the clinic including providing all required information and documentation.

(c) Applications are valid for 180 days from the date of submission. If the applicant fails to provide all required information and documentation the application will be deemed withdrawn.

(d) If the application is approved, the registration is good for two years from the date of approval.

#### §173.9. Operation of PKT Clinics

(a) The provision of PKT must comply with all applicable federal and state laws.

(b) The physician prescribing PKT for psychiatric indications must have successfully completed within the past two years a formal airway management education or must have completed a course on airway management for moderate sedation and:

(1) training in mental health treatment; or

(2) a course on the use of ketamine for psychiatric conditions.

(c) The physician ordering the PKT must have a properly established physician-patient relationship and have properly documented and diagnosed psychiatric indications supporting PKT.

(d) PKT may be administered only by a physician, certified registered nurse anesthetist (CRNA), advanced practice registered nurse (APRN), or physician assistant (PA) acting under appropriate delegation by a licensed physician for psychiatric indication as identified in the definition of PKT.

(e) If the patient is simultaneously receiving ketamine treatment for any other medical condition, such as pain, then the physician must follow whichever standards or requirements are stricter, such as rules governing standards for office-based anesthesia, relating to Subchapter A of this Chapter.

(f) A CRNA, APRN, or PA working under physician delegation to administer PKT, or a CRNA, APRN, PA, or registered nurse (RN) working under physician delegation to monitor a patient during and after administration of PKT must have successfully completed within the past two years a formal airway management education or must have completed a course on airway management for moderate sedation.

(g) There must be a physician, CRNA, APRN, PA, or RN present as required in Sections 173.11 and 173.12 of this Subchapter.

(h) In cases requiring consultation, the physician owner, medical director, or delegating physician must be immediately available throughout the PKT administration as follows:

(1) in-person on-site; or

(2) by two-way audiovisual technology.

(i) In cases requiring emergency management, if the physician owner, medical director, or delegating physician is not in-person on-site, then the physician owner, medical director, or

delegating physician must have the ability to be on-site within 30 minutes by ground transportation.

(j) Any location administering PKT must keep and maintain an adverse event reporting log, organized by year. Each log must be maintained for a period of at least three years. The log must list any event involving airway intervention, EMS transport, hospitalization, or death. The log must include the following information:

- (1) patient name;
- (2) date of adverse event;
- (3) type of adverse event; and
- (4) outcome, if known.

(k) A physician owner, medical director, or delegating physician must physically inspect each clinic site once every 30 days.

(l) A medical director shall:

- (1) be limited to registering and acting as medical director for a maximum of three PKT clinics; and
- (2) meet the requirements of the prescribing physician under subsection (b) of this section.

(m) The physician owner or medical director may designate one or more delegating physicians who must be the physician ordering the PKT. Any delegating physician shall:

- (1) be limited to delegating to no more than six delegates total or delegates at no more than three PKT clinics, whichever is less; and
- (2) meet the requirements of the prescribing physician under subsection (b) of this section.

#### §173.10. Physician Requirements

(a) The physician ordering PKT for psychiatric indications must have successfully completed:

- (1) training in mental health treatment; or
- (2) a course on the use of ketamine for psychiatric conditions.

(b) The physician ordering PKT must have a properly established physician-patient relationship and have properly documented and diagnosed psychiatric indications supporting PKT.

(c) The physician ordering PKT must ensure that the patient evaluation, the administration of PKT, and the monitoring of the patient meets the latest moderate sedation guidelines as published

by the American Society of Anesthesiologists, depending on the intended level of anxiolysis or sedation to be achieved.

(d) The following physicians shall be considered equally responsible for meeting the American Society of Anesthesiologists moderate sedation guidelines, depending on the intended level of anxiolysis or sedation to be achieved, for all patients being treated with PKT regardless if the patient was treated by a physician, CRNA, APRN, or PA:

- (1) the physician owner;
- (2) the medical director; and
- (3) the delegating physician.

(e) For women of childbearing age, a negative urine pregnancy test must be administered at the clinic on the day of treatment and documented in the records, unless it is documented in the medical record that such patient is medically unable to become pregnant.

(f) The physician ordering PKT must review the Prescription Monitoring Program when establishing a physician-patient relationship, and on at least a quarterly basis for existing patients.

(g) If the physician ordering PKT delegates the administration of PKT, the physician ordering PKT must have protocols or standing delegation orders issued and maintained at the location where the PKT is being administered.

