Board of Dental Examiners

Den 304, Notice #2024-126
Summary of Comments on Initial Proposal with Board Responses
August 9, 2024

Background

The public hearing was held on August 9, 2024 at 9:00 a.m. 2 members of the public were present to provide testimony. There were 12 written comments submitted as outlined below.

Public Comments

Thomas F. Burk, DMD, MD, President, NH Society of Oral and Maxillofacial Surgeons (NHSOMS)

Den 304.03 Permit Types:
Comment: NHSOMS supports the development of a facility permit.
Response: A facility permit has been created in Den 304.03(a)(1) and (2).

Den 304.07 Facility or Facility Hosting Requirements:
Comment: The title of this section, specifically (b), is related to personal permit requirements rather than facility or facility hosting permits. Recommend revision to reflect the nature of this section.
Response: Den 304.07(b) has been reworded to clarify that it refers to facility and facility hosting requirements.

Comment: Equipment, supply, or emergency medication requirements should be tied to the facility permits rather than individual permits. This would ensure that host facility practices are appropriately equipped with necessary devices.
Response: Den 304.07 has been reworded to clarify that equipment, supply, and emergency medication requirements are for the facility.

Comment: We propose maintaining required drugs be specified classes rather than individual formularies whenever possible. Greater flexibility is needed so providers can quickly pivot between appropriate medications and allow for the use of new drugs entering the market.
Response: Den 304.07(b) has been reworded to refer to drug classes instead of individual formularies where appropriate.

Den 304.08 Administering General Anesthesia, Deep Sedation, or Moderate Sedation:
Comment: There are serious concerns with the proposal as drafted, specifically that the outright banning of the self-administration of deep sedation, general anesthesia to the 0-8 population will create both an access to care and patient safety concern and does not solve one.
Response: The New Hampshire legislature in RSA 317-A:12, XII-a(h)(1) requires that for administration of general anesthesia or deep sedation, in addition to the dentist performing the procedure, a dedicated anesthesia provider shall be present to monitor the procedure and recovery from anesthesia for patients under the age of 13. The legislature in RSA 317-A:12, XII-a(h)(1) has tasked the Board of Dental Examiners with the responsibility of adjudicating

exemptions for dentist's board eligible or board certified in dental anesthesiology or oral and maxillofacial surgery from the requirement for the presence of a dedicated anesthesia provider to monitor the procedure and recovery from anesthesia in patients under the age of 13 years. The Board has identified the age range 0-8 years for requiring a dedicated anesthesia provider regardless of a dentist's level of training. The Board's concerns regarding administration of deep sedation/general anesthesia to children in this age range are not for circumstances when the anesthesia administration and procedure are going as planned, but rather when an emergency situation arises during administration of anesthesia in a dental office setting. It is during this critical time that appropriate office procedures and staffing are necessary to rescue the child. Largely, this is due to anatomical differences in these younger children vs. older children. Younger children have larger heads relative to their bodies, which can more easily cause airway obstruction with neck positioning. These younger pediatric patients require increased supplemental oxygen during procedures and can lose oxygen more rapidly compared to older children. Younger children have a narrowed airway at a lower portion of their trachea from older children, and an emergency rescue cricothyrotomy is often more difficult in this patient population requiring more sophisticated needle-based surgical airway intervention. Alternatively, when a child 0-8 years of age requires dental treatment, the qualified dentist could administer moderate sedation to the child in accordance with Den 304.08(i), bring in a separate qualified dentist to their office pursuant to RSA 415:18-h, or could bring the child to a hospital or surgery center for treatment pursuant to RSA 415:18-g, RSA 420-A:17-b, and RSA 420-B:8-ee. There were several resources considered by the Board in identifying the age range 0-8 years for requiring a dedicated anesthesia provider for administration of deep sedation or general anesthesia regardless of a dentist's level of training, including:

- NHSOMS Comments Regarding Den 304 Proposal. Thomas F. Burk, DMD, MD, NHSOMS President. July 26, 2024.
- Wiemer SJ, Mediratta JK, Triana RR, et al. What is the Incidence of Anesthesia Related Adverse Events in Oral and Maxillofacial Surgery Offices? A Review of 61,237 Sedation Cases from a Large Private Practice Consortium. Journal of Oral and Maxillofacial Surgery (2024).
- Chapter 6: Pediatric Anesthesia. Office Anesthesia Evaluation Manual, 9th edition. American Association of Oral and Maxillofacial Surgeons.
- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).
- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- Avva U, Lata JM, Kiel J. Airway Management. [Updated 2023 May19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. (https://www.ncbi.nlm.nih.gov/books/NBK470403/).

Comment: **Paragraph (e)** - NHSOMS supports the inclusion of the requirement for providers seeking the 9-12 age patient exemption to complete a course such as the OBEAM, there are other, similar courses available and request clarification that the Board may choose to recognize those courses as applicable.

Response: Paragraph (e) has been changed to (f). Den 304.08(f)(1) has been reworded to remove reference to any specific advanced airway course with hands-on training.

Comment: **Paragraph (e) specific to assistant requirements** – Den 304.08(e) has been renumbered Den 304.08(f). NHSOMS has concerns over the assistant requirements for the 9-12 age patient exemption, specifically mandating they be PALS certified. The NHSOMS requests BLS-HCP, PALS, or 36 hours of didactic instruction plus 4+ hours of clinical training in assisting an anesthesia provider.
Response: Multiple pediatric anesthesia resources recommend a second observer who is specifically PALS certified to assist the sedation provider during administration of deep sedation/general anesthesia in case of a pediatric anesthetic emergency. References:

- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).
- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- American Academy of Pediatric Dentistry. Use of anesthesia providers in the administration of office-based deep sedation/general anesthesia to the pediatric dental patient. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2023:429-33.

