**21 NCAC 16Q .0103 EQUIPMENT, PERSONNEL, AND CLINICAL REQUIREMENTS TO ADMINISTER ANESTHESIA OR MODERATE SEDATION**

(a) Before administering general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation ("anesthesia or moderate sedation"), or supervising a CRNA to administer or an RN employed to deliver anesthesia or moderate sedation, a dentist shall hold an unexpired permit issued by the Board in accordance with this Subchapter permitting the dentist to administer that level of sedation.

(b) Before performing sedation procedures in a facility other than a hospital or credentialed surgery center, the permit holder shall ensure that the Board has been notified that the permit holder intends to administer anesthesia or moderate sedation at the facility and shall ensure that the facility has passed a facility inspection by the Board in accordance with this Subchapter. For purposes of these Rules, "credentialed surgery center" means a surgical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities.

(c) The permit holder shall ensure that the facility where the sedation procedure is to be performed meets the following requirements at the time of the procedure:

(1) The permit holder shall ensure the facility is equipped as follows and that the following listed equipment is immediately available and accessible from the operatory and recovery rooms:
   (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 dental chair suitable for providing emergency treatment;
   (C) lighting as necessary for the procedure to be performed, and back-up lighting;
   (D) suction equipment as necessary for the procedure to be performed, 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) a blood pressure monitoring device;
   (H) an EKG monitor;
   (I) a pulse oximeter;
   (J) an automatic external defibrillator (AED);
   (K) a capnograph;
   (L) a precordial or pretracheal stethoscope;
   (M) a thermometer;
   (N) vascular access set-up as necessary for the procedure to be performed, including hardware and fluids;
   (O) a laryngoscope with working batteries;
   (P) intubation forceps and advanced airway devices;
   (Q) tonsillar suction with back-up suction;
   (R) syringes as necessary for the procedure to be performed; and
   (S) tourniquet and tape.

(2) The permit holder shall ensure all monitoring and other equipment in the facility receives preventive maintenance no less frequently than once per year, including safety and function checks per the manufacturers' recommendations. The permit holder shall maintain documentation of all preventive maintenance performed, and shall ensure equipment is replaced upon its expiration or as clinically required.

(3) The permit holder shall ensure the following unexpired drugs are immediately available and are accessible from the operatory and recovery rooms:
   (A) epinephrine;
   (B) atropine;
   (C) an antiarrhythmic;
   (D) an antihistamine;
   (E) an antihypertensive;
   (F) a bronchodilator;
   (G) an antihypoglycemic agent;
   (H) a vasopressor;
   (I) a corticosteroid;

(J) an anticonvulsant;
(K) appropriate reversal agents;
(L) nitroglycerine; and
(M) an antiemetic.

(4) The permit holder shall maintain written emergency and patient discharge protocols accessible from the operatory and recovery rooms. The written emergency manual shall include a protocol for activation of emergency management services for life-threatening complications along with the information set out in Rule .0101(17) of this Section.

(5) The permit holder shall satisfy any additional facility requirements applicable to the level of the permit, as set out in Rule .0202, .0206, .0302, or .0405 of this Subchapter.

(d) The permit holder shall ensure that the following staffing, education, and training requirements are met prior to performing a sedation procedure:

(1) The permit holder shall provide training to familiarize all auxiliaries in the treatment of clinical emergencies including the following, and shall review and practice responding to clinical emergencies with all auxiliaries as a team and in person every six months;
(A) airway obstruction;
(B) allergic reactions;
(C) angina pectoris;
(D) apnea;
(E) bradycardia;
(F) bronchospasm;
(G) cardiac arrest;
(H) convulsions;
(I) emesis and aspiration;
(J) hypertension;
(K) hypoglycemia;
(L) hypotension;
(M) hypoventilation and respiratory arrest;
(N) hypoxemia and hypoxia;
(O) laryngospasm;
(P) myocardial infarction; and
(Q) syncope.

(2) All auxiliaries in the facility shall be BLS certified.

(3) Except as set out in Subparagraph (d)(4) of this Rule, the permit holder performing the surgery or other dental procedure shall ensure that an RN or a BLS-certified auxiliary is dedicated to patient monitoring and recording anesthesia or sedation data throughout the sedation procedure.

