.0101 GENERAL ANESTHESIA AND SEDATION DEFINITIONS

For the purposes of these rules relative to the administration of general anesthesia, parenteral conscious sedation, and enteral conscious sedation by or under the direction of a dentist, the following definitions shall apply:

(1) “Analgesia” – the diminution or elimination of pain.

(2) “Anti-anxiety sedative” – a sedative agent administered in a dosage intended to reduce anxiety without diminishing consciousness or protective reflexes.

(3) “Anxiolysis” – pharmacological reduction of anxiety through the administration of a minor psychosedative, which allows for uninterrupted interactive ability in a totally awake patient with no compromise in the ability to maintain a patent airway continuously and without assistance.

(4) “Behavioral management” – the use of pharmacological or psychological techniques, singly or in combination, to modify behavior to a level that dental treatment can be performed effectively and efficiently.

(5) “Competent” – displaying special skill or knowledge derived from training and experience.

(6) “Conscious sedation” – an induced state of a depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command, and that is produced by pharmacologic or non-pharmacologic agents, or a combination thereof. In accordance with this particular definition, the drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

(7) “Deep sedation” – an induced state of a depressed level of consciousness accompanied by partial loss of protective reflexes, including the ability to continually maintain an airway independently or respond purposefully to verbal command, and is produced by pharmacological agents.

(8) “Direct supervision” – the dentist responsible for the sedation/anesthesia procedure shall be physically present in the
facility and shall be continuously aware of the patient's physical status and well being.

(9) “Enteral conscious sedation” is conscious sedation that is achieved by administration of pharmacological agents through the alimentary tract either orally or rectally. Enteral conscious sedation is administered primarily for behavioral management.

(10) “Facility” – the location where a permit holder practices dentistry and provides anesthesia/sedation services.

(11) “Facility inspection” – an on-site inspection to determine if a facility where the applicant proposes to provide anesthesia/sedation is supplied, equipped, staffed and maintained in a condition to support provision of anesthesia/sedation services that meet the minimum standard of care.

(12) "General anesthesia" is the intended controlled state of depressed consciousness produced by pharmacologic agents and accompanied by a partial or complete loss of protective reflexes, including the ability to maintain an airway and respond purposefully to physical stimulation or verbal commands.

(13) “Immediately available” – on-site in the facility and available for immediate use.

(14) “Local anesthesia” – the elimination of sensations, especially pain, in one part of the body by the regional application or injection of a drug.

(15) “May” – indicates freedom or liberty to follow a reasonable alternative.

(16) “Minor psychosedative/Minor tranquilizer” – pharmacological agents which allow for uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent airway continuously and without assistance and carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

(17) “Must” or “shall” – indicates an imperative need or duty or both; an essential or indispensable item; mandatory.

(18) “Parenteral conscious sedation” is conscious sedation achieved by the administration of pharmacological agents intravenously, intramuscularly, subcutaneously, submucosally, intranasally, or transdermally. Parenteral conscious sedation is administered primarily for behavioral management.
“Protective reflexes” – includes the ability to swallow and cough.

“Vested adult” – a responsible adult who is the legal parent or guardian, or designee of a legal parent or guardian, entrusted with the care of a minor following the administration of general anesthesia or conscious sedation.

History Note: Statutory Authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Temporary Amendment Eff. December 11, 2002;

SECTION .0400 ENTERAL CONSCIOUS SEDATION

.0401 ENTERAL CONSCIOUS SEDATION CREDENTIALS AND PERMIT

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a certified registered nurse anesthetist to administer enteral conscious sedation, he or she shall obtain either a parenteral conscious sedation permit issued by the Board, a general anesthesia permit issued by the Board, or an enteral conscious sedation permit issued by the Board. A permit is not required for prescription administration of DEA controlled drugs prescribed for postoperative pain control intended for home use. A dentist may obtain an enteral conscious sedation permit from the Board by submitting the appropriate information on an application form provided by the Board and paying a fee of fifty dollars ($50.00). Such permit must be renewed annually and shall be displayed with the current renewal at all times in a conspicuous place in the office of the permit holder.

(b) A dentist who holds only an enteral conscious sedation permit shall not administer deep sedation or general anesthesia.

(c) Application:

(1) An enteral conscious sedation permit may be obtained by completing an application form provided by the Board, a copy of which may be obtained from the Board office, and meeting the requirements of Section .0400 of this Subchapter.

(2) The application form must be filled out completely and appropriate fees paid.
(3) Prior to issuance of an enteral conscious sedation permit the applicant shall undergo a facility inspection. The Board shall direct an evaluator to perform this inspection. The applicant shall be notified in writing that an inspection is required and provided with the name of the evaluator who shall perform the inspection. The applicant shall be responsible for successful completion of inspection of his or her facility within three months of notification. An extension of no more than 90 days shall be granted if the designated evaluator or applicant requests one.