Comment: **Paragraph (e)(2) (addendum to original comments received on 8/6/2024)** – Need clarification on section Den 304.08(e)(2)(c), which in part addresses special needs patients. "Children with special needs" can be very broad, subject to interpretation, and range in both needs and risk during the administration of deep sedation or general anesthesia. Clarification is needed in this area, including the ability to allow for provider discretion as it would be impossible to codify every possibility.
Response: Paragraph (e)(2) has been renumbered to (f)(2). According to the American Dental Association, "Patients with special needs require unique consideration when receiving dental treatment due to physical, mental, developmental or cognitive conditions. This can include people with Autism Spectrum Disorder, Alzheimer's disease, Down syndrome, spinal cord injuries and other conditions or injuries that can make standard dental procedures more difficult." Children with special needs are also identified by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry as presenting "issues that require additional and individual consideration, particularly for moderate and deep sedation." References:

- https://www.mouthhealthy.org/all-topics-a-z/patients-with-special-needs
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).

Comment: **Paragraph (f)(2)** referring to the administration of moderate sedation for those patients between 9 and 12 years of age. Clarification is needed to this section as it is unclear if this requirement would also apply to those individuals holding a general anesthesia, deep sedation, and moderate sedation permit or only to individuals with a moderate sedation permit with pediatric qualification.

Response: Paragraph (f)(2) has been renumbered to (g)(2). Den 304.08(g)(1) specifically requires that a qualified dentist shall possess a permit for general anesthesia, deep sedation, and moderate sedation for all ages or a permit for moderate sedation with pediatric qualification for 9 years of age and older when treating patients between 9 and 12 years of age with administration of moderate sedation only and without a separate dedicated anesthesia provider present.

Den 304.09 – Facility or Facility Hosting Documentation Requirements:
Comment: It is recommended that such records be kept in a time-oriented model and that a time interval be specified by the Board for such records. NHSOMS suggests that records be maintained in 5-minute intervals, consistent with AAOMS and ASA standards.
Response: Den 304.08(a) references the American Dental Association "Guidelines for the Use of Sedation and General Anesthesia by Dentists" revised 2016 regarding guidelines for maintaining a time-oriented anesthetic record while administering moderate sedation, deep sedation, or general anesthesia. Den 304.09(a)(2)d. and e. have been reworded to additionally highlight these requirements from Den 304.08(a).

Den 304.13 – Morbidity and Mortality Reports:
Comment: It is recommended that the initial notification occur within 24 hours, in addition to the full report to be submitted within 15 working days.
Response: Den 304.13(b) requires morbidity and mortality report submission to the Board through the OPLC "as soon as is reasonably and practically possible, but no later than 15 working days after discovery of the event." The Board is satisfied with this wording.

Comment: – NHSOMS recommends that condensed and deidentified data from these events be published on the Board's website to allow for public inspection and study of the information. Transparency would allow state dental societies to provide any necessary education to NH dentists based on the data. Alternatively, NHSOMS would recommend reporting the information to a national registry such as DAIRS.
Response: Den 304.13(i) explains that the process of root cause analysis of a morbidity or mortality event utilizing the OPLC enforcement division, as well as the dentist's corrective action plan and report of findings subject to this investigation, are confidential and shall be held in accordance with RSA 91-A.

General Recommendation:
Comment: While a majority of the document focuses on pediatric anesthesia delivery, the NHSOMS noted that staffing requirements for adult patients are absent. NHSOMS would recommend that the regulations include a requirement for at least one other person besides the dental provider to be present during the administration of moderate sedation, and 2 individuals during the administration of DS/GA.
Response: Personnel requirements for moderate sedation, as well as for deep sedation or general anesthesia, are outlined in the American Dental Association "Guidelines for the Use of Sedation and General Anesthesia by Dentists" revised 2016 as referenced in Den 304.08(a).

Michael P. Auerbach, Executive Director, NH Dental Society:

Den 304 Use of Dental Anesthesia and Sedation by a Dentist

Comment: There is no evidence that changes requiring a third, non-team member are warranted as demonstrated by the Journal of Oral and Maxillofacial Surgery. Requiring a third, non-team member could delay treatment in emergency situations if a case had to be delayed or paused in order to deliver deep sedation, when moderate sedation was insufficient. Such a situation would unnecessarily add time and increased risk to the patient.

Requiring an additional clinical professional to the operatory inevitably will increase costs. During previous Board meetings, nurse anesthetists have insisted without evidence that there would be no additional cost, but the state's dental Medicaid office, along with other oral health stakeholders like NHDS are not unconvinced that the presence of an additional professional would not add to the patient's bill. As written, the proposed changes could delay care and access to patients most in need, especially in emergency situations. If a patient can't get care from an oral surgeon, they may be forced go to the emergency room, a situation every health care stakeholder seeks to avoid.

If an additional professional is added to the operatory in these very infrequent but very delicate situations, they should be subject to the rules and standards of the Board of Dental Examiners and, in the event of an adverse event, should be thereby held accountable just as are dentists, hygienists, and the rest of the dental team. Presently, nurse anesthetists are not required to follow the Dental Practice Act or the Code of Ethics.

Response: The New Hampshire legislature in RSA 317-A:12, XII-a(h)(1) requires that for administration of general anesthesia or deep sedation, in addition to the dentist performing the procedure, a dedicated anesthesia provider shall be present to monitor the procedure and recovery from anesthesia for patients under the age of 13. The legislature in RSA 317-A:12, XII-a(h)(1) has tasked the Board of Dental Examiners with the responsibility of adjudicating exemptions for dentists board eligible or board certified in dental anesthesiology or oral and maxillofacial surgery from the requirement for the presence of a dedicated anesthesia provider to monitor the procedure and recovery from anesthesia in patients under the age of 13 years. The Board has identified the age range 0-8 years for requiring a dedicated anesthesia provider regardless of a dentist's level of training. The Board's concerns regarding administration of deep sedation/general anesthesia to children in this age range are not for circumstances when the anesthesia administration and procedure are going as planned, but rather when an emergency situation arises during administration of anesthesia in a dental office setting. It is during this critical time that appropriate office procedures and staffing are necessary to rescue the child. Largely, this is due to anatomical differences in these younger children vs. older children. Younger children have larger heads relative to their bodies, which can more easily cause airway obstruction with neck positioning. These younger pediatric patients require increased supplemental oxygen during procedures and can lose oxygen more rapidly compared to older children. Younger children have a narrowed airway at a lower portion of their trachea from older children, and an emergency rescue cricothyrotomy is often more difficult in this patient population requiring more sophisticated needle-based surgical airway intervention. Alternatively, when a child 0-8 years of age requires emergency dental treatment, the qualified dentist could administer moderate sedation to the child in accordance with Den 304.08(i), bring in a separate qualified dentist to their office pursuant to RSA 415:18-h, or could bring the child to a hospital or surgery center for treatment pursuant to RSA 415:18-g, RSA 420-A:17-b, and

