

21 NCAC 16Q .0401 is proposed for amendment as follows:

SECTION .0400 - ENTERAL CONSCIOUS SEDATION

21 NCAC 16Q .0401 MINIMAL CONSCIOUS SEDATION CREDENTIALS, EVALUATION AND PERMIT

(a) Before a dentist licensed to practice in North Carolina may administer or supervise a certified registered nurse anesthetist to administer minimal conscious sedation, the dentist shall obtain a Board-issued permit for minimal conscious sedation, moderate pediatric conscious sedation, moderate conscious sedation or general anesthesia. 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 a minimal conscious sedation permit from the Board by completing an application form provided by the Board and paying a fee of three-hundred seventy-five dollars (\$375.00) that includes the ~~one-hundred dollars~~ one-hundred dollar (\$100.00) application fee and the two-hundred seventy-five dollar (\$275.00) inspection fee. 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) Only a dentist who holds a general anesthesia license may administer deep sedation or general anesthesia.

(c) Application:

- (1) A minimal conscious sedation permit may be obtained by completing an application form provided by 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) An applicant for a minimal 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"good standing" means that the applicant is not subject to a disciplinary investigation and his or her licensee has not been revoked or suspended and is not subject to a probation or stayed suspension order.

(d) Evaluation:

- (1) Prior to issuance of a minimal conscious sedation permit the applicant shall pass an evaluation and undergo a facility inspection. The Board shall direct an evaluator qualified to administer minimal sedation 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 passing the evaluation and inspection of his or her facility. ~~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.~~
- (2) During an inspection or evaluation, the applicant shall demonstrate the administration of minimal conscious sedation on a patient while the evaluator observes. During the observation, the applicant ~~or permit holder~~ shall demonstrate competency in the following areas:
 - (A) Monitoring of blood pressure, pulse, pulse oximetry and respiration;

- (B) Drug dosage and ~~administration~~ administration; ~~(by verbal demonstration)~~;
- (C) Treatment of untoward reactions including respiratory or cardiac depression (by verbal demonstration);
- (D) ~~Sterilization~~ sterile technique;
- (E) ~~Use of CPR certified personnel~~; Use of BLS certified auxiliaries;
- (F) Monitoring of patient during ~~recovery~~ recovery; ~~(by verbal demonstration)~~; and
- (G) Sufficiency of patient recovery ~~time~~ time. ~~(by verbal demonstration)~~.
- (3) During an inspection or evaluation, the applicant or permit holder shall ~~verbally~~ demonstrate competency to the evaluator in the treatment of the following clinical emergencies:
- (A) Laryngospasm;
- (B) Bronchospasm;
- (C) Emesis and aspiration;
- (D) Respiratory depression and arrest;
- (E) Angina pectoris;
- (F) Myocardial infarction;
- (G) Hypertension/Hypotension;
- (H) Syncope;
- (I) Allergic reactions;
- (J) Convulsions;
- (K) Bradycardia;
- (L) ~~Insulin shock~~ Hypoglycemia; and
- (M) Cardiac ~~arrest~~ arrest; and
- (N) Airway obstruction.
- (4) During the evaluation, the permit applicant shall take a written examination on the topics set forth in sections (d)(2) and (d)(3) of this Rule. The permit applicant must obtain a passing score on the written examination by answering eighty percent (80%) 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 Subparagraph (d)(7) of this Rule.
- ~~(4)~~(5) The evaluator shall assign a recommended grade of pass or fail and shall report his or her recommendation to the Board, setting out the basis for his conclusion. The Board is not bound by the evaluator's recommendation and shall make a final determination regarding whether the applicant has passed the evaluation. The applicant shall be notified of the Board's decision in writing.
- (6) An applicant who fails an inspection or evaluation may request a re-evaluation or re-inspection within 15 days of receiving the notice of failure. The request shall be directed to the Board in writing and shall include a statement of the grounds supporting the re-evaluation or re-inspection. Except as set forth in Subparagraph (d)(7) of this Rule, the Board shall require the applicant to

- 1 receive additional training prior to the re-evaluation to address the areas of deficiency determined
2 by the evaluation. The Board shall notify the applicant in writing of the need for additional training.
3 (7) A permit applicant who has failed the written examination portion of the evaluation but passed all
4 other aspects of the evaluation and inspection may retake the written examination two additional
5 times at the Board office. The applicant must wait a minimum of 72 hours before attempting to
6 retake a written examination. Any applicant who has failed the written portion of the examination
7 three times shall successfully complete an additional Board approved course of study in the area(s)
8 of deficiency and provide the Board evidence of the additional study before written reexamination.
9 (8) Re-evaluations and re-inspections shall be conducted by Board-appointed evaluators not involved
10 in the failed evaluation or inspection.
11 (9) An applicant must complete all the requirements of this Rule, including passing the written
12 examination, evaluation and inspection, within twelve (12) months of submitting the application to
13 the Board.

