## New Anesthesia & Sedation Rules O.A.C. §4715-5-07 Effective Date – April 1, 2024

## 4715-5-07 Use of moderate sedation.

- (A) Use of moderate sedation
  - (1) The following may be administered by any dentist, unless otherwise restricted by the board:
    - (a) Patients thirteen years of age or older may receive enteral minimal sedation, limited to a single dose of a single drug at not more than the maximum recommended dose on the FDA-approved labeling indicated for unmonitored home use, with or without nitrous oxide-oxygen minimal sedation and local anesthesia:
    - (b) Patients of any age may receive nitrous oxide-oxygen inhalation for minimal sedation.
  - (2) Notwithstanding paragraph (A)(1) of this rule, no dentist shall administer moderate sedation in the state of Ohio, in accordance with the definition of "moderate sedation", as defined in paragraph (B)(19) of rule 4715-3-01 of the Administrative Code, unless such dentist possesses a moderate sedation permit or provisional moderate sedation privileges as set forth in paragraph (C) of this rule is pending. The dentist holding such permit shall be subject to review and such permit must be renewed biennially.
  - (3) The moderate sedation provider's education, training, experience, and current competence must clinically coincide with the progression of a patient along the anesthesia continuum as defined in paragraph (B)(6) of rule 4715-3-01 of the Administrative Code. The moderate sedation provider must be prepared to manage a level of anesthesia deeper than intended as it is not always possible to predict how a given patient will respond to anesthesia. The moderate sedation provider's ultimate responsibility is to protect the patient including, but not limited to, identification and management of any complication(s) occurring during the anesthesia time.
  - (4) With the exception of nitrous oxide-oxygen, no dentist shall administer to a patient under thirteen years of age, any drug, or techniques, or any combination thereof that would likely render the patient minimally or moderately sedated unless the dentist is qualified as described in paragraph (B)(2) of this rule and holds a moderate sedation permit with a pediatric endorsement, provisional moderate sedation privileges with a pediatric endorsement, a general anesthesia permit or provisional general anesthesia privileges.
  - (5) No dentist shall administer or employ any agent(s) with a narrow margin for maintaining consciousness including, but not limited to, potent volatile inhalation anesthetic agents, ultra-short acting barbiturates, propofol, ketamine, and similarly acting drugs, or quantity of agent(s), or techniques, or any combination thereof that would likely render a patient deeply sedated, generally anesthetized or otherwise not meeting the conditions of the definition of minimal sedation or moderate sedation in paragraph (B)(18) or (B)(19) of rule 4715-3-01 of the Administrative Code, unless the dentist holds a valid general anesthesia permit or provisional general anesthesia privileges as issued by the board.
- (B) Moderate sedation permit In order to receive a moderate sedation permit, the dentist must apply on a prescribed application form to the board, indicate whether applying for a permit to sedate patients age thirteen and over, patients under thirteen or both, submit the fee as established by division (A) of section 4715.13 of the Revised Code, and produce evidence showing that the dentist:
  - (1) Has satisfactorily completed one of the following within two years of submitting the application for moderate sedation permit to treat patients age thirteen or older:

- (a) A comprehensive predoctoral or advanced dental education program accredited by the commission on dental accreditation which includes training in moderate sedation commensurate with the "Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students" as adopted by the October 2016 American dental association house of delegates; or
- (b) A continuing education course in moderate sedation commensurate with the "Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students" as adopted by the October 2016 American dental association house of delegates. The course must be approved by either the American dental association commission for continuing education provider recognition or the academy of general dentistry program approval for continuing education council. The course must be designed to assess and document competency in all aspects of moderate sedation. At a minimum, such courses must include all the following:
  - (i) No fewer than sixty hours of didactic instruction, excluding advanced cardiac life support (ACLS) and basic life support for the healthcare provider (BLS-HCP) instruction time, plus administration of moderate sedation as defined in this document for at least twenty individually managed dental patients, ensuring that only a single course participant earns credit for each patient encounter. An individual patient may be sedated no more than once per day for these sedation encounters;
  - (ii) Written certification by the course director of competence in moderate sedation techniques;
  - (iii) Written certification of competence by the course director in rescuing patients from a level of sedation deeper than intended including managing the airway, intravascular or intraosseous access, and reversal medication use; and
  - (iv) Provision of additional clinical experience if the participant competency has not been demonstrated in the alloted time.
- (2) Has satisfactorily completed one of the following within two years of submitting the application for a moderate sedation permit to treat patients under age thirteen:
  - (a) An advanced dental education program in pediatric dentistry accredited by the commission on dental accreditation; or
  - (b) A program in pediatric moderate sedation for children under age thirteen which includes:
    - (i) Sixty hours of didactic instruction in pediatric sedation;
    - (ii) Written documentation of competency in pediatric moderate sedation after having completed a minimum of:
      - (a) Twenty-five moderate pediatric sedation cases with other sedative agent(s) (with or without being combined with nitrous oxide-oxygen) administered by any route, ensuring that only a single course participant earns credit for each patient sedation encounter. An individual patient may be sedated no more than once per day for these sedation encounters;
      - (b) Twenty-five additional sedation experiences by individual or group participation or with human sedation/anesthesia simulation experiences or a combination thereof; and
      - (c) Four weeks of a hospital anesthesiology rotation experience that includes preoperative evaluation/assessment, risk management, pharmacology, venipuncture, advanced airway

placement, patient monitoring, recognition and management of anesthetic emergencies in pediatric patients.