RSA 420-B:8-ee. The legislature in RSA 317-A:12, XII-a(h)(1) has identified a dentist who is qualified to administer general anesthesia or deep sedation, a physician anesthesiologist, or a certified registered nurse anesthetist (CRNA) are all appropriate to be a dedicated anesthesia provider to patients under the age of 13. There were several resources considered by the Board in identifying the age range 0-8 years for requiring a dedicated anesthesia provider for administration of deep sedation or general anesthesia regardless of a dentist's level of training, including:

- Michael P. Auerbach, Executive Director, New Hampshire Dental Society. July 31, 2024.
- Wiemer SJ, Mediratta JK, Triana RR, et al. What is the Incidence of Anesthesia Related Adverse Events in Oral and Maxillofacial Surgery Offices? A Review of 61,237 Sedation Cases from a Large Private Practice Consortium. Journal of Oral and Maxillofacial Surgery (2024).
- Chapter 6: Pediatric Anesthesia. Office Anesthesia Evaluation Manual, 9th edition. American Association of Oral and Maxillofacial Surgeons.
- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).
- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- Avva U, Lata JM, Kiel J. Airway Management. [Updated 2023 May19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. (https://www.ncbi.nlm.nih.gov/books/NBK470403/).

Mark A. Egbert, DDS, FACS, AAOMS President:

Concerns with 0-8 Anesthesia Administration Proposal

Comment: AAOMS strongly opposes the provisions that expressly prohibit general anesthesia, deep sedation, and moderate sedation permit holders from self-administering deep sedation or general anesthesia (DS/GA) to patients 8 years and under without the use of a separate anesthesia provider. As an alternative it is recommended that the Board incorporate the ASDA-AAOMS-AAP model regulations to establish a pathway for OMSs to continue providing care to young patients.

Response: The New Hampshire legislature in RSA 317-A:12, XII-a(h)(1) requires that for administration of general anesthesia or deep sedation, in addition to the dentist performing the procedure, a dedicated anesthesia provider shall be present to monitor the procedure and recovery from anesthesia for patients under the age of 13. The legislature in RSA 317-A:12, XII-a(h)(1) has tasked the Board of Dental Examiners with the responsibility of adjudicating exemptions for dentists board eligible or board certified in dental anesthesiology or oral and maxillofacial surgery from the requirement for the presence of a dedicated anesthesia provider to monitor the procedure and recovery from anesthesia in patients under the age of 13 years. The Board has identified the age range 0-8 years for requiring a dedicated anesthesia provider regardless of a dentist's level of training. The American Society of Dentist Anesthesiologists, American Association of Oral & Maxillofacial Surgeons, & American Academy of

Periodontology (ASDA-AAOMS-AAP) Model State Sedation/General Anesthesia Rules, in Section 2, acknowledge that a "Pediatric Endorsement" should be required when treating patients 8 years of age and under. Further, under Section 2, these Model Rules require that a physician anesthesiologist or nurse anesthetist must provide a hosting dentist with documentation of their competence when providing deep sedation/general anesthesia to patients age 8 years of age or under and, in Section 4, that with a pediatric endorsement a dentist may administer deep sedation/general anesthesia to a patient age 8 years of age or under with only the presence of 2 dental assistants trained in BLS-HCP. In New Hampshire, physician anesthesiologists are licensed under RSA 329 and nurse anesthetists are licensed under RSA 326-B:18, and their competence is not subject to review by the Board of Dental Examiners. The Board appreciates the ASDA-AAOMS-AAP acknowledgement of the special anesthetic considerations for the 0-8 years age group. The Board's concerns regarding administration of deep sedation/general anesthesia to children in this age range are not for circumstances when the anesthesia administration and procedure are going as planned, but rather when an emergency situation arises during administration of anesthesia in a dental office setting. It is during this critical time that appropriate office procedures and staffing are necessary to rescue the child. Largely, this is due to anatomical differences in these younger children vs. older children. Younger children have larger heads relative to their bodies, which can more easily cause airway obstruction with neck positioning. These younger pediatric patients require increased supplemental oxygen during procedures and can lose oxygen more rapidly compared to older children. Younger children have a narrowed airway at a lower portion of their trachea from older children, and an emergency rescue cricothyrotomy is often more difficult in this patient population requiring more sophisticated needle-based surgical airway intervention. It is at this time that the presence of 2 PALS certified providers is imperative according to multiple pediatric anesthesia resources. Alternatively, when a child 0-8 years of age requires dental treatment, the qualified dentist could administer moderate sedation to the child in accordance with Den 304.08(i), bring in a separate qualified dentist to their office pursuant to RSA 415:18-h, or could bring the child to a hospital or surgery center for treatment pursuant to RSA 415:18-g, RSA 420-A:17-b, and RSA 420-B:8-ee. There were several resources considered by the Board in identifying the age range 0-8 years for requiring a dedicated anesthesia provider for administration of deep sedation or general anesthesia regardless of a dentist's level of training, including:

- Comments Regarding Den 304 Proposal. Mark A. Egbert, DDS, FACS, AAOMS President. July 29, 2024.
- Wiemer SJ, Mediratta JK, Triana RR, et al. What is the Incidence of Anesthesia Related Adverse Events in Oral and Maxillofacial Surgery Offices? A Review of 61,237 Sedation Cases from a Large Private Practice Consortium. Journal of Oral and Maxillofacial Surgery (2024).
- Chapter 6: Pediatric Anesthesia. Office Anesthesia Evaluation Manual, 9th edition. American Association of Oral and Maxillofacial Surgeons.
- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).

- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- Avva U, Lata JM, Kiel J. Airway Management. [Updated 2023 May19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. (https://www.ncbi.nlm.nih.gov/books/NBK470403/).

Roger A. Achong, DMD, MS:

Den 304.07 Facility or Facility Hosting Requirements:
Comment: Requested that the Board modify Den 304.07(a)(8)a. so that ACLS is not required for dentists who only see pediatric patients under the age of 13 years of age. Require PALS for those dentists who see only pediatric patients under the age of 13.
Response: Den 304.07(a)(8)a has been reworded to remove the requirement for ACLS certification.

Dr. Nader Moavenian, CEO/Founder, NHOMS LLC:

Den 304.08 Administering General Anesthesia, Deep Sedation, or Moderate Sedation:
Comment: I strongly oppose the provisions in Den 304.08 that remove the ability for OMSs to self-administer deep sedation/general anesthesia to patients aged 0-8 years. No other state in the nation currently has such a provision, and there is no evidence to suggest it is necessary for public safety. This will significantly impact patients' access to timely care, inflicting undue pain, burden, and access to care challenges.
Response: The New Hampshire legislature in RSA 317-A:12, XII-a(h)(1) requires that for administration of general anesthesia or deep sedation, in addition to the dentist performing the procedure, a dedicated anesthesia provider shall be present to monitor the procedure and recovery from anesthesia for patients under the age of 13. The legislature in RSA 317-A:12, XII-a(h)(1) has tasked the Board of Dental Examiners with the responsibility of adjudicating exemptions for dentists board eligible or board certified in dental anesthesiology or oral and maxillofacial surgery from the requirement for the presence of a dedicated anesthesia provider to monitor the procedure and recovery from anesthesia in patients under the age of 13 years. The Board has identified the age range 0-8 years for requiring a dedicated anesthesia provider regardless of a dentist's level of training. The Board's concerns regarding administration of deep sedation/general anesthesia to children in this age range are not for circumstances when the anesthesia administration and procedure are going as planned, but rather when an emergency situation arises during administration of anesthesia in a dental office setting. It is during this critical time that appropriate office procedures and staffing are necessary to rescue the child. Largely, this is due to anatomical differences in these younger children vs. older children. Younger children have larger heads relative to their bodies, which can more easily cause airway obstruction with neck positioning. These younger pediatric patients require increased supplemental oxygen during procedures and can lose oxygen more rapidly compared to older children. Younger children have a narrowed airway at a lower portion of their trachea from older children, and an emergency rescue cricothyrotomy is often more difficult in this patient population requiring more sophisticated needle-based surgical airway intervention. Alternatively, when a child 0-8 years of age requires dental treatment, the qualified dentist could administer moderate sedation to the child in accordance with Den 304.08(i), bring in a separate

qualified dentist to their office pursuant to RSA 415:18-h, or could bring the child to a hospital or surgery center for treatment pursuant to RSA 415:18-g, RSA 420-A:17-b, and RSA 420-B:8-ee. There were several resources considered by the Board in identifying the age range 0-8 years for requiring a dedicated anesthesia provider for administration of deep sedation or general anesthesia regardless of a dentist's level of training, including:

- Feedback on draft for Den 304. Dr. Nader Moavenian, CEO/Founder, NHOMS LLC. August 5, 2024.
- Wiemer SJ, Mediratta JK, Triana RR, et al. What is the Incidence of Anesthesia Related Adverse Events in Oral and Maxillofacial Surgery Offices? A Review of 61,237 Sedation Cases from a Large Private Practice Consortium. Journal of Oral and Maxillofacial Surgery (2024).
- Chapter 6: Pediatric Anesthesia. Office Anesthesia Evaluation Manual, 9th edition. American Association of Oral and Maxillofacial Surgeons.
- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).
- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- Avva U, Lata JM, Kiel J. Airway Management. [Updated 2023 May19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. (https://www.ncbi.nlm.nih.gov/books/NBK470403/).

Comment: I urge the Board to provide alternative options to the PALS requirement in Den 304.08 for dental assistants monitoring patients aged 9-12 years of age.
Response: Multiple pediatric anesthesia resources recommend a second observer who is specifically PALS certified to assist the sedation provider during administration of deep sedation/general anesthesia in case of a pediatric anesthetic emergency. References:

- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).
- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- American Academy of Pediatric Dentistry. Use of anesthesia providers in the administration of office-based deep sedation/general anesthesia to the pediatric dental patient. The Reference Manual of Pediatric Dentistry. Chicago, Ill.: American Academy of Pediatric Dentistry; 2023:429-33.

Comment: I urge the Board to consider tying medication and equipment requirements to the facility permit, implementing time-oriented anesthesia records maintained in 5-minute intervals, public reporting of morbidity and mortality data in a deidentified manner, and adopting staffing requirements for the treatment of adult patients receiving moderate sedation, deep sedation, and general anesthesia in accordance with the OMS team model.

Response: Den 304.07(b) has been reworded to clarify that the mandated equipment and supplies are referring to facility and facility hosting requirements. Den 304.08(a) reference the American Dental Association "Guidelines for the Use of Sedation and General Anesthesia by Dentists" revised 2016 regarding guidelines for maintaining a time-oriented anesthetic record while administering moderate sedation, deep sedation, or general anesthesia. Den 304.09(a)(2)d. and e. have been reworded to additionally highlight these requirements from Den 304.08(a). Den 304.13(i) explains that the process of root cause analysis of a morbidity or mortality event utilizing the OPLC enforcement division, as well as the dentist's corrective action plan and report of findings subject to this investigation, are confidential and shall be held in accordance with RSA 91-A. Personnel requirements for moderate sedation, as well as for deep sedation or general anesthesia, are outlined in the American Dental Association "Guidelines for the Use of Sedation and General Anesthesia by Dentists" revised 2016 as referenced in Den 304.08(a).

Dwayne Thibeault, DNP, CRNA, ARNP, Blue Sky Anesthesia Associates:

Den 304.03(f) Permit Types
Comment: This section could have what qualifications are needed for the dentist to obtain the moderate sedation with pediatric qualification for ages 9 and older beneath it for clarity.
Response: Den 304.03(f) has been renumbered Den 304.03(a)(5). The qualifications needed for the moderate sedation permit with pediatric qualification are listed in Den 304.04(e).