(4) An applicant for an enteral conscious sedation permit shall be licensed and in good standing with the Board in order to be approved. For purposes of these rules “good standing” means that a licensee is not suspended, whether or not the suspended licensee is on probation. Applications from licensees who are not in good standing shall not be approved.

(d) Educational/Professional Requirements:

(1) The dentist applying for an enteral conscious sedation permit shall meet one of the following criteria:

(A) successful completion of training consistent with that described in Part I or Part III of the American Dental Association (ADA) Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry, and have documented administration of enteral conscious sedation in a minimum of five cases;

(B) successful completion of an ADA accredited post-doctoral training program which affords comprehensive training necessary to administer and manage enteral conscious sedation;

(C) successful completion of an eighteen hour enteral conscious sedation course which must be approved by the Board based on whether it affords comprehensive training necessary to administer and manage enteral conscious sedation;

(D) successful completion of an ADA accredited postgraduate program in pediatric dentistry; or
(E) is a North Carolina licensed dentist in good standing who has been utilizing enteral conscious sedation in a competent manner for the five years preceding January 1, 2002, and his or her office facility has passed an on-site inspection by a Board evaluator as required in paragraph (b)(3) of this Rule. Competency shall be determined by presentation of successful administration of enteral conscious sedation in a minimum of five clinical cases.

(2) Prior to administering enteral conscious sedation to children under the age of 13, a dentist who qualifies only for an enteral conscious sedation permit shall also successfully complete a six hour course in pediatric enteral conscious sedation developed by the Pediatric Dentistry Department at the University of North Carolina or an equivalent course and submit documentation showing successful completion of such course to the Board. The requirements of this paragraph shall not apply to Pediatric Dentists who meet the requirements of paragraph (c)(1)(D) of this rule nor to those dentists who otherwise meet the requirements of paragraph (c)(1)(E) of this rule and in addition have administered enteral conscious sedation to children under the age of 13 in a competent manner for the five years preceding January 1, 2002. Competency shall be determined by presentation of successful administration of enteral conscious sedation in a minimum of five clinical cases.

History Note: Authority G.S. 90-28; 90-30.1; Temporary Adoption Eff. March 13, 2003; December 11, 2002; Amended Eff. August 1, 2004.

.0402 PERMIT REQUIREMENTS, CLINICAL PROVISIONS AND EQUIPMENT

(a) Enteral conscious sedation is indicated for use only for conscious sedation as defined in Rule .0101(9) of this Subchapter (relating to Definitions). Enteral conscious sedation is not indicated for use to achieve deep sedation.

(b) An enteral conscious sedation permit is not required for minor psychosedatives used for anxiolysis prescribed for administration outside of the dental office when pre-procedure instructions are likely to be followed.
Medication administered for the purpose of enteral conscious sedation shall not exceed the maximum doses recommended by the drug manufacturer, sedation textbooks, or juried sedation journals. When medications for enteral conscious sedation are used in combination, the total sedation dose shall not exceed recommended dosages for medications used in combination. During longer periods of enteral conscious sedation, in which the amount of time of the procedures exceeds the effective duration of the sedative effect of the drug(s) used, the incremental doses of the sedative(s) shall not exceed total safe dosage levels based on the effective half-life of the drugs used.

(c) Each dentist shall:

(1) adhere to the clinical requirements as detailed in paragraph (e) of this Rule;

(2) maintain under continuous direct supervision any auxiliary personnel who shall be capable of assisting in procedures, problems, and emergencies incident to the use of enteral conscious sedation or secondary to an unexpected medical complication;

(3) utilize sufficient auxiliary personnel for each procedure performed who shall document annual successful completion of basic life support training; and

(4) not allow an enteral conscious sedation procedure to be performed in his or her office by a Certified Registered Nurse Anesthetist (CRNA) unless the dentist holds a permit issued by the Board for the procedure being performed. This provision addresses dentists and is not intended to address the scope of practice of persons licensed by any other agency.

(d) Each dentist shall meet the following requirements:

(1) Patient Evaluation. Patients who are administered enteral conscious sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals Physical Status I, II (ASA I, II, as defined by the American Society of Anesthesiologists). An evaluation is a review of the patient’s current medical history and medication use. However, with individuals who are not medically stable or who have a significant health disability Physical Status III (ASA III, as defined by the American Society of Anesthesiologists) consultation with their primary care physician or consulting
medical specialist regarding potential procedure risk is required.

(2) Pre-procedure preparation, informed consent:

(A) The patient or guardian must be advised of the procedure associated with the delivery of the enteral conscious sedation.

