

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

FILED SENATE
Apr 6, 2023
S.B. 723
PRINCIPAL CLERK

S

D

SENATE BILL DRS45313-NB-101

Short Title: Henry's Law.

(Public)

Sponsors: Senator Lee (Primary Sponsor).

Referred to:

A BILL TO BE ENTITLED
AN ACT TO ESTABLISH DENTAL SEDATION REQUIREMENTS AND TO DIRECT THE
COLLABORATORY TO CONDUCT A STUDY OF ANESTHESIA PROVIDER
REQUIREMENTS.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 90-30.1 reads as rewritten:

"§ 90-30.1. Standards for general anesthesia and enteral and parenteral sedation; fees authorized.

~~The~~ Subject to the requirements of G.S. 90-30.3 through G.S. 90-30.7, the North Carolina Board of Dental Examiners may establish by regulation reasonable education, training, and equipment standards for safe administration and monitoring of general anesthesia and enteral and parenteral sedation for outpatients in the dental setting. Regulatory standards may include a permit process for general anesthesia and enteral and parenteral sedation by dentists. The requirements of any permit process adopted under the authority of this section shall include provisions that will allow a dentist to qualify for continued use of enteral sedation, if he or she is licensed to practice dentistry in North Carolina and shows the Board that he or she has been utilizing enteral sedation in a competent manner for the five years preceding January 1, 2002, and his or her office facilities pass an on-site examination and inspection by qualified representatives of the Board. For purposes of this section, oral premedication administered for minimal sedation (anxiolysis) shall not be included in the definition of enteral sedation. In order to provide the means of regulating general anesthesia and enteral and parenteral sedation, including examination and inspection of dental offices involved, the Board may charge and collect fees established by its rules for each permit application, each annual permit renewal, and each office inspection in an amount not to exceed the maximum fee amounts set forth in G.S. 90-39."

SECTION 2.(a) Article 2 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-30.3. Dental sedation procedure.

(a) Definitions. – The following definitions apply to G.S. 90-30.3 through G.S. 90-30.7:

(1) Adverse event. – Any of the following clinical emergencies: anaphylaxis, aspiration, cardiac arrest, or unplanned advanced airway placement.

(2) Analgesia. – The diminution or elimination of pain.

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

(4) Anxiolysis. – Pharmacological reduction of anxiety through the administration of a single dose of a minor psychosedative, possibly in



* D R S 4 5 3 1 3 - N B - 1 0 1 *

combination with nitrous oxide, to children or adults prior to commencement of treatment on the day of the appointment that allows for uninterrupted interactive ability in an awake patient with no compromise in the ability to maintain a patent airway independently and continuously.

(5) ASA guidelines. – American Society of Anesthesiologists guidelines.

(6) BLS-certified. – Basic Life Support certified.

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

(8) Certified registered nurse anesthetist or CRNA. – A licensed registered nurse who completes a program accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs, is credentialed as a certified registered nurse anesthetist by the Council on Certification of Nurse Anesthetists, and who maintains recertification through the Council on Recertification of Nurse Anesthetists and performs nurse anesthesia activities in collaboration with a physician, dentist, podiatrist, or other lawfully qualified health care provider.

(9) Credentialed surgery center. – 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.

(10) Licensed dentist. – An individual licensed to practice dentistry under this Article who holds a permit for an approved level of anesthesia under this Article and issued by the Board.

(11) Sedation procedure. – A process beginning when any pharmacological agent is first administered to a patient to induce general anesthesia or sedation and continues until the dentist permit holder determines that the patient has met the recovery and discharge criteria set forth in this Article.

(b) Dental Sedation Permit Requirements. – A licensed dentist shall hold an unexpired permit issued by the Board in accordance with G.S. 90-30.1 permitting the dentist to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, or supervising a CRNA to administer or an RN employed to deliver anesthesia or moderate sedation. Before performing sedation procedures in a facility other than a hospital or credentialed surgery center, the licensed dentist shall ensure that the Board has been notified that the licensed dentist 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 Article.