Den 304.07 Facility or Facility Hosting Requirements
Comment: (a) – Consider a basic emergency medication kit with the following:

a. Epi pens x 2 or equivalent that are age specific based on the population seen at the facility for allergic reactions;
b. Benadryl for an allergic reaction;
c. Albuterol metered dose inhaler for bronchospasm or asthma; and
d. Aspirin non-enteric coated chewable 162mg or equivalent.

Response: The facility requirements for these items at the time of anesthesia administration are listed in Den 304.07(b).

Comment: **(a)(2)(b) and (c) –** Consider that the yankauer and portable suction able to be used in a power failure is brought by the anesthesia provider and duplication is not cost effective or enhancing public safety in any way.
Response: The facility requirements for these items at the time of anesthesia administration are listed in Den 304.07(b).

Comment: **(a)(3)(c) and (d)** – The supraglottic airways and a cricothyrotomy kit with regards to their use on a patient under anesthesia/sedation is outside the hosting dentist airway management techniques. They will never use these airway adjuncts and it is provided by the anesthesia provider. This requirement provides no additional safety to the public since the hosting dentist does not know how to use these adjuncts nor will they be taught in ACLS or PALS.
Response: The facility requirements for these items at the time of anesthesia administration are listed in Den 304.07(b).

Comment: **(a)(4)** – This standard monitoring equipment would be brought by the anesthesia/sedation provider and should not require the facility to have on sight. This is not cost effective for the hosting dentist and provides no additional safety to the public.
Response: The Board requires that each facility applying for a facility or a facility hosting permit have basic vital signs monitoring equipment (pulse oximeter and blood pressure monitor) in all operatories where moderate sedation, deep sedation, or general anesthesia is administered and recovery rooms, as listed in Den 304.07(a)(4). The Board requirements for more advanced monitoring equipment (continuous ECG, capnography, and stethoscope) are only mandated to be on-site at the time of moderate sedation, deep sedation, or general anesthesia administration, as listed in Den 304.07(b)(4).

Comment: Consider requiring a wheelchair as part of the facility hosting permit inspection. This would aid in the transportation of the patient upon discharge from the dental facility.
Response: The facility requirement for a wheelchair is listed in Den 304.07(a)(3).

Den 304.08 Administering General Anesthesia, Deep Sedation, or Moderate Sedation.
Comment: **(b)** – Consider the unintended consequence of not specifying medication that should or should not be used in moderate sedation. Certain medications such as propofol, for example, are used in deep sedation/general anesthesia and the way 304.8 (c) is written, a moderate sedation qualified dentist could use such a medication.
Response: Paragraph (b) is renumbered as (c). The limitation for use of only reversible drugs for administration of moderate sedation is now delineated in Den 304.08(c).

Comment: **(b)** – I ask the Board to form an anesthesia subcommittee made up of anesthesia experts to look into moderate sedation and provide the board with a recommendation that protects the public and allows the dentist to provide moderate sedation in a safe manner.
Response: A Dental Sedation and Anesthesia Committee has now been formed, composed of 5 experts in anesthesia, and has been meeting.

Comment: **(c)** – Consider the following changes to Den 304.08(d):
A dentist shall not delegate to a dental assistant or hygienist any task that is outside of their scopes of practice, as defined in Den 400 and Den 501.01(c), such as placement of an intravenous catheter**,** drawing up **medications, or [**~~and~~] administering medications.
Response: Paragraph (c) is renumbered as (d). Den 304.08(d) has been reworded to address drawing up medications or administering medications separately.

Comment: **(e)** – Clarify what the qualifications are for a dentist to provide deep sedation/general anesthesia for pediatric patients ages 9-12.
Response: Paragraph (e) is renumbered as (f). The reference to "Qualified dentists" in Den 304.08(f) is defined in Den 304.01(n).

Comment: **(g)** – Clarify who the provider administering and monitoring the sedation in this section such as: A second oral surgeon, dental anesthesiologist, physician anesthesiologist, or nurse anesthesiologist.
Response: Paragraph (g) is renumbered as (h). The provider administering and monitoring the sedation to patients 8 years of age and under in Den 304.08(h) would have to meet the requirements outlined in Den 304.08(e)(2) and defined in Den 304.01(o).

Dr. Timothy Smith, Pediatric Dentist:

Den 304.07 Facility or Facility Hosting Requirements
Comment: Recommendation to remove the requirement to maintain unexpired ACLS certification if only treating patients under the age of 13, as PALS training gives adequate knowledge and proficiency to respond effectively to Pediatric emergencies.
Response: Den 304.07(a)(8)a has been reworded to remove the requirement for ACLS certification.

Matt Smith:

Den 304.07 Facility or Facility Hosting Requirements
Comment: The "Facility Hosting Requirements" specifically says "The operating dentist maintains an unexpired ACLS Certification, as well as an unexpired PALS certification if patients under the age of 13 at the facility". If as a pediatric dentist we are treating patients under the age of 13 PALS certification would be appropriate and sufficient to competently handle all emergency situations found in any sedation setting.
Response: Den 304.07(a)(8)a has been reworded to remove the requirement for ACLS certification.

Sarah A. Finne, DMD, MPH, NH DHHS DMS Dental Director:

Den 304 Use of General Anesthesia and Sedation by Dentists
Comment: The proposed rule changes could unintentionally create additional safety issues or harm. Dental teams in their current configuration include a Board-Certified Oral Surgeon (the vast majority possessing dual DMD/MD degrees) with the appropriate additional staff as described in Den 304.05. These teams have the extensive training required in Den 304.03 in addition to clinical experience which have allowed them to safely practice under the current rules. The requirement to bring in a third non-dental team member, at the moment a situation changes to require deep sedation, could significantly delay the timely delivery of care. This is most concerning for any emergency procedures being performed, where time is of the essence.

