

STANDARD OF PRACTICE

Approved by the College - November 2018

This is replacing the document
last published in April 2015.

Use of Sedation and General Anesthesia in Dental Practice

CONTENTS

Use of Sedation and General Anesthesia in Dental Practice	3
General Standards for all Modalities of Sedation or General Anesthesia	5
Specific Standards for Particular Modalities	
Part I – Minimal and Moderate Sedation	10
(A) Minimal Sedation	11
(B) Moderate Sedation	15
Part II – Deep Sedation and General Anesthesia	27
Appendices	34

NOTE TO READER

Effective April 1, 2020, all dentists administering minimal sedation, including nitrous oxide and oxygen sedation and oral minimal sedation, must have authorization from the RCDSO to do so. In addition, all facilities where minimal sedation is administered, including nitrous oxide and oxygen sedation and oral minimal sedation, will be subject to random on-site inspections and evaluation by the RCDSO.

Visit our website for more information about the implementation of this Standard.

INTRODUCTION

The Standards of Practice of the Royal College of Dental Surgeons of Ontario describe the minimum requirements that all dentists must meet in a particular area of clinical practice to maintain patient safety. On a regular basis, the RCDSO reviews and revises Standards to address any changes that are required. We urge all dentists to achieve excellence in every aspect of their work. They must ensure they are always up-to-date with the latest knowledge.

Sedation and general anesthesia are often beneficial and sometimes essential for our patients. This Standard is one of the most important documents we have because it literally concerns matters of life or death.

The use of sedation and general anesthesia carries an element of risk. Mitigating this risk requires advanced training, planning and assessment during administration. These extra levels of care and diligence are needed before, during and after a dental procedure that requires sedation or general anesthesia.

The RCDSO requires that a properly trained sedation or anesthetic team is in place to administer and monitor deeper levels of sedation and general anesthesia. Each member of the team must be trained for specific duties. A team composed of a minimum of three individuals in three different roles must be in the operatory at



Royal College of
Dental Surgeons of Ontario

6 Crescent Road
Toronto, ON Canada M4W 1T1
T: 416.961.6555 F: 416.961.5814
Toll Free: 800.565.4591 www.rcdso.org

all times when general anesthesia, deep sedation or parenteral moderate sedation is administered. Concerns for patient safety are always the first priority and the team must continuously monitor, assess and address how their patient is responding to sedation or general anesthesia.

Certain patient groups need greater attention; children, the elderly and medically-compromised people face particular challenges when receiving sedation or general anesthesia. Children under 12 years of age - especially under 3 years of age - require even more diligent monitoring; they have reduced physical reserves and impairment may occur rapidly. In particular, it can be difficult to diagnose hypoventilation and airway obstruction quickly.

A key goal with this Standard is to identify what will provide patient safety with a wide enough margin to meet unforeseen circumstances and still ensure success. Safety is dependent on training, careful patient selection and preparation, monitoring, equipment and emergency drugs, as well as continuing education on all of these elements.

This revision of the Standard on the Use of Sedation and General Anesthesia in Dental Practice sets enhanced requirements and higher standards throughout. The RCDSO is committed to continuous improvement in every area of clinical practice. Recent advancements in training, technology and knowledge are represented in this version of the Standard.

Properly equipped sedation and general anesthesia facilities are critical. The RCDSO operates a robust inspection and review program to ensure that all sedation and general anesthesia facilities in dentistry meet the required Standard.

Contravention of this or any Standard of the RCDSO may be considered professional misconduct. Dentists employing any modality of sedation or general anesthesia must be familiar with its content, be appropriately trained and regulate their practices accordingly. It must be read in conjunction with the by-laws of the RCDSO, which form part of this Standard.

Use of Sedation and General Anesthesia in Dental Practice

Sedation or general anesthesia may be indicated to:

- treat patients with fear or anxiety associated with dental treatment;
- enable treatment for patients who have cognitive impairment or motor dysfunction that prevents adequate dental treatment;
- treat patients below the age of reason; or
- treat patients for traumatic or extensive dental procedures.

These techniques are to be used only when indicated, as an adjunct to appropriate non-pharmacological means of patient management.

