

Chapter 173
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.

- (a) Ketamine Administration--The administration of parenteral ketamine (IV, subcutaneous and IM) is the practice of medicine under §157.002 of the Act and is subject to regulation by the Texas Medical Board, including required registration under this Chapter.
- (b) 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 ketamine administration for patients enrolled in a hospice program licensed by Texas Health and Human Services.

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 If the applicant fails to provide all required information and documentation the application will be deemed withdrawn.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:
 - (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 indication supporting PKT.

- (d) PKT may be administered only by a physician, advanced practice registered nurse (APRN), physician assistant (PA), or registered nurse (RN) acting under appropriate delegation by a licensed physician for psychiatric indication as identified in the definition of PKT.
- (e) A physician, APRN, PA, or RN working under physician delegation must have formal airway management education or must have completed a course on airway management for moderate sedation.
- (f) There must be an APRN, PA, or RN present at all times when administering PKT, and the delegating physician must be immediately available onsite for in-person consultation and emergency management throughout the PKT administration.
- (g) 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.

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 the PKT must have a properly established physician/patient relationship and have properly documented and diagnosed psychiatric indication supporting PKT.
- (c) 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.
- (d) If the physician ordering the PKT delegates the administration of PKT, they need to have protocols or standing delegation orders issued and maintained at the location where the PKT is being administered.

173.11 Minimum Standards When Administering PKT

- (a) The physician, APRN, PA or RN administering PKT must:
 - (1) verify the PKT order from the delegating physician, if applicable;
 - (2) follow the standard of care;
 - (3) obtain informed consent including:
 - A. a discussion of known risks of PKT; and
 - B. the identity and licensure credentials of the person administering the PKT;
 - (4) implement a time out period immediately prior to beginning administration of PKT;
 - (5) maintain complete, contemporaneous, and legible medical records regarding patient monitoring and status throughout the administration of PKT.
- (b) Patient monitoring and status must include continuous appropriate physiologic monitoring of the patient, both during and post procedure until ready for discharge.
- (c) Continuous monitoring of the following:
 - (1) blood pressure;
 - (2) pulse;
 - (3) respiration;

- (4) O2 saturation;
 - (5) cardiovascular status; and
 - (6) appropriate responsiveness to verbal stimuli.
- (d) Discharge assessment requires:
 - (1) A minimum 30-minute observation period upon completion of PKT;
 - (2) at least two blood pressure readings 10 minutes apart; and
 - (3) a full cognitive assessment (including an Aldrete score).
- (e) Minimum Equipment Requirements. The following equipment must be utilized for continuous cardiorespiratory monitoring of the patient during and after administration of PKT:
 - (1) pulse oximetry;
 - (2) incremental blood pressure checks; and
 - (3) an end-tidal carbon dioxide (CO2) analyzer.
- (f) 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, and
 - (3) an AED (or defibrillator).

173.12 Prohibited PKT Uses

Any home use, prescribing, or administration of parenteral ketamine is prohibited.

173.13 Complaints and Investigations

The Medical Director and physician owner(s) are responsible for the clinic's operations and patient care and ensuring compliance with all applicable regulations.

173.14 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.

173.15 Audits, Inspections, and Investigations.

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