

Recently, the Board was asked if a moderate conscious sedation permit holder could administer or supervise a Certified Registered Nurse Anesthetist (CRNA) administering Ketalar (ketamine hydrochloride) to induce a level of moderate conscious sedation in a patient.

The answer to this inquiry is governed by 21 NCAC 16Q .0101(29) and (30), which provides that a moderate conscious sedation or a moderate pediatric conscious sedation permit holder shall not use drugs designed by the manufacturer for use in general anesthesia or deep sedation, or drugs contraindicated for use in moderate conscious sedation.

For Ketalar, the manufacturer's label approved by the Federal Drug Administration (FDA) states that it is a "rapid-acting general anesthetic producing an anesthetic state...." The "Precautions" section of the FDA-approved manufacturer's label states: "KETALAR should be used by or under the direction of physicians experienced in administering general anesthetics and in maintenance of an airway and in the control of respiration."

The FDA-approved manufacturer's label does not mention use of Ketalar for moderate conscious sedation. It is described by the manufacturer **only** for use in general anesthesia or deep sedation and by or under the direction of a doctor experienced in administering general anesthetics. Based on these FDA-approved manufacturer's label restrictions, it would be a violation of the Board's rules for a moderate conscious sedation or a moderate pediatric conscious sedation permit holder to administer Ketalar.

Because Ketalar is not designed by the manufacturer or approved by the FDA for moderate conscious sedation use, it also would be a violation of the Board's rules for a moderate conscious sedation permit holder to supervise a CRNA in administering Ketalar. The Board's rules do not allow a permit holder to supervise a CRNA if the level of sedation produced by the CRNA exceeds the level of sedation allowed by the permit. [21 NCAC 16Q .0301(b)].

This response does not address a CRNA's scope of practice but rather a licensed dentist's proper supervision and direction of a CRNA in administering anesthetics, as required by N.C. Gen. Stat. § 90-29(b)(6). This response also does not address or prohibit the use of Ketalar by a dentist holding a general anesthesia or deep sedation permit.

The Board's response to this inquiry is based on a review of the FDA-approved manufacturer's label for Ketalar. If additional information is provided, the Board will review and may issue additional guidance. The response does not address potential FDA-approved uses for ketamine in other forms.