(4) The requirement set out in Subparagraph (d)(3) of this Rule shall not apply if the permit holder or an additional sedation provider is dedicated to patient care and monitoring regarding anesthesia or moderate sedation throughout the sedation procedure and is not performing the surgery or other dental procedure. The additional sedation provider shall be:
(A) a dentist holding a permit or mobile permit in satisfaction of this Subchapter to administer the anesthesia or sedation level at the facility where the sedation procedure is performed;
(B) an anesthesiologist licensed and practicing in accordance with the rules of the North Carolina Medical Board; or
(C) a CRNA licensed and practicing in accordance with the rules of the North Carolina Board of Nursing, under the supervision and direction of the permit holder who shall ensure the level of sedation administered does not exceed the level of the sedation allowed by the permit holder's permit.

(5) The permit holder shall satisfy any additional staffing, education, and training requirements applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(e) Before starting any sedation procedure, the permit holder shall conduct a pre-operative patient evaluation which shall include the following:

(1) evaluating the patient for health risks relevant to the potential sedation procedure;

(2) evaluating the patient's food and fluid intake following the ASA guidelines for pre-operative fasting applicable to elective procedures involving the administration of anesthesia or moderate

sedation. The ASA guidelines are incorporated by reference, including subsequent amendments and editions, and may be accessed at https://www.asahq.org at no cost; and

(3) satisfying any additional requirements for pre-operative patient evaluation and procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(f) During the sedation procedure:

(1) Prescriptions intended to accomplish procedural sedation, including enteral dosages, shall be administered only under the direct supervision of the permit holder.

(2) 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.

(3) Capnography shall be used to monitor patients unless an individual patient's behavior or condition prevents use of capnography. In that event, the permit holder shall document in the sedation record the clinical reason capnography could not be used.

(4) The permit holder shall ensure the patient's baseline vital signs are taken and recorded, including temperature, SPO2, blood pressure, and pulse.

(5) The permit holder shall ensure the patient's blood pressure, oxygen saturation, ET CO2 (unless capnography cannot be used), pulse, and respiration rates ("vital sign information") are monitored continuously in a manner that enables the permit holder to view vital sign trends throughout the procedure.

(6) The permit holder shall ensure the intraoperative vital sign information is recorded on the anesthesia or sedation record contemporaneously throughout the procedure in intervals of five minutes or less for patients over twelve years old, and in intervals of ten minutes or less for pediatric patients twelve years old or younger.

(7) The permit holder shall satisfy any additional requirements for operative procedures applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

(g) Post-operative monitoring and discharge shall include the following:

(1) The permit holder or an auxiliary under his or her direct supervision shall monitor the patient's post-operative vital sign information until the patient is recovered and is ready for discharge from the office. Recovery from anesthesia or moderate sedation shall include documentation of the following:

(A) stable cardiovascular function;

(B) uncompromised airway patency;

(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 with minimal assistance, if applicable; and

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

(2) Before allowing the patient to leave the office, the permit holder shall determine that the patient has met the recovery criteria set out in Subparagraph (g)(1) 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 post-operative instructions have been provided to the patient or a person responsible for the patient at time of discharge; and

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

(h) The permit holder shall maintain the following in the patient treatment records for 10 years:

(1) the patient's current written medical history, including known allergies and previous surgeries;

(2) a pre-operative assessment as set out in Paragraph (e) of this Rule;

(3) consent to the procedure and to the anesthesia or sedation, signed by the patient or guardian, identifying the procedure and its risks and benefits, the level of anesthesia or sedation and its risks and benefits, and the date signed;

(4) the anesthesia or sedation record that shall include:

(A) the patient's baseline vital signs and intraoperative vital sign information as set out in Subparagraphs (f)(4)-(6) of this Rule;

(B) the printed or downloaded vital sign information from the capnograph. A permit holder's failure to maintain capnograph documentation, except as set out in Subparagraph (f)(3) of this Rule, shall be deemed a failure to monitor the patient as required pursuant to this Subchapter;
(C) procedure start and end times;
(D) gauge of needle and location of IV on the patient, if used;
(E) the total amount of any local anesthetic administered during the procedure;
(F) any analgesic, sedative, pharmacological, or reversal agent, or other drugs administered during the procedure, including route of administration, dosage, strength, time, and sequence of administration, with separate entries for each increment of medication that is titrated to effect;
(G) documentation of complications or morbidity, and clinical responses; and
(H) status of patient upon discharge, including documentation of satisfying the requirements set out in Paragraph (g) of this Rule; and

(5) any additional documentation applicable to the level of the permit, as set out in Rule .0202, .0302, or .0405 of this Subchapter.

*History Note:* *Authority G.S. 90-28; 90-30.1; 90-31.1; 90-48;*
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