

**INTERPRETIVE STATEMENT REGARDING  
ADMINISTRATION OF ANXIOLYSIS  
TO PEDIATRIC PATIENTS  
Date Issued: May 17, 2023**

To protect the public interest, the North Carolina Board of Dental Examiners ("Board") provides interpretation and guidance regarding acceptable standards of care, consistent with the Board's rules, to administer anxiolytics. On March 13, 2023, the Board issued an Interpretive Statement Regarding Administration of Anxiolysis to Adult and Geriatric Patients, which is available on the Board's website.

The Board now issues this separate statement addressing the administration of anxiolysis to pediatric patients, which the Food and Drug Administration defines as being younger than 17 years old. This statement includes acceptable anxiolytic drugs, permissible dose amounts, and the appropriate timing of a single dose that constitutes anxiolysis and, therefore, does not require the dentist to hold a current, unrestricted sedation permit.

**The Board's Sedation Rules**

A dentist may administer anxiolysis, as defined in the Board's rules, without need for a sedation permit issued by the Board. However, a dentist may not administer minimal conscious sedation or moderate pediatric conscious sedation, as defined by the Board's rules, without a current, unrestricted permit that allows a dentist to administer that level of sedation (hereafter, "Permit"). **Therefore, a dentist who is seeking to administer anxiolysis but does not have a Permit must exercise caution to ensure he or she is not actually administering minimal or moderate pediatric conscious sedation, in violation of the Board's rules.**

The Board's rules define **anxiolysis** as the "pharmacological reduction of anxiety through the administration of a single dose of a minor psychosedative, possibly in 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." 21 NCAC 16Q .0101(3). A **minor psychosedative** is defined as one that carries "a margin of safety wide enough to render unintended loss of consciousness unlikely." 16Q .0101(28).

In comparison, under the Board's rules, **minimal conscious sedation** is "characterized by a minimally depressed level of consciousness," is "provided to patients 13 years or older" by administration of "one or more doses" of a pharmacological agent, and "may be provided for behavioral management" by a dentist holding a Permit to do so ("Minimal Permit"). 16Q .0101(27). **Moderate pediatric conscious sedation** is "characterized by a drug induced depression of consciousness, during which patients respond to verbal commands, either alone or accompanied by light tactile stimulation," may be provided to pediatric patients up to 18 years of age, and "may be provided for behavior control" by a dentist holding a Permit to do so ("Pediatric Permit"). 16Q .0101(30).

Thus, under the Board's rules, pediatric anxiolysis is limited to administration of a single dose of an anxiolytic agent for purposes of anxiety reduction. The patient remains alert and responsive. Anxiolysis may not be administered for behavioral management or control. If the pediatric patient is behaving in an uncooperative manner that requires behavior control or management through sedation, anxiolysis is not appropriate and the patient should be referred to a dentist who holds a Pediatric Permit, or a Minimal Permit if 13 years or older.

### **Administration of Pediatric Anxiolysis**

Anxiolysis should be administered to the pediatric patient as a single dose on the day of the appointment. It should not be administered as a divided dose to a pediatric patient. The preferred practice for a pediatric patient is to provide the anxiolytic agent to the patient on-site prior to the appointment to ensure the dentist can monitor the patient's reaction to the anxiolytic agent until the patient is ready for the dental procedure.

The proper dose of the anxiolytic agent must be calculated based on the pediatric patient's weight. The dentist must review the FDA-approved manufacturer's label for the selected drug and be familiar with maximum recommended dose, if included on the label, as well as contraindications and other warnings applicable to the pediatric patient. Some drug labels do not include maximum recommended doses for pediatric patients, not necessarily because the drug is not safe for pediatric patients, but due to the lack of adequate pediatric studies to provide the data.

If a drug label does not include pediatric dosing information, the dentist must review additional scientific resources to confirm that the drug is appropriate for anxiolysis in pediatric patients and, if so, the proper drug amount by weight for a single dose. As a best practice, the dentist should be familiar with and follow the guidelines for safe pediatric sedation developed collaboratively by the American Academy of Pediatric Dentistry and the American Academy of Pediatrics.

The following table provides some common examples with the maximum dose that may be administered for anxiolysis.

#### **Examples of Maximum Single Dose for Commonly Used Pediatric Anxiolytics:**

Hydroxyzine (Vistaril, Atarax)	0.6 mg/kg
Diphenhydramine (Benadryl)	1.5 mg/kg
Diazepam (Valium)	0.4 mg/kg

*Source: PDR.net*

### **Permissible Anxiolytics**

As discussed above, the Board's rules limit anxiolysis to the use of minor psychosedative agents, which are those that carry a "margin of safety wide enough to render unintended loss of consciousness unlikely."

A dentist complies with this limitation by administering pharmacological agents that function as antianxiety drugs and which carry a wide enough margin of safety, in compliance with the Board's

rules. Preferred anxiolytic agents for pediatric patients include certain antihistamines, hormones, and benzodiazepines that carry a wide enough margin of safety.

**Example agents that generally may be used safely as anxiolytics for pediatric patients without the need for a Permit:**

- Hydroxyzine
- Diphenhydramine
- Diazepam
- Melatonin

**Example benzodiazepines that do not comply with the Board's rules or the standard of care for the administration of anxiolysis and would require a Permit :**

- Midazolam
- Triazolam

*See, e.g., Sedation, Stanley F. Malamed, pp. 100-109, 6th edition (2018).*

### **Local Anesthesia**

Local anesthetic agents are cardiac depressants. In a pediatric patient, an excessive dose of local anesthetic may be what pushes the child over the desired level of anxiolysis into minimal or moderate sedation, or into a dangerous overdose condition. To minimize the chance of accidental overdose, the dentist should calculate the maximum allowable safe dosage based on the child's weight prior to starting the procedure.

As a best practice, the dentist should be familiar with the guidance on local anesthesia for pediatric dentistry issued by the American Academy of Pediatric Dentistry.

### **Summary Guidance for Pediatric Patient Safety in Anxiolysis**

To maximize patient safety, a dentist should administer the lowest possible effective dose of an anxiolytic, calculated by weight and individualized according to the patient's health and personal circumstances, after conducting a thorough examination and assessment. Even the manufacturer's maximum recommended individual dose could be excessive depending on the patient's circumstances and the administration of other agents, including local anesthetics and nitrous oxide. Within the parameters set forth in this statement, the dentist is responsible for determining an appropriate amount of an anxiolytic medication to reach, and not exceed, the desired reduction of anxiety based on the individualized patient assessment.

For dentists without a current sedation permit, the following actions in treating pediatric patients would violate the Board's regulations and could result in disciplinary action or other adverse events or results:

- prescribing or administering more than a single dose of an anxiolytic per visit,
- prescribing or administering a divided dose of an anxiolytic for a single visit,
- prescribing or administering an amount exceeding the maximum recommended single dose of an anxiolytic, or
- prescribing a medication not appropriate for anxiolysis.