(B) Equipment must be evaluated and maintained for proper operation.

(C) Baseline vital signs shall be obtained at the discretion of the operator depending on the medical status of the patient and the nature of the procedure to be performed.

(D) Dentists administering enteral conscious sedation shall use sedative agents that he/she is competent to administer and shall administer such agents in a manner that is within the standard of care.

(e) Patient monitoring:

(1) Patients who have been administered enteral conscious sedation shall be monitored during waiting periods prior to operative procedures. An adult who has accepted responsibility for the patient and been given written pre-procedural instruction may provide such monitoring. The patient shall be monitored for alertness, responsiveness, breathing and skin coloration.

(2) Dentists administering enteral conscious sedation shall maintain direct supervision of the patient during the operative procedure and for such a period of time necessary to establish pharmacologic and physiologic vital sign stability.

(A) Oxygenation. Color of mucosa, skin or blood shall be continually evaluated. Oxygen saturation shall be evaluated continuously by pulse oximetry, except as provided in Paragraph (e)(4) of this Rule.

(B) Ventilation. Shall perform observation of chest excursions or auscultation of breath sounds or both.

(C) Circulation. Shall take and record an initial blood pressure and pulse and thereafter as appropriate except as provided in Paragraph (e)(4) of this Rule.

(3) An appropriate time oriented anesthetic record of vital signs shall be maintained in the permanent record including
documentation of individual administering the drug(s) and showing
the name(s) of drug(s) and dosage(s) used.

(4) If the dentist responsible for administering enteral conscious
sedation must deviate from the requirements set out in this Rule,
he or she shall document the occurrence of such deviation and the
reasons for such deviation.

(f) Post-operative procedures:

(1) Following the operative procedure, positive pressure oxygen and
suction equipment shall be immediately available in the recovery
area or operatory.

(2) Vital signs shall be continuously monitored when the sedation is
no longer being administered and the patient shall have direct
continuous supervision until oxygenation and circulation are
stable and the patient is sufficiently responsive for discharge
from the office.

(3) Patients who have adverse reactions to enteral conscious sedation
shall be assisted and monitored either in an operatory chair or
recovery area until stable for discharge.

(4) Recovery from enteral conscious sedation shall include:

(A) cardiovascular function stable;
(B) airway patency uncompromised;
(C) patient easily 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 child who is very young or disabled, and
incapable of the usually expected responses, the pre-
sedation level of responsiveness or the level as
close as possible for that child shall be achieved.

(5) Prior to allowing the patient to leave the office, the dentist
shall determine that the patient has met the recovery criteria
set out in paragraph (f)(4) of this Rule and the following
discharge criteria:
(A) oxygenation, circulation, activity, skin color and level of consciousness are sufficient and stable and have been documented;

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

(C) responsible individual is available for the patient to transport the patient after discharge;

(D) for a patient who must use a child restraint system designed for use in a motor vehicle, a vested adult is available to transport the patient after discharge and an additional responsible individual is available to attend to the patient.

(g) The dentist, personnel and facility shall be prepared to treat emergencies that may arise from the administration of enteral conscious sedation, and shall have the ability to provide positive pressure ventilation with 100% oxygen with an age appropriate device.

History Note: Authority G.S. 90-28; 90-30.1;
Temporary Adoption Eff. December 11, 2002;

.0403 TEMPORARY APPROVAL PRIOR TO SITE INSPECTION

(a) If a dentist meets the requirements of Rule .0401 of this Section, he or she shall be granted temporary approval to administer enteral conscious sedation until a permit can be issued. Temporary approval may be granted based solely on credentials until all processing and investigation has been completed. Temporary approval may not exceed three months.

(b) Temporary approval shall not be granted to a provisional licensee.

History Note: Authority G.S. 90-28; 90-30.1.
Temporary Adoption Eff. December 11, 2002;
.0500 RENEWAL OF PERMITS

.0501 ANNUAL RENEWAL REQUIRED

(a) General anesthesia, parenteral conscious sedation, and enteral conscious sedation permits shall be renewed by the Board on an annual basis. Such renewal shall be accomplished in conjunction with the license renewal process, and applications for permits shall be made at the same time as applications for renewal of licenses.

(b) Anesthesia, parenteral conscious sedation, and enteral conscious sedation permits shall be subject to the same renewal deadlines as are dental practice licenses, in accordance with G.S. 90-31. If the permit renewal application is not received by the date specified in G.S. 90-31, continued administration of anesthesia, parenteral conscious sedation, or enteral conscious sedation shall be unlawful and shall subject the dentist to the penalties prescribed by Section .0700 of this Subchapter.