(h) When providing or delegating PKT services, physicians must ensure compliance with delegation and supervision laws under Chapter 157 of the Act and Chapter 169 of this title.

#### §173.11. Minimum Standards When Administering PKT

(a) The following minimum standards must be met when PKT is administered:

- (1) the PKT order from the delegating physician must be verified, if applicable;
- (2) the physician is responsible for ensuring the standard of care is met;
- (3) informed consent must be provided to the patient, including:
  - (A) a discussion of known risks of PKT; and
  - (B) the identity and licensure credentials of the person administering PKT;
- (4) a time out period must be implemented immediately prior to beginning administration of PKT; and
- (5) complete, contemporaneous, and legible medical records regarding patient monitoring and status must be maintained throughout the administration of PKT.

(b) Patient monitoring and status must include continuous appropriate physiologic monitoring of the patient, both during PKT administration and post administration until ready for discharge.

(c) Continuous monitoring for administration and discharge must include the following:

- (1) blood pressure;
- (2) pulse;
- (3) respiration;
- (4) oxygen saturation;
- (5) cardiovascular status; and
- (6) appropriate responsiveness to verbal stimuli.

(d) The administration of PKT is limited to a qualified physician, CRNA, APRN, or PA.

(e) If a physician is present on-site during the administration of PKT, then:

(1) the physician is limited to administering PKT to no more than four patients at a time; and

(2) if the physician is delegating the administration of PKT, then the physician has the discretion to allow each delegate to administer PKT to no more than four patients at a time.

(f) If a physician is not present on-site during the administration of PKT, then the delegating physician's delegate may not administer PKT to more than two patients at a time.

(g) If the administering physician or delegate is administering PKT to more than one patient simultaneously, then the administering physician or delegate cannot also be the sole person monitoring the patient during PKT administration.

(h) The administration of PKT is complete:

- (1) Upon completion of the IV drip; or
- (2) 40 minutes after the completion of the IM or subcutaneous injection.

#### §173.12. Monitoring Requirements During PKT Administration

(a) In addition to the general monitoring requirements set forth in Section 173.11 of this Subchapter, the administering or delegating physician must ensure there is monitoring of each patient until the PKT administration is complete as follows:

(1) If the delegating physician is on-site, then the delegating physician has the discretion to allow no more than four patients to be monitored by a single monitoring physician, CRNA, APRN, PA or RN; or

(2) If the delegating physician is not on-site, then no more than one patient may be monitored by a single monitoring CRNA, APRN, PA or RN.

(b) The monitoring of PKT administration is limited to a qualified physician, CRNA, APRN, PA, or RN.

#### §173.13. Monitoring Requirements After the Completion of PKT Administration

(a) Upon completion of the PKT administration, each patient must meet the following recovery and monitoring requirements prior to discharge:

- (1) A minimum 30-minute observation period;
- (2) at least two blood pressure readings 10 minutes apart; and
- (3) a full cognitive assessment (including an Aldrete score).

(b) The recovery, monitoring, and discharge assessment of patients shall have a maximum ratio of one monitoring delegate to every four patients.

#### §173.14. Minimum Equipment Requirements

(a) The following equipment must be utilized for continuous cardiorespiratory monitoring of the patient during and after administration of PKT:

- (1) pulse oximetry; and
- (2) incremental blood pressure checks.

(b) The following items must be on-site at all times and readily available, in case of an emergency:

- (1) Supplemental oxygen,
- (2) a bag-valve mask,
- (3) an AED (or defibrillator) and
- (4) an end-tidal carbon dioxide analyzer.

#### §173.15. Prohibited PKT Administration

The following prohibitions on parenteral PKT apply:

(1) the administration of PKT outside of a registered clinic or an exempt setting set forth under Section 173.8 of this Subchapter; and

- (2) the prescribing of PKT for home use.

#### §173.16. Complaints and Investigations

The physician owner and medical director are responsible for the clinic's operations and patient care and ensuring compliance with all applicable regulations.

§173.17. Renewal of PKT Clinic Registration

(a) Registration is effective for two years following the date of initial registration. At least 60 days prior to the expiration of the PKT registration, a physician, clinic or facility seeking renewal must submit:

(1) a board-approved application; and

(2) an attestation stating that the requirements, standards and equipment comply with all applicable laws and board rules.

(b) Upon expiration of the current registration, the clinic must cease PKT operations until the registration is renewed.

§173.18. Audits, Inspections, and Investigations

PKT clinics are subject to audits, inspections and investigations as outlined in Chapter 172 of the Board rules related to pain management clinics.