(c) Facility Equipment Requirements. – The licensed dentist shall ensure that the facility where the sedation procedure is to be performed meets all of the following requirements at the time of the sedation procedure:

(1) The facility must be equipped with all of the following equipment and ensure that the 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. CPR board or dental chair suitable for providing emergency treatment.

c. Lighting as necessary for the procedure to be performed and backup lighting.

d. Suction equipment as necessary for the procedure to be performed, including non-electrical backup suction.

- e. Positive pressure oxygen delivery system, including full-face masks for small, medium, and large patients, and backup E-cylinder portable oxygen tanks 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.
- k. Capnograph.
- l. Precordial or pretracheal stethoscope.
- m. Thermometer.
- n. Vascular access setup 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 backup suction.
- r. Syringes as necessary for the procedure to be performed.
- s. Tourniquet and tape.
- (2) The licensed dentist 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 manufacturer's recommendations. The licensed dentist shall maintain documentation of all preventive maintenance performed and shall ensure equipment is replaced upon its expiration or as clinically required.
- (3) The licensed dentist 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.
 - m. An antiemetic.
 - n. A neuromuscular blocking agent.
- (4) The licensed dentist 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 any information as required by rule.
- (5) The licensed dentist shall satisfy any additional facility requirements applicable to the permit level as required by the Board or this Article.
- (d) The licensed dentist shall ensure that the following staffing, education, and training requirements are met prior to performing a sedation procedure:

- 1 (1) The licensed dentist shall review and practice responding to clinical
2 emergencies with all auxiliaries as a team and in person every six months and
3 shall provide training to familiarize all auxiliaries in the treatment of clinical
4 emergencies including, at a minimum, all of the following:
5 a. Airway obstruction.
6 b. Allergic reactions.
7 c. Angina pectoris.
8 d. Apnea.
9 e. Bradycardia.
10 f. Bronchospasm.
11 g. Cardiac arrest.
12 h. Convulsions.
13 i. Emesis and aspiration.
14 j. Hypertension.
15 k. Hypoglycemia.
16 l. Hypotension.
17 m. Hypoventilation and respiratory arrest.
18 n. Hypoxemia and hypoxia.
19 o. Laryngospasm.
20 p. Myocardial infarction.
21 q. Syncope
22 (2) All auxiliaries in the facility shall be BLS-certified.
23 (3) Except as provided in subdivision (4) of this subsection, the licensed dentist
24 performing the surgical procedure or other dental procedure shall ensure that
25 a registered nurse or a BLS-certified auxiliary is dedicated to patient
26 monitoring and recording anesthesia or sedation data throughout the sedation
27 procedure.
28 (4) A licensed dentist does not need to comply with subdivision (3) of this
29 subsection if the licensed dentist or an additional sedation provider is
30 dedicated to patient care and monitoring regarding anesthesia or moderate
31 sedation throughout the sedation procedure and is not performing the surgery
32 or other dental procedure. For the purposes of this subdivision, an additional
33 sedation provider must be one of the following individuals:
34 a. A licensed dentist holding a permit or mobile permit in satisfaction of
35 this Article to administer the anesthesia or sedation level at the facility
36 where the sedation procedure is performed.
37 b. An anesthesiologist licensed and practicing in accordance with Article
38 1 of this Chapter and the rules of the North Carolina Medical Board.
39 c. A certified registered nurse anesthetist licensed and practicing in
40 accordance with the rules of the North Carolina Board of Nursing,
41 under the supervision and direction of the licensed dentist who shall
42 ensure the level of sedation administered does not exceed the level of
43 the sedation allowed by the licensed dentist's permit.
44 (5) The licensed dentist shall satisfy any additional staffing, education, and
45 training requirements applicable to the level of the permit, consistent with this
46 Article or rule approved by the Board.
47 (e) Before starting any sedation procedure, the licensed dentist shall conduct a
48 preoperative patient evaluation which shall include the following:
49 (1) Evaluating the patient for health risks relevant to the potential sedation
50 procedure.

