ADDENDUM H: Inhalation Conscious Sedation Administration Guidelines

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INHALATION CONSCIOUS SEDATION ADMINISTRATION GUIDELINES

I. OVERVIEW

Nitrous oxide with oxygen inhalation conscious sedation is a valuable adjunct for the management of apprehensive patients during dental treatment. The analgesic, anxiolytic, and sedative properties of nitrous oxide have been used since 1844 with a remarkable record of safety. Although nitrous oxide is safe when used properly by knowledgeable providers, it does have potential risks and chronic effects that must be controlled for patient and provider safety.

A. GUIDELINES

The guidelines are designed to help assure:

- Consistency of teaching and application of policies in all departments within the college.
- Adequate case documentation for medico legal protection of the college and its faculty.
- Compliance with existing local, state, and federal regulations that apply to bottled gasses, including nitrous oxide scavenging, environmental contamination, and security.

B. SITES

These guidelines apply to all locations where nitrous oxide/oxygen is administered, which include the following:

- POSTGRADUATE CLINICS: Oral and Maxillofacial Surgery, Periodontics, Pediatric Dentistry, Orthodontics, Advanced Education in General Dentistry (AEGD), Endodontics, Prosthodontics
- UNDERGRADUATE CLINICS: Oral and Maxillofacial Surgery, Periodontics, Pediatric Dentistry, Prosthodontics, Endodontics, Special Care (DAU), and the main 3rd Floor Clinic.

II. ADMINISTRATIVE OVERSIGHT

The Associate Dean for Clinical Affairs (ADCA) will have oversight over the administration of conscious sedation in the college clinics, and will monitor compliance with these guidelines, and any applicable guidelines issued by local, state, and federal governmental agencies. The ADCA will work in cooperation with the Environmental Health and Safety Manager, the college’s Clinical Affairs Committee, and/or faculty experts in the Department of Oral & Maxillofacial Surgery and Department of Pediatric Dentistry involved with the sedation curriculum, when implementing any future modifications to these guidelines.
DEFINITIONS: As used in these guidelines, the following definitions apply:

CERTIFIED: Has completed the specified number of academic and clinical hours by the Texas State Board of Dental Examiners (TSBDE), has successfully completed all requirements by the state, and has obtained a proper certification/permit from the TSBDE for inhalation conscious sedation. Other states will have their own rules and might not accept the certificate obtained from our college.

MINIMAL SEDATION: A minimally depressed level of consciousness, produced by a pharmacological method that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.

RESPONSIVENESS: The patient is arousable, responsive to questions or commands and cooperative at all times.

VITAL SIGNS: Include pulse (heart rate), blood pressure, and breathing rate.

III. MINIMAL EQUIPMENT REQUIREMENTS

A. CALIBRATION
All equipment used to administer conscious sedation gases anywhere in the college will be calibrated annually and incapable of administering concentrations exceeding 70% nitrous oxide, and will have:

- A fail-safe mechanism that prevents administration of nitrous oxide if the oxygen pressure drops below approximately 20 psi.
- 100% oxygen flushing capability
- a reservoir bag
- A scavenging-capable nasal mask that is suitable for the patient’s physical stature and is either sterilizable or disposable after single use.
- If portable, uses only pin-indexed, color coded tanked gasses.

B. TRACE GAS SCAVENGING
Wherever nitrous oxide-based conscious sedation is used it will be administered in a well-ventilated space and will be connected to a properly vented, high flow vacuum system to remove trace residual gases from the nasal mask.