(c) As a condition for renewal of the general anesthesia permit, the permit holder shall ensure that the requirements of 21 NCAC 16Q.0202 are met and document current, successful completion of advanced cardiac life support (ACLS) training, or its age-specific equivalent or other equivalent course, and auxiliary personnel shall document annual, successful completion of basic life support (BLS) training.

(d) As a condition for renewal of the parenteral conscious sedation permit, the permit holder shall ensure that the requirements of 21 NCAC 16Q.0302 are met and also meet one of the following criteria:

1. document current, successful completion of advanced cardiac life support (ACLS) training or its age-specific equivalent, or other equivalent course; or

2. document annual, successful completion of basic life support (BLS) training and obtain three hours of continuing education each year in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:

(A) sedation;
(B) medical emergencies;
(C) monitoring IV sedation and the use of monitoring equipment;
(D) pharmacology of drugs and agents used in IV sedation;
(E) physical evaluation, risk assessment, or behavioral
management; or
(F) audit ACLS/PALS courses.

(e) As a condition for renewal of the enteral conscious sedation permit, the permit holder shall ensure that the requirements of 16Q.0402 are met and shall document annual, successful completion of basic life support (BLS) training and obtain six hours of continuing education every two years in one or more of the following areas, which may be counted toward fulfillment of the continuing education required each calendar year for license renewal:

1. pediatric or adult sedation;
2. medical emergencies;
3. monitoring sedation and the use of monitoring equipment;
4. pharmacology of drugs and agents used in sedation;
5. physical evaluation, risk assessment, or behavioral management;
   or
6. audit ACLS/PALS courses.

History Note: Statutory Authority G.S. 90-28; 90-30.1; 90-48;
Eff. February 1, 1990;
Amended Eff. August 1, 2002;
Transferred and Recodified from 16Q.0401 to 16Q.0501;
Temporary Amendment Eff. December 11, 2002;

.0502 PAYMENT OF FEES

A fee of fifty dollars ($50.00) shall accompany the permit renewal application, such fee to be separate and apart from the annual license renewal fee imposed by the Board.

HISTORY NOTE: Authority G.S. 90-28; 90-30.1;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0402 to .0502.

.0503 INSPECTION AUTHORIZED

Incident to the renewal of an anesthesia or sedation permit, for cause, or routinely at reasonable time intervals in order to ensure compliance, the Board may require an on-site inspection of the dentist's facility, equipment, personnel and procedures. Such inspection shall be conducted in accordance with Rules .0204, .0205, .0303, and .0401 of this Subchapter.
.0601 REPORTS OF ADVERSE OCCURRENCES

(a) A dentist who holds a permit to administer general anesthesia or sedation shall submit a report to the Board within 72 hours after each adverse occurrence related to the administration of general anesthesia or sedation which results in the death of a patient within 24 hours of the procedure.

(b) A dentist who holds a permit to administer general anesthesia or sedation shall report to the Board, within 30 days after each adverse occurrence related to the administration of general anesthesia or sedation, any situation which results in permanent organic brain dysfunction of a patient within 24 hours of the procedure or which results in physical injury causing hospitalization of a patient within 24 hours of the procedure.

(c) The adverse occurrence report shall be in writing and shall include:
   (1) The dentist's name, license number and permit number;
   (2) The date and time of the occurrence;
   (3) The facility where the occurrence took place;
   (4) The name and address of the patient;
   (5) The surgical procedure involved;
   (6) The type and dosage of sedation or anesthesia utilized in the procedure; and
   (7) The circumstances involved in the occurrence.

(d) Upon receipt of any such report, the Board shall make such investigation as it deems appropriate and shall take such action as it deems necessary.

HISTORY NOTE: Authority G.S. 90-28; 90-30.1; 90-41;
Eff. February 1, 1990;
Transferred and Recodified from 16Q .0501 to 16Q .0601.
.0602 FAILURE TO REPORT

If a dentist fails to report any incident as required by these Rules, the dentist shall be subject to discipline in accordance with Section .0700 of this Subchapter.

History Note: Statutory Authority G.S. 90-28; 90-30.1; 90-41;
Eff. February 1, 1990;
Transferred and Recodified from 16Q.0502 to 16Q.0602;
Temporary Amendment Eff. December 11, 2002;

SECTION .0700 – PENALTY FOR NON-COMPLIANCE

.0701 FAILURE TO COMPLY

Failure to comply with the provisions of this Subchapter may result in suspension or revocation of the permit and/or the dentist’s license to practice dentistry in accordance with G.S. 90-41.

History Note: Statutory Authority G.S. 90-28; 90-30.1; 90-41;
Eff. February 1, 1990;
Transferred and Recodified from 16Q.0601 to 16Q.0701;