- 1 (2) Evaluating the patient's food and fluid intake following the ASA guidelines
2 for preoperative fasting applicable to elective procedures involving the
3 administration of anesthesia or moderate sedation.
4 (3) Satisfying any additional requirements for preoperative patient evaluation and
5 procedures applicable to the level of the permit as set out in this section.
6 (f) During the sedation procedure, the licensed dentist shall ensure all of the following
7 occur:
8 (1) Prescriptions intended to accomplish procedural sedation, including enteral
9 dosages, shall be administered only under the direct supervision of the permit
10 holder.
11 (2) If IV sedation is used, IV infusion shall be administered before the start of the
12 procedure and maintained until the patient is ready for discharge.
13 (3) Capnography shall be used to monitor patients unless an individual patient's
14 behavior or condition prevents use of capnography. In that event, the permit
15 holder shall document in the sedation record the clinical reason capnography
16 could not be used.
17 (4) The licensed dentist shall ensure the patient's baseline vital signs are taken and
18 recorded, including temperature, SPO2, blood pressure, and pulse.
19 (5) The licensed dentist shall ensure the patient's blood pressure, oxygen
20 saturation, ET CO2, unless capnography cannot be used, pulse, and respiration
21 rates are monitored continuously in a manner that enables the licensed dentist
22 to view vital sign trends throughout the procedure.
23 (6) The licensed dentist shall ensure the intraoperative vital sign information is
24 recorded on the anesthesia or sedation record contemporaneously throughout
25 the procedure in intervals of five minutes or less for patients over 12 years old
26 and in intervals of 10 minutes or less for pediatric patients 12 years old or
27 younger.
28 (7) The licensed dentist shall satisfy any additional requirements for operative
29 procedures applicable to the level of the permit, as set out in this section.
30 (g) Post-operative monitoring and discharge by the licensed dentist shall include all of
31 the following:
32 (1) The licensed dentist or an auxiliary under his or her direct supervision shall
33 monitor the patient's post-operative vital sign information until the patient is
34 recovered and is ready for discharge from the office. Recovery from
35 anesthesia or moderate sedation shall include documentation of the following:
36 a. Stable cardiovascular function.
37 b. Uncompromised airway patency.
38 c. Patient arousable and protective reflexes intact.
39 d. State of hydration within normal limits.
40 e. Patient can talk, if applicable.
41 f. Patient can sit unaided, if applicable.
42 g. Patient can ambulate with minimal assistance, if applicable.
43 h. For a special needs patient, the pre-sedation level of responsiveness or
44 the level as close as possible for that patient shall be achieved.
45 (2) Before allowing the patient to leave the office, the licensed dentist shall
46 determine that the patient has met the recovery criteria set out in subdivision
47 (1) of this subsection and all of the following discharge criteria:
48 a. Oxygenation, circulation, activity, skin color, and level of
49 consciousness are stable and have been documented.

- 1 b. Explanation and documentation of written post-operative instructions
2 have been provided to the patient or a person responsible for the
3 patient at time of discharge.
4 c. A person authorized by or responsible for the patient is available to
5 transport the patient after discharge.
6 (h) The licensed dentist shall maintain all of the following information in the patient's
7 treatment records for a period of 10 years:
8 (1) The patient's current written medical history, including known allergies and
9 previous surgeries.
10 (2) A preoperative assessment.
11 (3) Consent to the procedure and to the anesthesia or sedation, signed by the
12 patient or guardian, identifying the procedure and its risks and benefits, the
13 level of anesthesia or sedation and its risks and benefits, and the date signed.
14 (4) The anesthesia or sedation record that shall include all of the following
15 information:
16 a. The patient's baseline vital signs and intraoperative vital sign
17 information in accordance with subsection (f) of this section.
18 b. The printed or downloaded vital sign information from the
19 capnograph. A permit holder's failure to maintain capnograph
20 documentation, except as set out in subsection (f) of this section, shall
21 be deemed a failure to monitor the patient as required pursuant to this
22 section.
23 c. Procedure start and end times.
24 d. Gauge of needle and location of IV on the patient, if used.
25 e. The total amount of any local anesthetic administered during the
26 procedure.
27 f. Any analgesic, sedative, pharmacological, or reversal agent, or other
28 drugs administered during the procedure, including route of
29 administration, dosage, strength, time, and sequence of administration,
30 with separate entries for each increment of medication that is titrated
31 to effect.
32 g. Documentation of complications or morbidity and clinical responses.
33 h. Status of patient upon discharge, including documentation of
34 satisfying the requirements set out in this subsection.
35 (5) Any additional documentation applicable to the level of the permit in
36 accordance with this section."