When a surgical procedure on a child under the age of 9 has to be delayed to a future appointment due to the lack of availability of a third non-dental team member, there is increased risk that in the interim the patient will need emergency care in an emergency department of a hospital. This not only increases the cost of care for this individual, but it also puts them at risk of needing more invasive treatment as the original condition has worsened. The proposed rule changes create an additional barrier to access to oral health care for children with some of the highest dental needs in the state.

The proposed rule changes bring in a member of the dental care team that is not subject to these same rules. Should an adverse event occur, all members of the team should be subject to the same set of rules.

The DMS believes that Den 304 should reflect the extensive training of oral surgeons which qualifies them to provide deep sedation for young children under the age of 9 without requiring the addition of another non-dental team member to provide anesthesia.

Response: The New Hampshire legislature in RSA 317-A:12, XII-a(h)(1) requires that for administration of general anesthesia or deep sedation, in addition to the dentist performing the procedure, a dedicated anesthesia provider shall be present to monitor the procedure and recovery from anesthesia for patients under the age of 13. The legislature in RSA 317-A:12, XII-a(h)(1) has tasked the Board of Dental Examiners with the responsibility of adjudicating exemptions for dentists board eligible or board certified in dental anesthesiology or oral and maxillofacial surgery from the requirement for the presence of a dedicated anesthesia provider to monitor the procedure and recovery from anesthesia in patients under the age of 13 years. The Board has identified the age range 0-8 years for requiring a dedicated anesthesia provider regardless of a dentist's level of training. The Board's concerns regarding administration of deep sedation/general anesthesia to children in this age range are not for circumstances when the anesthesia administration and procedure are going as planned, but rather when an emergency situation arises during administration of anesthesia in a dental office setting. It is during this critical time that appropriate office procedures and staffing are necessary to rescue the child. Largely, this is due to anatomical differences in these younger children vs. older children. Younger children have larger heads relative to their bodies, which can more easily cause airway obstruction with neck positioning. These younger pediatric patients require increased supplemental oxygen during procedures and can lose oxygen more rapidly compared to older children. Younger children have a narrowed airway at a lower portion of their trachea from older children, and an emergency rescue cricothyrotomy is often more difficult in this patient population requiring more sophisticated needle-based surgical airway intervention. Alternatively, when a child 0-8 years of age requires emergency dental treatment, the qualified dentist could administer moderate sedation to the child in accordance with Den 304.08(i), bring in a separate qualified dentist to their office pursuant to RSA 415:18-h, or could bring the child to a hospital or surgery center for treatment pursuant to RSA 415:18-g, RSA 420-A:17-b, and RSA 420-B:8-ee. The legislature in RSA 317-A:12, XII-a(h)(1) has identified a dentist who is qualified to administer general anesthesia or deep sedation, a physician anesthesiologist, or a certified registered nurse anesthetist (CRNA) are all appropriate to be a dedicated anesthesia provider to patients under the age of 13. There were several resources considered by the Board in identifying the age range 0-8 years for requiring a dedicated anesthesia provider for administration of deep sedation or general anesthesia regardless of a dentist's level of training, including:

- Sarah A. Finne, DMD, MPH, NH DHHS DMS Dental Director. August 13, 2024.
- Wiemer SJ, Mediratta JK, Triana RR, et al. What is the Incidence of Anesthesia Related Adverse Events in Oral and Maxillofacial Surgery Offices? A Review of 61,237 Sedation Cases from a Large Private Practice Consortium. Journal of Oral and Maxillofacial Surgery (2024).
- Chapter 6: Pediatric Anesthesia. Office Anesthesia Evaluation Manual, 9th edition. American Association of Oral and Maxillofacial Surgeons.
- "Joint Statement on Pediatric Dental Sedation" from Society for Pediatric Anesthesia (https://pedsanesthesia.org/joint-statement-on-pediatric-dental-sedation/).
- Cote CJ, Wilson S for American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatrics. 2019;143(6).

- Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. Pediatrics. 2018;141(4).
- Avva U, Lata JM, Kiel J. Airway Management. [Updated 2023 May19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. (https://www.ncbi.nlm.nih.gov/books/NBK470403/).

Dr. Peter Reich:

Den 304 Use of General Anesthesia and Sedation by Dentists

Comment: It is my opinion only Doctors with approved and accredited residency training and certification in Anesthesia can provide IV anesthesia to patients. The general public needs to be made aware of the Doctors Anesthesia certification prior to any IV sedation procedure. The public needs to be made aware if a Nurse Anesthetist (CRNA) is administering Anesthesia and that the second provider in these cases - the Dentist- May not have completed an approved and accredited residency training in Anesthesia. You may now have a dentist without approved and certified residency anesthesia training performing dentistry/surgery/sedation on a patient in conjunction with a Nurse Anesthetist (CRNA). All ages apply, the age of the patient is irrelevant except for infants. The training of the provider is what matters. No state in America has adopted anything less stringent. Separating patients eight and under would only create a false sense of security and allow patients to be sedated by an unprepared team.

Response: The New Hampshire legislature in RSA 317-A:12, XII-a(h)(1) requires that for administration of general anesthesia or deep sedation, in addition to the dentist performing the procedure, a dedicated anesthesia provider shall be present to monitor the procedure and recovery from anesthesia for patients under the age of 13. The legislature in RSA 317-A:12, XII-a(h)(1) has identified a dentist who is qualified to administer general anesthesia or deep sedation, a physician anesthesiologist, or a certified registered nurse anesthetist (CRNA) are all appropriate to be a dedicated anesthesia provider to patients under the age of 13.

Dave C. Pak, DMD, MD, PA:

Den 304 Use of General Anesthesia and Sedation by Dentists

Comment: Den 304 covers the use of general anesthesia and sedation by dentists, but does not have permits, evaluations, or means of qualifications for mobile anesthetists or mobile anesthesiologists. I propose that any mobile anesthetist or anesthesiologist also undergo an evaluation process under the Dental Board if they are to practice within the influence or realm of dentistry.