Sedation and general anesthesia are produced along a continuum, ranging from the relief of anxiety with little or no associated drowsiness (i.e. minimal sedation), up to and including a state of unconsciousness (i.e. general anesthesia).

DEFINITIONS:

Minimal sedation is 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.

Moderate sedation is a drug-induced depression of consciousness during which patients respond *purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

The inherent safety of minimal and moderate sedation is dependent on the patient remaining clearly conscious throughout.

Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

See Appendix III - Characteristics of the Levels of Sedation and General Anesthesia

It is not always possible to predict how an individual patient will respond and, at times, it can be difficult to precisely define the end-point of one level of sedation and the starting point of a deeper level of sedation. Therefore, the drugs and techniques used for sedation must carry a margin of safety wide enough to render loss of consciousness highly unlikely.

Practitioners intending to produce a given level of sedation must be able to diagnose and manage the physiological consequences (rescue) for patients whose level of sedation becomes deeper than initially intended. For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (e.g. emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

The following are the **minimum** standards for the use of sedation and/or general anesthesia in dentistry. For the purposes of this document, these standards are divided into the following sections:

- General standards for all modalities of sedation or general anesthesia
- Specific standards for the following modalities:
 - Minimal sedation
 - + Administration of nitrous oxide and oxygen
 - + Oral administration of a single sedative drug
 - Moderate sedation
 - + Oral administration of a sedative drug, with or without nitrous oxide and oxygen
 - + Parenteral administration of a sedative drug (intravenous, intramuscular, subcutaneous, submucosal or intranasal)
 - Deep sedation
 - General anesthesia

General Standards For All Modalities of Sedation or General Anesthesia

PROFESSIONAL RESPONSIBILITIES

The following professional responsibilities apply to all modalities of sedation or general anesthesia.

1. Successful completion of a training program designed to produce competency in the specific modality of sedation or general anesthesia utilized is mandatory.
2. The dental facility must comply with all applicable building codes, including fire safety, electrical and access requirements. The size and layout of the facility must be adequate for all procedures to be performed safely and provide for the safe evacuation of patients and staff in case of an emergency.
3. The dental facility must be suitably staffed and equipped for the specific modality(ies) practiced as prescribed in this document.
4. An adequate, clearly recorded current medical history, including present and past illnesses, hospital admissions, current medications and dose, allergies (in particular to drugs), and a functional inquiry or review of systems (ROS), along with an appropriate physical examination must be completed for each patient prior to the administration of any form of sedation or general anesthesia. For medically compromised patients, consultation with their physician may be indicated. This must form a permanent part of each patient's record, consistent in content with Appendix I. Additionally, the medical history must be reviewed for any changes at each sedation appointment. Such a review must be documented in the permanent record.
5. A determination of the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (see Appendix II), as well as careful evaluation of any other factors that may affect a patient's suitability for sedation or general anesthesia, must be made prior to its

administration. These findings will be used as a guide in determining the appropriate facility and technique used.

6. In general, when it is indicated, the administration of sedation or general anesthesia in out-of-hospital dental facilities is most appropriate for patients who are ASA I and ASA II. Patients who are ASA III and/or present with other medical concerns (e.g. difficult airway) may not be acceptable for treatment by practitioners who are qualified to administer minimal and/or moderate sedation only. Such patients must be carefully assessed and consideration should be given to referring them to a more qualified practitioner.
7. Patients who are under 12 years of age are not acceptable for the administration of parenteral moderate sedation in out-of-hospital dental facilities, except by those practitioners who are qualified to administer deep sedation or general anesthesia.
8. Patients who are under 3 years of age **OR** under 15 kilograms are not acceptable for the administration of oral sedation, with or without nitrous oxide and oxygen, except by those practitioners who are qualified to administer deep sedation or general anesthesia, and by those practitioners who have completed a formal post-graduate program in pediatric dentistry suitable for certification in the Province of Ontario.
9. Patients who are ASA IV and above are not acceptable for the administration of deep sedation or general anesthesia in out-of-hospital dental facilities. The administration of nitrous oxide and oxygen may be considered for these patients. Other modalities for minimal and moderate sedation may be considered **only** by those practitioners who are qualified to administer deep sedation or general anesthesia.

