

**INTERPRETIVE STATEMENT REGARDING
ADMINISTRATION OF ANXIOLYSIS
TO ADULT AND GERIATRIC PATIENTS**

Date Issued: March 13, 2023

To protect the public interest, the North Carolina Board of Dental Examiners ("Board") provides interpretation and guidance regarding acceptable standards of care to administer anxiolytics to adult and geriatric patients, consistent with the Board's rules. This statement addresses 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. Proper administration and dosages of drugs for minimal conscious sedation are set forth in the Board rules, 21 NCAC .0504 to .0507, and beyond the intended scope of this interpretive statement, except to distinguish it from anxiolysis. This statement is further limited to the administration of anxiolysis to adult and geriatric patients and does not address pediatric patients, which the Food and Drug Administration defines as being younger than 17 years old. The Board will issue a separate interpretive statement addressing the administration of anxiolysis to pediatric patients.

Definitions in Board's Sedation Rules

"Anxiolysis" – 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. Nitrous oxide may be administered in addition to the minor psychosedative without constituting multiple dosing for purpose of these Rules. 21 NCAC 16Q .0101(3)

"Minor psychosedative/Minor tranquilizer" – pharmacological agents that allow for uninterrupted interactive ability in a patient with no compromise in the ability to maintain a patent airway continuously and without assistance and carry a margin of safety wide enough to render unintended loss of consciousness unlikely. 21 NCAC 16Q .0101(28)

"Minimal conscious sedation" – conscious sedation characterized by a minimally depressed level of consciousness, in which the patient retains the ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command, provided to patients 13 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment, possibly in combination with nitrous oxide. Minimal conscious sedation may be provided for behavioral management. 21 NCAC 16Q .0101(27)

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, as defined by the Board's rules, without a current, unrestricted permit that allows a dentist to administer at least minimal 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 conscious sedation, in violation of the Board's rules.

Under the Board's Rule 21 NCAC 16Q .0101(3), set out above, anxiolysis is the administration of a "single dose" of a "minor psychosedative" prior to and "on the day of" treatment. The Board offers the following guidance regarding the interpretation and application of these three terms to assist dentists in remaining compliant with the Board's rules and acceptable standards of care.

A Single Dose

An important distinction between anxiolysis and minimal conscious sedation is the use of a single dose of an appropriate pharmacological agent for anxiolysis. Minimal conscious sedation allows providers to administer more than one dose as long as they do not exceed the manufacturer's maximum recommended daily dosage. In contrast, under the Board's rules, the proper administration of anxiolysis involves and allows only a single dose.

A dentist remains within the Board's definition of anxiolysis by administering an anxiolytic in an amount not exceeding the manufacturer's maximum recommended individual dose ("dose"). A dentist must review the FDA-approved manufacturer's label and be familiar with recommended doses for different populations, which may be significantly lower than the recommended dose for a young, healthy, Caucasian adult. For example, lower doses are recommended by manufacturers for special populations where the elimination half-life of the drug is longer. The actual dose a dentist prescribes or administers must be individually tailored to meet the patient's personal and health circumstances but cannot exceed the maximum individual dose.

The single dose of anxiolytic may be administered all at once or in divided/partial doses, provided the total amount administered or prescribed does not exceed the maximum amount recommended for an individual dose. The maximum individual dose for anxiolysis is different than the maximum recommended daily dosage ("dosage"), which typically would be taken in multiple doses over a 24-hour period.

The following table provides some common examples with the maximum total dose amount that may be administered for anxiolysis, whether all at once or in divided/partial doses.

Examples of Maximum Single Dose for Commonly Used Anxiolytics:

Agent	Adult Patient	Elderly/Debilited Patient*
Alprazolam (Xanax)	0.5 mg	0.25 mg
Diazepam (Valium)	10 mg	2.5 mg
Lorazepam (Ativan)	4 mg	2 mg

*The federal regulations governing drug labeling define "elderly" or "geriatric" as patients aged 65 years or older. *See 21 CFR § 201.57(c)(9)(v)*. "Debilited" as used here means a patient with a debilitating disease, such as renal, hepatic, or pulmonary disease.

Minor Psychosedative – Permissible Anxiolytics

Another important distinction between anxiolysis and minimal conscious sedation is the limitation of anxiolysis to minor psychosedative agents. Under the Board's rules (above), a minor psychosedative is one that carries 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. Certain benzodiazepines generally are considered the preferred drugs for the management of preoperative anxiety in the dental setting.

Example benzodiazepines that generally may be used safely as anxiolytics for adult and geriatric patients without the need for a Permit:

- Alprazolam
- Clorazepate
- Diazepam
- Halazepam
- Lorazepam
- Prazepam

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).

On The Day of Treatment

For anxiolysis, the Board's rule states that the psychosedative agents must be administered "prior to commencement of treatment on the day of the appointment." The Board recognizes that the necessary reduction of anxiety for some patients may require that they take medication before bed the night before as well as in the morning prior to the treatment, provided that it is safe for the patient and clinically appropriate to do so.

A dentist remains in compliance with the Board's rules by administering or prescribing a divided dose of a psychosedative agent within the 24-hour period prior to the commencement of treatment, provided the total amount prescribed or administered does not exceed the manufacturer's maximum recommended individual dose, as discussed above, and doing so is safe, necessary, and appropriate for a particular patient. A dentist administering anxiolysis may not administer multiple doses, but in these circumstances may, for example, divide a single dose and instruct the patient to take one partial dose before bed the night before and the other partial dose in the morning prior to the appointment.

Summary Guidance for Patient Safety in Anxiolysis

To maximize patient safety, a dentist should administer the lowest possible effective dose of an anxiolytic, 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. Within the parameters set forth in this statement, the dentist is responsible for determining an appropriate amount of an anxiolytic medication and potentially titrating or dividing that single dose 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 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 an amount exceeding the maximum recommended single dose of an anxiolytic,
- prescribing a medication not appropriate for anxiolysis, or
- prescribing an anxiolytic to be taken other than within the 24 hours surrounding a dental procedure or visit.