37 **SECTION 2.(b)** Article 2 of Chapter 90 of the General Statutes is amended by
38 adding a new section to read:

39 **"§ 90-30.4. Moderate parenteral and enteral conscious sedation clinical requirements and**
40 **equipment.**

41 (a) A dentist holding or applying for a permit to administer moderate conscious sedation
42 or supervising any CRNA employed to administer or RN employed to deliver moderate
43 conscious sedation shall comply with the requirements of this section, in addition to other
44 requirements of this Article.

45 (b) In addition to the drugs listed G.S. 90-30.3, an unexpired muscle relaxant shall be
46 immediately available and be accessible from the operatory and recovery rooms.

47 (c) As part of the preoperative assessment required by G.S. 90-30.3, the licensed dentist
48 shall evaluate the patient for health risks as follows:

- 49 (1) A patient who is medically stable and who is ASA I or II shall be evaluated
50 by reviewing the patient's current medical history and medication use.

(2) A patient who is not medically stable or who is ASA III or higher shall be evaluated by the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

(d) During the sedation procedure, a moderate conscious sedation licensed dentist shall not administer anesthetic or sedative agents satisfying any of the following criteria:

(1) Designed by the manufacturer for use in administering general anesthesia or deep sedation.

(2) Determined by the manufacturer to be contraindicated for use in moderate conscious sedation.

(3) In amounts exceeding the manufacturers' maximum recommended dosages unless the licensed dentist documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient."

SECTION 2.(c) Article 2 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-30.5. Moderate pediatric conscious sedation clinical requirements and equipment.

(a) A dentist holding or applying for a permit to administer moderate pediatric conscious sedation shall comply with the requirements of this section, in addition to other requirements of this Article.

(b) In addition to the drugs listed G.S. 90-30.3, an unexpired muscle relaxant shall be immediately available and be accessible from the operatory and recovery rooms.

(c) In addition to the requirements set out in G.S. 90-30.3, the licensed dentist's emergency manual shall include assignments to be performed in the event of emergency by a BLS-certified auxiliary dedicated to patient monitoring.

(d) In addition to the requirements set out in G.S. 90-30.3 concerning preoperative procedures, the licensed dentist shall ensure that patients who have been administered moderate pediatric conscious sedation are monitored for alertness, responsiveness, breathing, and skin coloration during waiting periods before operative procedures by the licensed dentist or an auxiliary dedicated to patient monitoring.

(e) As part of the preoperative assessment required by G.S. 90-30.3, the licensed dentist shall evaluate the patient for health risks 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.

(2) A patient who is not medically stable or who is ASA III or higher shall be evaluated by the permit holder's consultation with the patient's primary care physician or consulting medical specialist regarding the potential risks posed by the planned dental procedure.

(f) If a patient immobilization device is used, the licensed dentist shall ensure that all of the following conditions are met:

(1) The device is applied to avoid airway obstruction or chest restriction.

(2) The patient's head position and respiratory excursions are checked frequently to ensure airway patency.

(3) A hand or foot is kept exposed.

(4) The patient is under observation by the licensed dentist or a BLS-certified auxiliary at all times.

(g) During the sedation procedure, a moderate pediatric conscious sedation licensed dentist shall not administer any of the following anesthetic or sedative agents:

(1) Designed by the manufacturer for use in administering general anesthesia or deep sedation.

(2) Determined by the manufacturer to be contraindicated for use in moderate pediatric conscious sedation.

(3) In amounts exceeding the manufacturers' maximum recommended dosages, unless the licensed dentist documents in the sedation record the clinical reason for exceeding the maximum recommended dosage for the patient.

(h) In addition to the requirements set out in G.S. 90-30.3 concerning the patient treatment record, the licensed dentist shall maintain documentation of pre-sedation instructions and information provided to the patient or person responsible for the patient, which shall include all of the following:

(1) Objectives of the sedation.

(2) Anticipated changes in patient behavior during and after sedation.