14 (e) Educational/Professional Requirements:

- 15 (1) The dentist applying for a minimal conscious sedation permit shall meet one of the following
16 criteria:
17 ~~(A) — successful completion of training consistent with that described in Part I or Part III of the~~
18 ~~American Dental Association (ADA) Guidelines for Teaching the Comprehensive Control~~
19 ~~of Pain and Anxiety in Dentistry, and have documented administration of minimal~~
20 ~~conscious sedation in a minimum of five cases;~~
21 ~~(B)(A)~~ (A) successful completion of an ADA accredited post-doctoral training program which affords
22 comprehensive training necessary to administer and manage minimal conscious sedation;
23 ~~(C)(B)~~ (B) successful completion of an 18-hour minimal conscious sedation course which must be
24 approved by the Board based on whether it affords comprehensive training necessary to
25 administer and manage minimal conscious sedation; or
26 ~~(D)(C)~~ (C) successful completion of an ADA accredited postgraduate program in pediatric dentistry;
27 or
28 ~~(E) — is a North Carolina licensed dentist in good standing who has been using minimal~~
29 ~~conscious sedation in a competent manner for at least one year immediately preceding~~
30 ~~October 1, 2007 and his or her office facility has passed an on-site inspection by a Board~~
31 ~~evaluator as required in Paragraph (d) of this Rule. Competency shall be determined by~~
32 ~~presentation of successful administration of minimal conscious sedation in a minimum of~~
33 ~~five clinical cases.~~
34 (2) All applicants for a minimal sedation permit must document successful completion of an ACLS a
35 Basic Life Saving (BLS) course within the 12 months prior to the date of application;
36 (3) The permit holder shall maintain written emergency and patient discharge protocols. The permit
37 holder shall also provide training to familiarize auxiliaries in the treatment of clinical emergencies.

1 (f) Annual Permit Renewal:

2 (1) Minimal conscious sedation permits shall be renewed by the Board annually at the same time as
3 dental licenses by the dentist paying a one-hundred dollar (\$100.00) fee and completing the
4 application requirements in this Rule. If the completed permit renewal application and renewal fee
5 are not received before January 31 of each year, a fifty dollar (\$50.00) late fee shall be paid.

6 (2) Any dentist who fails to renew a minimal conscious sedation permit before March 31 of each year
7 shall complete a reinstatement application, pay the renewal fee, late fee, and comply with all
8 conditions for renewal set out in this Rule. Dentists whose sedation permits have been lapsed for
9 more than 12 calendar months shall pass an inspection and an evaluation as part of the reinstatement
10 process.

11 (3) As a condition for renewal of the minimal conscious sedation permit, the permit holder shall meet
12 the requirements of Rule .0402 of this Subchapter and shall document unexpired ACLS certification
13 and obtain three hours of continuing education every year in one or more of the following areas,
14 which may be counted toward fulfillment of the continuing education required each calendar year
15 for license renewal:

16 (A) pediatric or adult sedation;

17 (B) medical emergencies;

18 (C) monitoring sedation and the use of monitoring equipment;

19 (D) pharmacology of drugs and agents used in sedation;

20 (E) physical evaluation, risk assessment, or behavioral management; or

21 (F) airway management.

22 (4) The minimal conscious sedation permit holder shall further document that the permit holder and all
23 auxiliaries involved in sedation procedures have read the practice's emergency manual in the
24 preceding year and that all auxiliaries involved in sedation procedures have completed BLS
25 certification and, within the past two years, completed three hours of continuing education in any of
26 the areas set forth in Subparagraphs (f)(3)(A)-(F) of this Rule.

27 (5) All permit holders applying for renewal of a minimal conscious sedation permit shall be in good
28 standing and their office shall be subject to inspection by the Board.

29 (g) A dentist who administers minimal conscious sedation in violation of this Rule shall be subject to the penalties
30 prescribed by Rule .0701 of this Subchapter.

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

33 *Temporary Adoption Eff. March 13, 2003; December 11, 2002;*

34 *Eff. August 1, 2004;*

35 *Amended Eff. _____; July 3, 2008;*

36 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9,*
37 *2018.*