- (iii) Written certification by the program director of competency in:
  - (a) Rescuing pediatric patients from a level of anesthesia deeper than intended; an
  - (b) Reversal of sedation medications.
- (iv) A course provision of additional clinical experience if participant competency has not been demonstrated in the allotted time.
- (3) Has maintained records of instruction and clinical experiences, including complete records of moderate sedation as defined in this document for all patients treated, and certification(s) of competence;
- (4) Documents successful completion of basic life support for healthcare providers (BLS-HCP) and;
  - (a) For sedating patients age thirteen and over, successful completion of advanced cardiac life support (ACLS) courses; or
  - (b) For sedating patients under age thirteen, successful completion of pediatric advanced life support (PALS) training.
- (5) Has a properly equipped facility for the administration of moderate sedation in which the permit holder has available and agrees to utilize adequate monitoring, personnel, emergency equipment and drugs as recommended in the "Guidelines for the Use of Sedation and General Anesthesia by Dentists" as adopted by the October 2016 American dental association house of delegates and/or the American association of oral and maxillofacial surgeon's "Office Anesthesia Evaluation Manual," 9th edition.
- (C) Provisional privileges Prior to the issuance of a moderate sedation permit, if the applicant dentist meets the requirements set forth in paragraph (B) of this rule:
  - (1) The board shall issue to the applicant dentist provisional moderate sedation privileges valid for up to one year pending successful completion of the clinical onsite evaluation.
  - (2) Unless otherwise authorized by the board, a dentist with provisional moderate sedation privileges shall request an extension no later than ninety days before the expiration of their provisional moderate sedation privileges if necessary to complete the onsite evaluation.

## (D) Clinical onsite evaluation

- (1) The board shall require an onsite evaluation of the facility(s), equipment, personnel, moderate sedation techniques and related document(s) to determine if the requirements set forth in paragraph (B) of this rule have been met. This evaluation shall be conducted by a qualified consultant appointed by the board and for sedating patients age thirteen and older must follow the "Guidelines for the Use of Sedation and General Anesthesia by Dentists" as adopted by the October 2016 American dental association house of delegates, or, for sedating children under thirteen, the "Guidelines for the Monitoring and Management of the Pediatric Patient, Before, During, and After Sedation for Diagnostic and Therapeutic Procedures" June 2019 revised policy of the American academy of pediatrics;
- (2) In the case of a mobile or portable facility, one inspection of that facility shall be conducted in the office of an Ohio-licensed dentist where moderate sedation is administered. A written list of all monitors, emergency equipment and other materials which the mobile moderate sedation provider agrees to have

- available at all times while administering moderate sedation in multiple locations shall be provided to the board; and
- (3) The applicant shall be responsible for the cost of this evaluation, which will be an amount not to exceed four hundred dollars.
- (E) Unsatisfactory permit application In the event the board deems the application or evaluation unsatisfactory, a written explanation documenting deficiencies and suggested remedies shall be forwarded to the applicant. The board may issue a permit based on documentation that the deficiencies have been corrected; or the board may require a formal re-evaluation; or the board may issue a notice of opportunity for hearing pursuant to Chapter 119. of the Revised Code to deny the application for a moderate sedation permit.
- (F) Permit renewal The board shall, without charge, renew the moderate sedation permit biennially at the time of dental licensure renewal, provided the permit holder attests to the board that the permit holder:
  - (1) Maintains successful completion of:
    - (a) A basic life support course for healthcare providers (BLS-HCP);
    - (b) A course in advanced cardiac life support (ACLS) for sedation of patients age thirteen and over, or for sedation of children under age thirteen, pediatric advanced life support (PALS); and
    - (c) A minimum of six hours of board approved continuing education devoted specifically to the management and/or prevention of emergencies which may result from the use of moderate sedation.
  - (2) Has performed emergency drills at least quarterly during the biennium, documenting in a log the date, nature of simulated emergencies, and names and roles of all participants. Required simulated emergencies include, on an annual basis, the following scenarios:
    - (a) Hypotensive, hypertensive, bradycardic and tachycardic emergencies;
    - (b) Recognition and management of loss of capnography tracing requiring appropriate management of the airway and of the underlying cause, e.g. anesthetic overdose, secretions, etc. due to:
      - (i) Hypoventilation that progresses to respiratory arrest;
      - (ii) Soft tissue or foreign body obstruction of the airway;
      - (iii) Laryngospasm; and
      - (iv) Bronchospasm.
    - (c) An unexpected decline in level of consciousness, including consideration of multiple possible etiologies, e.g. over-sedation, stroke, seizure, street drug use, hypoxia, anaphylaxis, etc.;
    - (d) With the exception of those who solely possess a pediatric endorsement, recognition and management of chest pain progressing to cardiac arrest;
    - (e) In offices where moderate sedation is performed less frequently than quarterly, or for the first time, the requirement for emergency drills may be satisfied by performing emergency drills for, at a minimum, all of the above scenarios immediately preceding the administration of moderate sedation for an actual patient.

