

Subchapter B – Parenteral Ketamine Therapy Standards

§173.6. Definitions

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

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

(b) Adverse Event – Any event that requires or results in:

- (1) emergency transportation;
- (2) a compromised airway;
- (3) resuscitative efforts on the patient;
- (4) psychotropic events;
- (5) hospitalization; or
- (6) death.

(c) Initial dose – For purposes of Parenteral Ketamine Therapy (PKT) means the starting dose for any PKT is not to exceed 0.5mg/kilogram of body weight over a 40-minute period. This dose can be titrated up based upon protocol and clinical judgment in conjunction and consistent with appropriate physician consultation.

(d) Medical Director – For purposes of this rule the term Medical Director means the physician who provides medical oversight at a PKT Practice.

(e) PKT Practice – For purposes of this rule, a PKT practice is any medical practice, clinic, or facility that administers PKT and is not regulated or licensed by another Texas agency or commission.

(f) Practitioner – Means an APRN or PA for the purpose of this subchapter.

(g) Psychotropic Ketamine Therapy (PKT) – The administration of parenteral ketamine by a physician, or by an advanced practice registered nurse (APRN), physician assistant (PA), or

registered nurse (RN) through a properly established physician-patient relationship under delegatory authority for psychiatric indications such as, but not limited to, post-traumatic stress disorder (PTSD), treatment-resistant depression, severe anxiety, obsessive compulsive disorder (OCD), bipolar depression and suicidal ideation. The psychiatric indications may have been originally diagnosed by a physician or by an APRN, PA, or licensed mental health provider (PsyD, LPC, LPC-A, LCSW, LMSW, LMFT) under proper delegation and supervision. Any physician or practitioner establishing the doctor-patient relationship under delegatory authority for PKT administration is responsible for evaluating the diagnosis for psychiatric indications if not making the original diagnosis indicating PKT therapy. The dosages for the administration of PKT must always be intended at a level below moderate sedation.

§173.7. Mandatory Registration.

(a) Subject to the exceptions under Section 173.8 of this Subchapter, all PKT Practices must be registered by the Medical Director with the Board.

(b) Registration requires completion of a board-approved application filed by the 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 timely 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.

(e) All PKT Practices must meet all requirements set forth under this Subchapter no more than 180 days after the date of adoption of this rule.

(f) Notwithstanding Subsection (e), all PKT Practices must comply with the adverse reporting requirements set forth in Section 173.14 of this Subchapter.

173.8 Exemptions from Registration.

The following are exempt from registration and the rules promulgated under this Subchapter:

(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;

(5) a health organization certified by the board under Section 162.001 of the Medical Practice Act; or

(6) a hospice program licensed by the Texas Health and Human Services Commission to administer ketamine to patients enrolled in such hospice programs.

§173.9. Renewal of PKT Practice Registration

(a) Registration is effective for two years following the date of initial registration.

(b) At least 60 days prior to the expiration of the PKT registration, the Medical Director of the PKT Practice seeking renewal must submit:

(1) a board-approved application;

(2) an attestation stating that the PKT Practice complies with all applicable laws and board rules; and

(3) the PKT Practice's adverse event log; and

(4) any other documentation required by the Board.

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

§173.10. Medical Director Requirements

(a) To be eligible to act as a Medical Director, the physician must:

(1) hold a current, full, and unrestricted Texas medical license;

(2) have no prior disciplinary action or history regarding any medical license in any state, including Texas; and

(3) not have a pending investigation or a proceeding regarding their medical license in any state, including Texas;

(b) A Medical Director is subject to the following requirements and restrictions:

(1) The Medical Director must physically inspect and document the inspection of each location where PKT is administered:

(A) within seven days of becoming the Medical Director; and

(B) at least once every 90 days;

(2) The Medical Director's name, title, and license number must be;

(A) disclosed in writing to all patients;

(B) displayed in each public area and treatment room of the PKT Practice; and

(C) clearly identified on the PKT Practice's website and advertising;

(3) A PKT Practice may not administer PKT without a Medical Director designated in writing, with written confirmation of the designation by the Medical Director;

(4) The Medical Director need not be physically present at the PKT Practice except that the Medical Director must be:

(A) physically present in Texas while providers at the clinic are administering PKT; and

(B) immediately available for emergency consultation;

(5) The Medical Director must approve in writing all physicians, practitioners, and RNs administering PKT or monitoring PKT patients. The Medical Director may approve one or more additional physicians to be delegating and supervising physicians of practitioners and RNs at the PKT Practice;

(6) The Medical Director has concurrent responsibility for the delegation and supervision of all practitioners and RNs at the PKT practice even if those practitioners and RNs are administering PKT or monitoring PKT patients under the direction of an approved physician as described in Subsection (5) above;

(7) The Medical Director is prohibited from requiring any practitioner or RN to obtain a separate delegating and supervising physician; and

(8) The Medical Director may provide oversight at no more than three (3) medical practices, clinics, or facilities of any type.

(c) The Medical Director has overall responsibility and oversight for the care provided at the PKT Practice and must ensure:

(1) any physicians or practitioners ordering PKT must demonstrate current and on-going proficiency in the use of PKT for psychiatric conditions, including but not limited to the possible adverse effects of treatment;

(2) the physician or practitioner ordering PKT has a properly established physician-patient relationship under delegatory authority, and has properly documented and diagnosed psychiatric indications supporting PKT;

(3) patient evaluation, administration of PKT, and patient monitoring is delivered in accordance with evidence-based protocols to treat diagnosed psychiatric indications with parenteral ketamine administration at dosages below moderate sedation, based on current peer-reviewed literature;

(4) the physician or practitioner ordering PKT has reviewed the Prescription Monitoring Program (PMP):

(A) upon establishing a physician-patient relationship with a new patient; and

(B) on at least a quarterly basis for existing patients;

(5) the practitioner ordering PKT is acting under protocols or standing delegation orders maintained at the location where the PKT is being administered;

(6) that all physicians, practitioners, and RNs administering PKT or monitoring a patient during and after administration of PKT have demonstrated current and on-going proficiency in managing adverse events as defined in this Subchapter; and

(7) that all standards under this Subchapter are being met and complied with by all physicians, practitioners, and RNs providing patient care.