IV. TRAINING AND SUPERVISION REQUIREMENTS

A. SBDE SEDATION PERMIT-TSBDE RULE 110.3 SUMMARIZED AS:
The State of Texas mandates that students must have completed training consistent with the 2017 Guidelines established for teaching the Comprehensive Control of Pain and Anxiety in Dentistry. The current ADA Guideline for Teaching Pain Control and Sedation to Dentists and Dental Students states that the combined didactic and clinical components should be a minimum of 14 hours during which competency in inhalation sedation technique is achieved. All sedation administrators and faculty supervisors should maintain currency of
their Basic Life Support Provider card at all times. Faculty members who supervise students administering nitrous oxide inhalation sedation must be certified by the Texas SBDE and have been vetted through The Office of Clinical Affairs credentialing process. Non-qualified faculty should refrain from supervising the administration of nitrous oxide/oxygen conscious sedations performed by students.

B. UNDERGRADUATE STUDENTS
D3 and D4 dental students will administer nitrous oxide inhalation in accordance with the guidelines promulgated in the Anxiety and Pain Control Course #7240. Students gain practical monitoring experience by attending a supervised inhalation sedation laboratory session which qualifies as their first case, or as an alternative, administer their first case under close supervision, with no additional responsibilities (as the operating or assisting student). Thereafter, in the Oral and Maxillofacial Surgery Undergraduate Clinic they may combine their inhalation sedation responsibilities with their other duties as the operating/assisting student. On the 7th and 8th floor Undergraduate Clinics the student must administer the inhalational sedation as a sole procedure with no other duties or responsibilities. Direct supervision will be provided by qualified clinical faculty in that clinical area.

C. ADVANCED DENTAL EDUCATION STUDENTS
Graduate students must either show evidence of didactic and clinical training that satisfies the requirements of the Texas SBDE for a sedation permit (as described above) or participate in an approved course of training that provides that level of training and experience before being allowed to administer unsupervised inhalation sedation. Until that time, all administrations must be provided under the supervision of a TSBDE permitted faculty member that has been vetted through Clinical Affairs credentialing process.

D. STATE CERTIFIED DENTAL ASSISTANTS
Dental assistants who have successfully passed the Texas SBDE’s “Nitrous Oxide Monitoring Examination” are allowed to assist in monitoring nitrous oxide cases under direct faculty supervision. Dental assistants without this certification status cannot participate in the inhalation sedation administration aspects of the case.

V. MONITORING AND DOCUMENTATION
A. ANESTHESIA CHECKLIST
This form must be used prior to administering nitrous oxide and any other sedation anesthesia procedures. It is used as a “Time Out” to ensure the clinician has assessed the patients’ health and that the proper procedure is being performed on the correct patient.

B. INFORMED CONSENT
All patients will undergo pre-sedation counseling on the objectives, alternatives, potential risks and complications, of conscious sedation. Adult patients will provide a witnessed signature on the supplemental “Consent for Nitrous Oxide – Oxygen Sedation” document acknowledging the counseling and giving permission for the sedation aspects of the treatment. In the case of pediatric patients, parental or guardian consent will be obtained, using the Pediatric Dentistry consent document. Other recognized guidelines governing informed consents shall also prevail.

C. MONITORING
To assure optimal patient safety, all inhalation sedation cases must be accompanied by documented monitoring. General guidelines may not meet the needs of all patients and all situations, so professional judgment should prevail as to the type and frequency of monitoring. The guidelines provided below are general recommendations that have established validity from specialty organizations or other authoritative sources.

1. **ADULTS**
   All adult patients will have a current or updated signed medical history, focal physical examination as dictated by the medical history and assignment of ASA patient physical status classification documented in the medical record. A review of the medical history, ASA status, confirmation of NPO status and baseline preoperative vital signs will be entered on the Inhalational Sedation Time Oriented Anesthesia Record. At the end of each nitrous oxide sedation case 100% oxygen for 5 minutes should be delivered to the patient before removing the nasal hood and disconnect the patients for the monitors. Prior to discharge, the patient’s vital signs will be monitored and documented to verify that the patient is stable to permit discharge without an escort. During the procedure, vital signs should be periodically monitored and documented in the Time Oriented Anesthesia Record, as dictated by the condition of the patient and the length of the procedure. There must be a note in the Time Oriented Anesthesia Record that the patient had sufficiently recovered and was deemed stable, responsive, and alert at the time of release.