An Affidavit or form of attestation, listing the various needs or attesting to the requirements relevant to the particular level of anesthesia and the respective host and facility requirements in Den 304, could be requested by the Dental Board per job site from the mobile anesthetist or mobile anesthesiologist, since their locations of practice can vary so much. A time limit should be considered for the attestation. All of this would suggest that the host, staff, facility, and mobile provider assume the necessary requirements and knowledge of the anesthesia level being used.

Response: Den 304.06 addresses administration of general anesthesia or sedation exclusively by a separate dedicated qualified provider, which would include a mobile anesthetist or anesthesiologist. In New Hampshire, physician anesthesiologists are licensed under RSA 329 and nurse anesthetists are licensed under RSA 326-B:18, and their competence is not subject to review by the Board of Dental Examiners. A form of attestation to verify compliance with Den 304.07(b) and (c) is being drafted by the OPLC.

Lily Hu, DMD:

Den 304.01 Definitions

Comment: **(b)** – "Facility hosting permit" – Clarify what "anesthesia equipment, drugs, and supplies beyond what is specified in Den 304.07(a)" are qualified to be brought to the hosting facility site. I would recommend the board to standardize regulation on the facility requirement, such as all the emergency equipment/medications that must be available on-site, regardless the type of anesthesia provider (dentist, physician anesthesiologist, and CRNA) practicing at a dental facility. This is common practice in various states as it ensures a standardized measure of facility requirement for anesthesia delivery in a dental office.
Response: Den 304.07(a), (b), and (c) have been reworded to clarify what equipment and supplies shall be on-site, as well as proper staffing, in order to apply for a facility or facility hosting permit, as well as what appropriate additional equipment and supplies must be on-site at the time that a qualified provider is administering moderate sedation, deep sedation, or general anesthesia.

Comment: **(c)** – I support the development of a facility permit. I would recommend revising the definition to the following:

> **"Facility permit" means a permit for a dental facility at which the permit holder is a license dentist that maintains additional anesthesia equipment, drugs, and supplies on site as specified in Den 304.07."**

Response: A facility permit has been created in Den 304.03(a)(1) and (2). The Board is satisfied with this wording.

Den 304.02 Requirements for All Permits Issued Under This Chapter

Comment: **(a)** – Under the new requirement, it appears that any new dentist seeking to provide anesthesia/sedation services in the State of NH must go through a 5 step process. With a undefined timeline for the completion of this entire process and the fact that OPLC currently have only 2 contracted qualified consultants to conduct those simulated emergency evaluations, the wait time for a new dentist to begin anesthesia practice may be significant and can severely delay a dentist anesthesia provider to deliver care. All dentists who seek to obtain a sedation/anesthesia permit should already have met the educational requirement for the sedation/anesthesia permit. Adding on this new and additional simulated emergency evaluation requirement that a dentist provider must pass initially in order to begin practicing anesthesia seems redundant and adds little value to patient safety.

If the goal is ensuring public safety, then such requirement should be instituted across the board for all anesthesia providers, not just the dentist anesthesia providers. This additional requirement creates a significant barrier of entry for dentist anesthesia providers to practice in NH, while non-dentist anesthesia providers are able to schedule cases at dental offices freely at any time. In

addition, the requirement creates an anti-competitive practice environment for dentist anesthesia providers. This additional requirement selectively enforced on dentists only should be eliminated as a requirement to obtain an initial anesthesia permit.
Response: In New Hampshire, physician anesthesiologists are licensed under RSA 329 and nurse anesthetists are licensed under RSA 326-B:18, and their competence is not subject to review by the Board of Dental Examiners. Pursuant to Plc 304.08(b), the OPLC shall decide on a completed application for an initial anesthesia permit within 60 days of determining that the application is complete if an inspection has been completed. For more information see Plc 304.08(c) through (e).

Comment: **(d)** – All proposed requirements on emergency medication, equipment, and including this emergency evaluation should be standardized and implemented across the board for all anesthesia providers, not just dentists. All anesthesia providers should be held to the same standard of care. This creates an anti-competitive practice environment and patient safety issues.
Response: Den 304.07(a), (b), and (c) have been reworded to clarify what equipment and supplies shall be on-site, as well as proper staffing, in order to apply for a facility or facility hosting permit, as well as what appropriate additional equipment and supplies must be on-site at the time that a qualified provider is administering moderate sedation, deep sedation, or general anesthesia.

Den 304.05 Applications and Permit Procedures
Comment: Additional clarification is needed on facility permit requirements for dentist anesthesia providers who travel to various location with their own self-contained facility.
Response: A form of attestation to verify compliance with Den 304.07(b) and (c) is being drafted by the OPLC.

Comment: Is the mobile dentist anesthesia provider required to apply and maintain a facility permit at each location, and undergo on-site facility inspection at each location, undergo simulated emergency evaluation at each location, along with associated fee for each location? The current proposal language is unclear on this aspect.
Response: No, the mobile dentist anesthesia provider is not required to maintain a facility permit. Rather, the hosting dentist maintains the facility or facility hosting permit.

Comment: Mobile dentist anesthesia providers have the same practice as mobile CRNAs and physician anesthesiologists. Their facility is mobile, self-contained, and maintained independently from the dental office location. Requiring separate inspection and facility permits at each location is a redundant process and would be a poor use of time and resources for the board members, anesthesia inspectors, and the mobile dentist anesthesia providers. In addition, it will place undue burden on mobile dentist anesthesiologist to continue this practice model in the state of NH.
Response: The mobile dentist anesthesia provider is not required to maintain a facility permit. Rather, the hosting dentist maintains the facility or facility hosting permit.

Comment: The BLS, ACLS, and PALS certification requirement should not be selectively enforced on dentist anesthesia providers only. All qualified anesthesia providers should be held to the same emergency training certificate requirements and have active BLS/ACLS/PALS.
Response: In New Hampshire, physician anesthesiologists are licensed under RSA 329 and nurse anesthetists are licensed under RSA 326-B:18, and their competence is not subject to review by the Board of Dental Examiners.