(3) Instructions to the person responsible for a patient transported in a child safety seat regarding patient head position to avoid airway obstruction.

(4) A 24-hour telephone number for the permit holder or his or her BLS-certified auxiliaries.

(5) Instructions on limitations of activities and dietary precautions.

(i) For purposes of this section, during an evaluation, a moderate pediatric conscious sedation licensed dentist or applicant shall demonstrate competency in the deployment of an intravenous delivery system as follows:

(1) A licensed dentist or applicant who uses intravenous sedation shall demonstrate the administration of moderate pediatric conscious sedation on a live patient, including the deployment of an intravenous delivery system.

(2) A licensed dentist or applicant who does not use intravenous sedation shall describe the proper deployment of an intravenous delivery system and shall demonstrate the administration of moderate pediatric conscious sedation on a live patient."

SECTION 2.(d) Article 2 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-30.6. Reports of adverse events.

(a) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse occurrence report to the Board within 72 hours after each adverse event if the patient dies or has permanent organic brain dysfunction within 24 hours after the administration of general anesthesia or sedation. Sedation permit holders shall cease administration of sedation until the Board has investigated the death or permanent organic brain dysfunction and approved resumption of permit privileges. General anesthesia permit holders shall cease administration of general anesthesia and sedation until the Board has reviewed the adverse event report and approved resumption of permit privileges.

(b) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse event report to the Board within 30 days after each adverse event if the patient is admitted to a hospital on inpatient status for a medical emergency or physical injury within 24 hours after the administration of general anesthesia or sedation.

(c) A dentist who holds a permit to administer general anesthesia or sedation shall submit an adverse event report to the Board within 30 days after each adverse event, as defined in G.S. 90-30.3.

(d) The adverse event report shall be in writing and shall include, at a minimum, all of the following:

(1) Dentist's name, license number, and permit number.

(2) Date and time of the occurrence.

(3) Facility where the occurrence took place.

(4) Name and address of the patient.

(5) Surgical procedure involved.

(6) Type and dosage of sedation or anesthesia utilized in the procedure.

(7) Circumstances involved in the occurrence.

(8) The entire patient treatment record, including anesthesia records.
(e) Upon receipt of an adverse event report under this section, the Board shall investigate and shall take disciplinary action if the evidence demonstrates that a licensee has violated this Article."

SECTION 2.(e) Article 2 of Chapter 90 of the General Statutes is amended by adding a new section to read:

"§ 90-30.7. Requirements for inspections and evaluations.

(a) During a facility inspection, for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or licensed dentist shall demonstrate satisfaction of the requirements set forth in G.S. 90-30.3.

(b) During an evaluation for a dentist applying for or holding a permit to administer general anesthesia, moderate conscious sedation, or moderate pediatric conscious sedation, the applicant or licensed dentist shall demonstrate the administration of anesthesia or sedation in accordance with the level of the permit and shall demonstrate competency in all of the following areas in accordance with G.S. 90-30.3:

(1) Preoperative patient evaluation and procedures.

(2) Operative procedures, including the deployment of an intravenous delivery system.

(3) Post-operative patient monitoring and discharge.

(4) Treatment of the clinical emergencies.

(c) During the evaluation, the applicant shall take a written examination on the topics set forth in subsection (b) of this section. The applicant shall obtain a passing score on the written examination by answering eighty percent (80%) of the examination questions correctly. If the applicant fails to obtain a passing score on the written examination, the applicant may be reexamined under reexamination procedures as set forth by the Board.

(d) A licensed dentist must be reevaluated once every five years. Each facility where the permit holder administers anesthesia or sedation shall be subject to a facility inspection upon the annual renewal of the permit."

SECTION 3. The North Carolina Policy Collaboratory at the University of North Carolina at Chapel Hill shall conduct a study to evaluate whether a second health care provider who is qualified to provide anesthesia services is needed when utilizing drugs that can lead to deep sedation, such as propofol. The Collaboratory shall submit a report to the Joint Legislative Oversight Committee on Health and Human Services by April 1, 2024, with any legislative recommendations addressing this issue.

SECTION 4. Sections 1 and 2 of this act become effective July 1, 2023. The remainder of this act effective when it becomes law.