21 NCAC 16Q .0302 MODERATE PARENTERAL AND ENTERAL CONSCIOUS SEDATION CLINICAL REQUIREMENTS AND EQUIPMENT

(a) A dentist administering moderate conscious sedation or supervising any CRNA employed to administer or RN employed to deliver moderate conscious sedation shall ensure that the facility where the sedation is administered meets the following requirements:

(1) The facility shall be equipped with the following:
- (A) an operatory of size and design to permit access of emergency equipment and personnel and to permit emergency management;
- (B) a CPR board or a dental chair without enhancements, suitable for providing emergency treatment;
- (C) lighting as necessary for specific procedures and back-up lighting;
- (D) suction equipment as necessary for specific procedures, including non-electrical back-up suction;
- (E) positive pressure oxygen delivery system, including full face masks for small, medium, and large patients and back-up E-cylinder portable oxygen tank apart from the central system;
- (F) small, medium, and large oral and nasal airways;
- (G) blood pressure monitoring device;
- (H) EKG monitor;
- (I) pulse oximeter;
- (J) automatic external defibrillator (AED);
- (K) precordial stethoscope or capnograph;
- (L) thermometer;
- (M) vascular access set-up as necessary for specific procedures, including hardware and fluids;
- (N) laryngoscope with working batteries;
- (O) intubation forceps and advanced airway devices;
- (P) tonsillar suction with back-up suction;
- (Q) syringes as necessary for specific procedures; and
- (R) tourniquet and tape.

(2) The following unexpired drugs shall be maintained in the facility and with access from the operatory and recovery rooms:
- (A) Epinephrine;
- (B) Atropine;
- (C) antiarrhythmic;
- (D) antihistamine;
- (E) antihypertensive;
- (F) bronchodilator;
- (G) antihypoglycemic agent;
- (H) vasopressor;
- (I) corticosteroid;
- (J) anticonvulsant;
- (K) muscle relaxant;
- (L) appropriate reversal agents;
- (M) nitroglycerine;
- (N) antiemetic; and
- (O) Dextrose.

(3) The permit holder shall maintain written emergency and patient discharge protocols. The permit holder shall also provide training to familiarize auxiliaries in the treatment of clinical emergencies;

(4) The dentist shall maintain the following records for at least 10 years:
- (A) patient's current written medical history and pre-operative assessment;
- (B) drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration; and
- (C) a sedation record;

(5) The sedation record shall include:

(A) base line vital signs, blood pressure (unless patient behavior prevents recording), oxygen saturation, ET CO2 if capnography is utilized, pulse and respiration rates of the patient recorded in real time at 15 minute intervals;
(B) procedure start and end times;
(C) gauge of needle and location of IV on the patient, if used;
(D) status of patient upon discharge;
(E) documentation of complications or morbidity; and
(F) consent form, signed by the patient or guardian, identifying the procedure, risks and benefits, level of sedation, and date signed; and

(6) The following conditions shall be satisfied during a sedation procedure:
(A) The facility shall be staffed with at least two BLS certified auxiliaries, one of whom shall be dedicated to patient monitoring and recording sedation data throughout the sedation procedure. This Subparagraph shall not apply if the dentist permit holder is dedicated to patient care and monitoring regarding sedation throughout the sedation procedure and is not performing the surgery or other dental procedure; and
(B) If IV sedation is used, IV infusion shall be administered before the start of the procedure and maintained until the patient is ready for discharge.

(b) During an inspection or evaluation, the applicant or permit holder shall demonstrate the administration of moderate conscious sedation on a patient, including the deployment of an intravenous delivery system, while the evaluator observes. During the demonstration, the applicant or permit holder shall demonstrate competency in the following areas:
(1) monitoring blood pressure, pulse, ET CO2 if capnography is utilized, and respiration;
(2) drug dosage and administration;
(3) treatment of untoward reactions including respiratory or cardiac depression if applicable;
(4) sterile technique;
(5) use of BLS certified auxiliaries;
(6) monitoring of patient during recovery; and
(7) sufficiency of patient recovery time.

(c) During an inspection or evaluation, the applicant or permit holder shall demonstrate competency to the evaluator in the treatment of the following clinical emergencies:
(1) laryngospasm;
(2) bronchospasm;
(3) emesis and aspiration;
(4) respiratory depression and arrest;
(5) angina pectoris;
(6) myocardial infarction;
(7) hypertension and hypotension;
(8) allergic reactions;
(9) convulsions;
(10) syncope;
(11) bradycardia;
(12) hypoglycemia;
(13) cardiac arrest; and
(14) airway obstruction.

(d) During the evaluation, the permit applicant shall take a written examination on the topics set forth in Paragraphs (b) and (c) of this Rule. The permit applicant must obtain a passing score on the written examination by answering 80 percent of the examination questions correctly. If the permit applicant fails to obtain a passing score on the written examination that is administered during the evaluation, he or she may be re-examined in accordance with Rule .0306(h) of this Section.

(e) A moderate conscious sedation permit holder shall evaluate a patient for health risks before starting any sedation procedure as follows:
(1) a patient who is medically stable and who is ASA I or II shall be evaluated by reviewing the patient's current medical history and medication use or;
(2) a patient who is not medically stable or who is ASA III or higher shall be evaluated by a consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the procedure.

(f) Post-operative monitoring and discharge:

(1) the permit holder or a BLS certified auxiliary under his or her direct supervision shall monitor the patient's vital signs throughout the sedation procedure until the patient is recovered as defined in Subparagraph (f)(2) of this Rule and is ready for discharge from the office.

(2) recovery from moderate conscious sedation shall include documentation of the following:

(A) cardiovascular function stable;

(B) airway patency uncompromised;

(C) patient arousable and protective reflexes intact;

(D) state of hydration within normal limits;

(E) patient can talk, if applicable;

(F) patient can sit unaided, if applicable;

(G) patient can ambulate, if applicable, with minimal assistance; and

(H) for the special needs patient or patient incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that patient shall be achieved.

(3) before allowing the patient to leave the office, the dentist shall determine that the patient has met the recovery criteria set out in Subparagraph (f)(2) of this Rule and the following discharge criteria:

(A) oxygenation, circulation, activity, skin color, and level of consciousness are stable, and have been documented;

(B) explanation and documentation of written postoperative instructions have been provided to the patient or a person responsible for the patient at the time of discharge; and

(C) a person authorized by the patient is available to transport the patient after discharge.

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