NC Dental Board Statement

on

Proposed Changes to General Anesthesia and Sedation Rules

September 9, 2022

The proposed changes approved by the Board today improve the delivery and safety margin of the use of general anesthesia and sedation in dental offices in several significant ways including:

- Requiring the use of capnography to contemporaneously monitor a patient's breathing, level of sedation, airway management, and timely deliver other critical information to the sedation provider.
- Imposing limits on the maximum dosage of medications that sedation providers can administer.
- Enhancing the requirements for reporting adverse occurrences.

In addition to these changes the Dental Board has added staff to resume the routine "post-Covid" inspection of dental offices where anesthesia and sedation services are offered. The Board also remains committed to working with our state's dental schools, community colleges, and continuing education providers to develop a required course designed especially for North Carolina permit holders and staff that comprehensively addresses medical emergencies, including emergency airway management, and to explore the feasibility of developing a certification program for dental assistants who are dedicated to patient support and monitoring when anesthesia or conscious sedation is utilized.

Notably absent from these proposed rules, however, is the requirement for a separate anesthesia provider to administer and deliver general anesthesia and sedation drugs when the treating dentists is performing certain dental procedures. This is often referred to as the "medical model" since in many, but not all instances, a separate anesthesia provider is required when a medical doctor performs certain medical interventions with anesthesia or sedation. The Dental Board considered moving toward the medical model but revised this proposal based on many comments received during the comment period.

First, a comment from the North Carolina Department of Health and Human Services opposed the medical model stating that it would "result in significant barriers to access to care for our NC Medicaid and NCHC [North Carolina Health Choice] beneficiaries." The Department states this is true because the number of medical and dental anesthesiologists and certified registered

nurse anesthetists (CRNA's) who voluntarily choose to participate in NC Medicaid and NCHC programs is very limited. NC DHHS noted that last year 36,000 adult and 21,000 pediatric Medicaid and NCHC beneficiaries received anesthesia or sedation services under the current "dental" model. The Board found credible a statement from NC DHHS that, "The proposed rule would create more demand for anesthesia professionals to work in Dental and Oral and Maxillofacial surgery offices than there is at the present time." The Board agrees with the NC DHHS assessment that this would result in delayed or denied dental treatment that would seriously jeopardize patient health and could increase the risk of serious harm or death from dental infections.

Second, a joint comment submitted by the UNC Adams School of Dentistry and the ECU School of Dental Medicine pointed out that the requirement of a second anesthesia provider is counter to the standards required by the Council on Dental Accreditation – the accrediting body through which all dental schools obtain and maintain their national accreditation. The Deans of both North Carolina dental schools stated: "...UNC and ECU residents would not be eligible to provide deep sedation, moderate sedation or pediatric moderate sedation as required by CODA for accreditation, which could be a fatal blow to our programs." They closed their comment by emphasizing that if a second anesthesia provider was required in a dental setting, "...it would seriously cripple our ability to train residents in multiple specialties and ultimately negatively affect access to care for the citizens of North Carolina."

Third, several comments referenced scientific peer-reviewed studies that indicated the medical model is not a failsafe or foolproof means of preventing anesthesia related deaths. One comment referenced a 2009 National Institutes of Health study entitled "Epidemiology of Anesthesia-related Mortality in the United States 1999-2005" concluded that during these years there were 2,211 anesthesia-related deaths in hospitals, ambulatory surgical centers, hospice and long-term care facilities, and other places where the medical anesthesia model is used consistently. These 2,211 deaths resulted from 105.7 million surgical discharges during the period of the study. The study concluded that "Each year in the United States, anesthesia/anesthetics are reported as the underlying cause in approximately 34 deaths and contributing factors in another 281 deaths..."

In the same vein, a study from the "Journal of Clinical and Diagnostic Research" reported that from 1955 - 2012 there were 218 anesthesia related deaths in dental offices out of 71,435,282 patient treatments. These and other studies [See: National Library of Medicine "Mortality and Morbidity in Office-based General Anesthesia for Dentistry in Ontario" Fall 2019] indicate that moving to the medical model from the current dental model used in North Carolina would not significantly increase public safety. Rather, requiring the medical model in dentistry could provide the public with the false sense that the medical model eliminates the risk of morbidity and mortality when this assumption is not supported by peer-reviewed studies.

Fourth, requiring the medical model would virtually eliminate the provision of office-based emergency dental services where the use of general anesthesia or sedation is required. Unless

a second provider is on staff or immediately available, treatment would have to be delayed by the dentist until an anesthesiologist could be located and a treatment time scheduled. Such delays in emergency situations could result in severe negative health impacts on many North Carolina citizens.

The Board realizes that proposing rules that do not require the "medical model" will come as a disappointment to many. We do not wish this decision to be viewed as a callous disregard of those who have died due to anesthesia mishaps in dental offices. We know that each person who passed away was valued, loved, and important to their family, friends, and the communities in which they lived, worked, and worshiped. This is especially true of Dr. Henry Patel about whom the Board received hundreds of comments highlighting his outstanding character and the breadth of his love and caring as a husband, father, friend, and physician. We extend our deepest sympathy to his and to each family.

However, the Board thinks its duty is to remind the public that each death occurred not because current rules were weak or unenforced, or the current model ineffective. Rather, these deaths occurred primarily because individual practitioners made extremely poor choices and were negligent in the practice of dentistry and emergency preparedness. Each licensee in each instance where a death occurred resulting from proven negligence by the dental provider received appropriate discipline from the Dental Board - including revocations and permanent loss of dental licenses and permits. We encourage the public to remember that when it comes to imposing statutes and regulations it is impossible, or nearly so, for a government agency to eliminate risk and prevent citizens, including professionals, from making poor decisions and being unprepared simply by adding more regulations.

In the end, it is the Board's belief based on the comments received that changing the rule to require a second anesthesia provider in dental offices would have far-reaching adverse consequences to numerous citizens in our state. It will impact the accreditation of North Carolina dental schools, require the revamping of NC Department of Health and Human Services regulations, severely impact the provision of office-based emergency services, impact access to dental care, and will impose a model that would be unique among the 50 states and whose safety record is not a significant improvement on the current standard. The Dental Board does not believe it is proper to impose a regulation with such far-reaching and potentially adverse consequences.

In the interim, the Board encourages patients to discuss general anesthesia and sedation services with your dentist when these services are recommended.

- Ask about your dentist's training and experience, and any adverse occurrences.
- Check the Board's website under the "License Verification" tab to determine if your dentist has been the subject of any disciplinary action.
- Ask your dentist to provide an estimate of the costs and availability of a separate anesthesia provider.
- Request a separate anesthesia provider if you believe it to be in your best interest and choose another dentist if your request is denied.

Early research indicates approximately 20-25% of dentists already use a separate provider and most will do so when the patient indicates the cost is not prohibitive and a second provider is available.

The Board wishes to thank all members of the public for your interest in and comments on these proposed rules. The version of the proposed rules approved here today will be posted on the Board's website and published in the "North Carolina Register." A public hearing will be scheduled, and the date and time clearly published for all who wish to attend. All written comments are welcomed and encouraged.

Thank you.