Den 304.06 Administration of General Anesthesia or Sedation Exclusively by a N.H. Licensed Physician Anesthesiologist, Certified Registered Nurse Anesthetist, or Visiting Qualified Dentist.
Comment: Hosting dentist shall not be obligated to obtain a sedation or anesthesia permit if the anesthesia administration is exclusively provided by all qualified anesthesia providers (dentist and non-dentist anesthesia providers) as long as the hosting dentist has the appropriate facility permit. I would recommend the revising the language to the following:

> **"Dentists shall not be obligated to obtain a sedation or anesthesia permit pursuant to this part if general anesthesia, deep sedation, or moderate sedation is being administered exclusively by a N.H. licensed physician anesthesiologist, certified registered nurse anesthetist, or a dentist anesthesia provider with general anesthesia, deep sedation, and moderate sedation permit, so long as the hosting dentist first provides to the board obtains an anesthesia facility permit described in Den 304.03."**

Response: Den 304.06 has been reworded to refer generally to a separate dedicated qualified provider.

Comment: A dentist anesthesia provider may wish not to travel with their own emergency equipment/medications. As long as the dentist anesthesia provider has the appropriate individual sedation/anesthesia permit, this provider should be allowed to administer sedation/anesthesia in a facility that meets all facility requirements, regardless if the facility permit holder has an anesthesia permit or not.
Response: Den 304.07(a), (b), and (c) have been reworded to clarify what equipment and supplies shall be on-site, as well as proper staffing, in order to apply for a facility or facility hosting permit, as well as what appropriate additional equipment and supplies must be on-site at the time that a qualified provider is administering moderate sedation, deep sedation, or general anesthesia.

Den 304.07 Facility or Facility Hosting Requirements
Comment: **(b) and (c)** – Equipment/medications/supplies should be tied to a facility permit and not individual anesthesia permits. This conflicts with proposed Den 304.05 (b)(3) and Den 304.05(c)(2) that lists the requirement for individual anesthesia permits. Individual anesthesia permits should be based on education requirement. Facility permit should be based on facility requirements. I would recommend revising the language to the following:

> **"Each facility applying for a facility permit for the administration of general anesthesia, deep sedation, moderation, or moderate sedation with pediatric qualification shall have the following additional equipment, drugs, and supplies on-site"**

"Each facility applying for a facility permit for the administration general anesthesia, deep sedation, and moderate sedation permit shall have the following additional equipment, drugs, and supplies on-site if inhaled volatile anesthetics are used or if succinylcholine is used on a regular basis (not just kept on-hand for emergencies):

Response: Den 304.07(a), (b), and (c) have been reworded to clarify what equipment and supplies shall be on-site, as well as proper staffing, in order to apply for a facility or facility hosting permit, as well as what appropriate additional equipment and supplies must be on-site at the time that a qualified provider is administering moderate sedation, deep sedation, or general anesthesia.

Den 304.08 Administering General Anesthesia, Deep Sedation, or Moderate Sedation.

Comment: **(b)** – The proposed administration technique for moderate sedation seems inconsistent with standard guidelines and practices on moderate sedation and is more consistent with minimal sedation that specifically applies to enteral route only. See the 2016 "ADA Guideline for Teaching Pain Control and Sedation to Dentist and Dental Students" and the "American Society of Anesthesiologist Practice Guideline for Moderate Procedural Sedation and Analgesia 2018". The proposed language will excessively limit dentist sedation/anesthesia provider to a very specific technique that may or may not be the most ideal, appropriate, or adequate option for the particular patient and procedure, while non-dentist anesthesia providers are not limited to such restrictions when providing moderate sedation.

Response: Paragraph (b) is renumbered as (c). Den 304.08(a) specifies that administration of moderate sedation follows the clinical guidelines set forth in Part IV B. of the American Dental Association "Guidelines for the Use of Sedation and General Anesthesia by Dentists" revised 2016. Den 304.08(c) has been reworded to specify that, for moderate sedation, with or without inhalation sedation, agents shall be limited to a single dose of one or more reversible drugs, or a multi-dose of a single reversible drug, in accordance with Den 304.01(i) using manufacturer guidelines as found in the FDA "Online Label Repository" found at labels.fda.gov.

Den 304.11 Minimal Sedation

Comment: This proposed administration technique for minimal sedation is inconsistent with standard practice and teaching guidelines on minimal sedation techniques. I am not aware of any published teaching and practice guidelines that limits the use of enteral medication within the MRD or combination of inhalation- enteral as a method of minimal sedation for pediatric patients under the age of 13 see 2021 "ADA Guideline for Teaching Pediatric Pain Control and Sedation to Dentist and Dental Students" and the "Commission on Dental Education Accreditation (CODA)" as standards for Advanced Dental Education Programs in Pediatric Dentistry". To eliminate these techniques as minimal sedation for patients under age 13 is not an evidenced based practice. This proposed regulation significantly deviates from established standard practice and teaching guidelines of minimal sedation for pediatric patients. I would recommend revising the language as follows.

(b) The following routes of administration shall apply to the use of minimal sedation for pediatric patients under 13 year of age:

- **Inhalation using nitrous oxide**
- **Enteral, using one or more doses of a single oral agent that is FDA-approved for pediatric use, not to exceed the maximum recommended**

Response: Den 304.11(a)(3) specifies that administration of minimal sedation must follow the guidelines set forth in Part IV A. of the American Dental Association "Guidelines for the Use of Sedation and General Anesthesia by Dentists" revised 2016. Den 304.11(b) has been reworded to specify, for minimal sedation, inhalation using nitrous oxide, enteral using one or more doses of one drug within a 24-hour period using manufacturers guidelines as found in the FDA "Online Label Repository" found on labels.fda.gov, or a combination of both.

Comments Received After Deadline:

The due date for public comment to be submitted was 8/15/2024. The following individuals submitted written comments outside of the deadline for submission as follows:

Dr Mindy Hall – October 12, 2024
S. Thikkurissy, DDS, MS, MA – October 14, 2024
S. Thikkurissy, DDS, MS, MA – October 18, 2024
John E. Beinoras, DDS – October 22, 2024
Dr. Richard Neal, Jr. – October 22, 2024
Nadarajah Ganeshkumar, DMD – October 23, 2024
Kristine Trontz, DDS – October 28, 20024

All though the Board did not consider these comments they are substantially similar to those described throughout this document.