- (3) Has reviewed the laws and rules governing the administration of moderate sedation; and
- (4) Has verified that all licensed/registered personnel involved in the administration of moderate sedation maintain current, active licensure or registration.
- (G) Licensed dentists who did not complete a comprehensive predoctoral or advanced dental education program accredited by the U.S. department of education as defined in paragraph (B)(1)(a) or paragraph (B)(2)(a) of this rule who hold a current permit and have been using or employing sedation prior to adoption of this rule and who desire to continue to use or employ sedation, shall within one year of the effective date of this rule submit an attestation to the board along with evidence demonstrating competency of successful administration of sedation to a minimum of twenty patients in the three years preceding attestation. Evidence of competency shall be commensurate with each intended patient age range whether:
  - (1) Patiens age thirteen and over;
  - (2) Patients twelve years or younger; or
  - (3) Both (forty case total).
- (H) Reciprocity The board may grant a moderate sedation permit to a dentist who has administered moderate sedation in another state when training as outlined in paragraphs (B)(1) and/or (B)(2) of this rule was completed more than two years before the submission of the application and the applicant provides a log of all moderate sedation cases performed during the previous three years. A minimum of twenty age-appropriate cases logged in the preceding three years is required to demonstrate current competency. The board may request complete moderate sedation records of cases selected from this log.
- (I) General anesthesia permit holders A dentist holding a general anesthesia permit under rule 4715-5-05 of the Administrative Code may administer moderate sedation without a moderate sedation permit.
- (J) Certified registered nurse anesthetist (CRNA) A dentist holding a moderate sedation permit may supervise a licensed, certified registered nurse anesthetist only for moderate sedation procedures for which the dentist is qualified by permit. The permitted dentist must provide direct, personal, on-site supervision of the CRNA within the scope of the permit of the CRNA throughout the entire anesthesia time.
- (K) New facility All moderate sedation permit holders shall provide written notification within ten business days to the board if conscious sedation services are to be provided an any new facility(s) other than those already listed with the board.
- (L) Anesthetic team During moderate sedation, the following persons must be physically present in the room and caring exclusively for the patient:
  - (1) A moderate sedation provider; and
  - (2) A person currently certified in BLS-HCP who may assist the moderate sedation provider, shares the patient monitoring and documentation duties and who is able to assist the moderate sedation provider in an emergency if needed.
- (M) Recovery monitoring The moderate sedation provider must remain on the premises of the dental facility until any patient given moderate sedation has been discharged. Assuming that the patient continues to respond appropriately to verbal command after the procedure has ended, further recovery until ready for discharge must be monitored by one person described in paragraph (L)(2) of this rule.

- (N) Employing a moderate sedation provider A dentist who employs or works with a moderate sedation provider must:
  - (1) Ensure that the anesthesia provider meets the requirements defined in paragraph (B)(4) or (B)(5) of rule 4715-3-01 of the Administrative Code;
  - (2) Ensure that the facility meets the requirements set forth in paragraph (B)(5) of this rule; and
  - (3) Be currently certified in BLS-HCP and able to assist the moderate sedation provider in an emergency if needed.
- (O) Reevaluation The board may conduct additional evaluations, as described in paragraph (D) of this rule, upon informing the permit holder in writing that a reevaluation is required of the permit holder's facility(s) and/or methods. In determining whether such reevaluation is necessary, the board shall consider such factors as it deems pertinent including, but not limited to, patient complaints, report of adverse occurrences, and random quality assurance audits. Such quality assurance audit(s), may include, but are not limited to, a review of documentation of pre-sedation evaluation(s), sedation and recovery records, and documentation of appropriateness for discharge. The permit holder shall be responsible for any costs incurred in a reevaluation, not to exceed four hundred dollars.
- (P) Reference materials for paragraphs (B)(1)(b), (B)(5), and (D) of this rule may be found at the following addresses:
  - (1) American dental association: 211 E. Chicago avenue, Chicago, Illinois, 60611-2678; telephone 312-440-2500; facsimile 312-440-2800; internet website address www.ada.org.
  - (2) American academy of pediatrics: 345 Park avenue, Itasca, Illinois 60143; internet website address www.aappublications.org/news.