§173.11 Operation of PKT Practices

(a) A PKT Practice must have a Medical Director.

(b) A PKT Practice may have no more than one Medical Director at any time.

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

(d) The practitioner ordering PKT must have a properly established a physician-patient relationship under delegatory authority, and have properly evaluated, documented, and diagnosed psychiatric indication supporting PKT.

(e) PKT may only be administered by a physician or a practitioner or RN acting under appropriate delegation by a physician for psychiatric indication as identified in the definition of PKT. If an RN is administering PKT, a physician or practitioner must be physically present on site at all times.

(f) Prior to administration of PKT, the following must be completed and documented:

(1) informed consent from the patient, including:

(A) a discussion of known risks of PKT;

(B) the identity and licensure credentials of the;

(i) the person administering PKT to the patient; and

(ii) the person delegating to and supervising the person in Subsection (i) above, if applicable; and

(2) a pregnancy test or written affirmation on the day of treatment from women of childbearing age that they are not pregnant; and

(3) a time out period must be utilized immediately prior to beginning administration of PKT.

(g) If the patient is simultaneously receiving ketamine treatment for any other medical condition, then protocols set forth by the Medical Director must require that the practitioner ordering or administering PKT:

(1) review the primary diagnosis and the standard of care that applies to that diagnosis;

(2) review the PMP before every treatment; and

(3) not exceed Initial Dose without consulting with the Medical Director or an approved physician.

(h) During PKT administration, continuous monitoring must include the following and be documented in the chart at minimum every 10 minutes:

(1) blood pressure;

(2) pulse;

(3) respiration;

(4) oxygen saturation;

(5) cardiovascular status by three-lead EKG; and

(6) appropriate responsiveness to verbal stimuli as documented by RASS or Aldrete Score.

(i) The following practitioner-patient ratios shall apply to administration of PKT:

(1) If a physician is on site:

(A) each practitioner may administer PKT to up to four patients at the same time; and

(B) an RN may administer PKT to up to two patients at a time; and

(2) If a physician is not on-site:

(A) a practitioner may administer PKT to up to three patients at the same time; and

(B) an RN may administer PKT to a single patient at a time.

(j) 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 After Completion of PKT Administration.

(a) Upon completing administration of PKT to a patient, the following recovery and monitoring requirements must be completed prior to discharge of the patient:

(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 practitioner-patient ratio of one monitoring delegate to every four patients.

§173.13 Minimum Equipment and Medication Requirements

(a) The following items must be on-site at all times and readily available to manage adverse events:

(1) Supplemental oxygen;

(2) a bag-valve mask;

(3) an AED (or defibrillator); and

(4) a monitor with a quantitative end-tidal carbon dioxide analyzer.

(b) Medications must be maintained on-site for managing adverse events, including but not limited to;

- (1) Airway management;
- (2) Hemodynamic instability;
- (3) Seizures; and
- (4) Other possible psychotropic events.

§173.14 Emergency Response Requirements and Adverse Event Reporting.

(a) In cases requiring non-emergency consultation, a physician must be immediately available throughout administration of PKT:

- (1) in-person at the location where PKT is being administered to the patient; or
- (2) by two-way audiovisual technology.

(b) At all times when PKT is being administered, the PKT Practice must have a Medical Director or an approved physician who:

- (1) has the reasonable ability to physically respond to the PKT clinic's location in an emergency situation in less time than the average emergency services response time for that location, as determined by the most recent data from the Texas Department of State Health Services; or
- (2) has:
 - (A) clinical privileges at a local hospital with an emergency department that the patient would be transferred, or to a hospital with a local affiliation agreement, if local emergency services were called; and
 - (B) physical availability to go to a local hospital to manage the patient according to the local hospital's rules for credentialed physicians to timely see their admitted patients.

(c) Each PKT Practice must document each adverse event within 24 hours of the event, including outcomes, if known.

(d) Each PKT Practice must keep and maintain an adverse event reporting log containing all adverse events occurring at the PKT Practice for three (3) years.

(e) The adverse event reporting log must include the following information:

- (1) the patient's name;
- (2) the date of the adverse event;
- (3) a list of personnel administering the PKT;
- (4) a list of all physicians, practitioners, and RNs present at the location when the adverse event occurred;
- (5) the type of adverse event; and
- (6) the outcome, if known.

(f) The Medical Director must ensure the PKT Practice completes and submits to the Board, on a Board approved form, a written report within 24 hours of the following adverse events:

- (1) emergency transportation; or
- (2) death.

§173.15. Prohibited PKT Administration.

PKT may not be:

- (1) administered outside of a registered clinic or an exempt setting set forth under Section 173.8 of this Subchapter; or
- (2) prescribed for home use.

§173.16. Complaints.

- (a) The Medical Director is responsible for the clinic's operations and patient care;
- (b) The Medical Director must ensure compliance with all applicable statutes and regulations including 22 T.A.C. Section 177.2 regarding posting instructions on how to file complaints with the Board.

§173.17. Audits, Inspections, and Investigations.

PKT Practices are subject to audits, inspection, and investigations as outlined in 22 T.A.C. Section 172.