10. Only the following persons may administer any sedative or general anesthetic agent in the dental setting:

- A dentist currently registered with the Royal College of Dental Surgeons of Ontario (RCDSO);
- A physician currently registered with the College of Physicians and Surgeons of Ontario (CPSO);
- A nurse practitioner (NP) currently registered with the College of Nurses of Ontario acting under the direction of a dentist or a physician, currently registered in Ontario;
- A registered nurse (RN) currently registered with the College of Nurses of Ontario acting under the required order and the direct control and supervision of a dentist or a physician, currently registered in Ontario;
- A respiratory therapist (RT) currently registered with the College of Respiratory Therapists of Ontario acting under the required order and the direct control and supervision of a dentist or a physician, currently registered in Ontario;
- **For minimal sedation only**, a registered practical nurse (RPN) currently registered with the College of Nurses of Ontario, who has completed an enhanced medication course in the administration and monitoring of minimal sedation, acting under the required order and the direct control and supervision of a dentist, currently registered in Ontario.

11. All dentists and dental office staff must be prepared to recognize and treat adverse responses using appropriate emergency equipment and appropriate and current drugs when necessary. All dentists and clinical staff must have the training and ability to perform basic life support (BLS) techniques. It

is strongly recommended that all dentists maintain current* BLS certification (CPR Level HCP), and that all dental offices are equipped with an automated external defibrillator (AED). All dentists providing minimal and/or oral moderate sedation must, as a minimum, maintain current* BLS certification (CPR Level HCP), which must include a hands-on component. All dentists providing oral moderate sedation to patients who are under 3 years of age **OR** under 15 kilograms must also maintain current* Pediatric Advanced Life Support (PALS) certification or current* Pediatric Emergency Assessment, Recognition and Stabilization (PEARS) certification, which must include a hands-on component. All dentists providing parenteral moderate sedation, deep sedation and/or general anesthesia must also maintain current* Advanced Cardiac Life Support (ACLS) certification, which must include a hands-on component. All dentists providing parenteral moderate sedation, deep sedation and/or general anesthesia to patients who are under 12 years of age must also maintain current* PALS certification, which must include a hands-on component. Dentists should establish written protocols for emergency procedures and review them with their staff regularly.

** For the purposes of fulfilling this requirement, "current" is defined as within 2 years.*

The following table outlines the six basic drugs that must be included in the emergency kit of every dental office. All dental offices providing sedation and/or general anesthesia are required to have additional emergency drugs and armamentaria, as described in the sections dealing with specific modalities.

DRUG	INDICATION	INITIAL ADULT DOSE	RECOMMENDED CHILD DOSE
Oxygen*	Most medical emergencies	100% inhalation	100% inhalation
Epinephrine** (at least 2 sources)	Anaphylaxis	0.3-0.5 mg i.m.** or 0.01-0.1 mg i.v.	0.01 mg/kg
	Asthmatic bronchospasm which is unresponsive to salbutamol	0.3-0.5 mg i.m.** or 0.01-0.1 mg i.v.	0.01 mg/kg
	Cardiac arrest	1 mg i.v.	0.01 mg/kg
Nitroglycerin	Angina pectoris	0.3 mg or 0.4 mg sublingual	Not indicated
Diphenhydramine	Allergic reactions	50 mg i.m.** or i.v.	1 mg/kg
Salbutamol inhalation aerosol	Asthmatic bronchospasm	2 puffs (100 micrograms/puff)	1 puff
ASA (non-enteric coated)	Acute Myocardial Infarction	160 to 325 mg	Not indicated

* An E-size cylinder is required. The unit must be portable and have an appropriate regulator and flowmeter, as well as connectors, tubing and reservoir bag, to allow use of a full face mask for resuscitative ventilation.

** At least 2 sources of 1:1,000 epinephrine are required, such as 2 ampules, 2 auto-injectors or a combination of ampules and auto-injectors. **If children under 30 kg are treated and auto-injectors are used, the pediatric formulation is required.**

*** The dose suggested for the i.m. route is also appropriate for sublingual injections. The total pediatric dose should not exceed the adult dose.

12. All dentists providing sedation and/or general anesthesia must be able to satisfy the RCDSO of their continuing competence and are expected to pursue continuing education related to the modality(ies) they use.