2. **CHILDREN (Defined as patients < 16 years of age)**
   The American Academy of Pediatric Dentistry’s guidelines for the elective use of conscious sedation in pediatric patients recommends baseline vital signs and that responsiveness and airway patency of the patient be monitored and documented at intervals “before and during the procedure and until patient is discharged”\(^2\). For mildly sedated (<50% Nitrous Oxide), totally awake patients (level 1) they recommend only continual observation; For an interactive patient with a minimally depressed level of consciousness (>50% nitrous oxide), eyes open or temporarily closed, responding on verbal commands (level 2), they recommend pulse and respirations be monitored before, every 15 minutes during, and after the procedure.\(^2\) At the end of each nitrous oxide sedation, 100% oxygen for 5 minutes should be delivered to the patient before removing the nasal hood and disconnect the patients for the monitors. Periodic documentation of intraoperative vital signs will be performed and documented in a Time Oriented Anesthesia Record when deemed prudent in the judgment of the supervising faculty. There must be an entry in the Time Oriented Anesthesia Record that the child was stable and responsive at the time of discharge, and released to the custody of a responsible adult. As noted above, dental assistants who have received state certification can be utilized for patient monitoring, under direct faculty supervision.

VI. AUTHORIZED MONITORING FORMS

For all sedation cases performed by undergraduate or graduate students, in any college clinic, the approved “Inhalation Sedation Monitoring Record” or equivalent will be used to document the various aspects of the case. Substitute forms must be approved by the Clinical
Affairs Committee. If a departmental chairperson deems that form unsuitable for use in cases administered by graduate students, a more-detailed, college-approved IV sedation or general anesthesia monitoring form can be substituted with the approval of the Associate Dean for Clinical Affairs.

VII. INFECTION CONTROL
There is a minimal risk for patient-to-patient disease transmission in the hose systems of the nitrous oxide administration setups, but there is a slightly higher risk for disease transmission via the masks, since the nasal mask is in intimate contact with the patient and subject to contamination. All masks used in the college will either be steam autoclaved or will be disposed of after a single use when they are disposable. Scavenger hoses must be steam autoclaved. If any of the other hoses are visibly contaminated, they should be washed with soap and water, rinsed, sprayed with an approved surface disinfectant and remain wet for the appropriate amount of time.

VIII. SAFETY AND SECURITY

A. SECURITY
All portable nitrous oxide tanks, and mobile and built-in administration units, will be kept secure in locked locations outside normal working hours, to prevent after hours abuse or theft. Distribution of keys to such spaces will be controlled and only on a need-for-access basis. Centrally-provided gasses will be cut off at designated times to prevent after-hours use.

B. PERSONNEL
Females who are or believe themselves to be pregnant may seek counseling by her OBGYN doctor on the increased risk of miscarriage and they are urged to refrain from chronic nitrous oxide exposures during the first trimester of their pregnancy. Any provider who is suspected of chronically abusing nitrous oxide should be reported (anonymously or otherwise) to the Associate Dean for Clinical Affairs for investigation and intervention.

D. SYSTEM INTEGRITY TESTING AND EQUIPMENT CALIBRATION
All nitrous oxide administration equipment will be calibrated and checked for proper operation annually, to verify the delivery dosages are accurately reflected on the gauges and dials. All centrally-installed lines and outlets will be annually tested to verify the integrity of the system, assuring there are not tank or line leaks in the system. Any damaged outlet boxes, lines, or tanks will be repaired or replaced before the system is used again. Such calibration or testing will be performed by a firm certified to perform testing or calibration of anesthetic equipment and gasses.
REFERENCES

5. Texas State Board of Dental Examiners, Rules for Anesthesia and Anesthetic Agents, Rule 108.171 through 108.177, April 19, 1996.