In addition to maintaining life-support certification at the required level(s), dentists must satisfy the following requirements:

For minimal sedation	<ul style="list-style-type: none"> • a minimum of 5 cases must be performed per year; and • if patients under 12 years of age are treated, a minimum of 5 cases involving patients under 12 years of age must be performed per year
For oral moderate sedation	<ul style="list-style-type: none"> • a minimum of 6 hours of continuing education (or 6 CE points) related to oral moderate sedation must be completed per 3-year period*; and • a minimum of 5 cases** must be performed per year; and • if patients under 12 years of age are treated, a minimum of 5 cases involving patients under 12 years of age must be performed per year
For parenteral moderate sedation	<ul style="list-style-type: none"> • a minimum of 12 hours of continuing education (or 12 CE points) related to parenteral moderate sedation must be completed per 3-year period*; and • a minimum of 10 cases must be performed per year
For deep sedation and/or general anesthesia	<ul style="list-style-type: none"> • a minimum of 12 hours of continuing education (or 12 CE points) related to deep sedation and/or general anesthesia must be completed per 3-year period*; and • a minimum of 10 cases must be performed per year; and • if patients under 12 years of age are treated, a minimum of 10 cases involving patients under 12 years of age must be performed per year

* For the purposes of fulfilling this requirement, courses in the management of medical emergencies are accepted. Courses to acquire or maintain life-support certification (BLS, ACLS, PALS and PEARS) are NOT accepted.

** For the purposes of fulfilling this requirement, minimal sedation cases are also accepted, provided that the cases are managed as if they are oral moderate sedation cases, including documentation of sedation records.

At the time of renewal of their authorization, dentists who have not completed the required number of CE points and/or performed the required number of cases to maintain their competence will be expected to provide an explanation for their shortfall.

13. Dentists must take into account the maximum dose of local anesthetic that may be safely administered, especially for children, elderly and medically compromised patients.

14. All dentists providing sedation or general anesthesia must monitor and report any serious adverse event (Tier One Event) or other incident (Tier Two Event) to the RCDSO, as described below.

Tier One Events:

Serious adverse events must be [reported to the RCDSO](#) in writing within 24 hours of knowledge of the event.

- Death of a patient within the facility.
- Death of a patient within 10 days of a procedure performed at the facility.
- Transfer of a patient from the facility directly to a hospital for care.

Tier Two Events:

Other incidents must be [reported to the RCDSO](#) in writing within 10 days of knowledge of the event.

- Unscheduled treatment of a patient in a hospital within 10 days of a procedure performed with sedation or general anesthesia.
 - Any use of a benzodiazepine or opioid antagonist.
 - Any serious cardiac or respiratory adverse event requiring administration of a medication for its management.
-

Dentists using sedative and/or general anesthetic agents must take reasonable precautions to prevent the unauthorized use of these substances by staff and other individuals with access to the office. Drugs stored in a dentist's office must be kept in a locked cabinet. Dentists are advised to avoid storing drugs in any other location, including their homes, and never leave drug bottles or vials unattended. [A drug register](#) must be maintained that records and accounts for all narcotics, controlled drugs, benzodiazepines and targeted substances that are kept on-site. The register should also be kept in a secure area in the office, preferably with the drugs, and reconciled on a routine basis, depending on the nature of the practice and reasonable clinical judgment.

Whenever drugs in the above-mentioned classes are used or dispensed, a record containing the name of the patient, the quantity used or dispensed, and the date must be entered in the register for each drug. Each entry must be initialed or attributable to the person who made the entry. In addition, this same information must be recorded in the patient record.

When dispensing monitored drugs for home use by patients, dentists are also required to record appropriate patient identification (e.g. OHIP number) in the drug register, as well as in the patient record.

Dentists are required to report within 10 days of discovery the loss or theft from their office of controlled substances, including opioids and other narcotics, to the [Office of Controlled Substances](#), Federal Minister of Health.

Dentists should use staff training sessions and meetings to discuss the dangers of drug and substance abuse, to remind staff of the safeguards and protocols in the office to prevent misuse of supplies, and to provide information about resources that are available to dental professionals to assist with wellness issues.

There is no provision for dentists or their staff to access in-office supplies of drugs that normally require a prescription for their own use or by their family members.

Specific Standards For Particular Modalities

Part I – Minimal and Moderate Sedation

Minimal sedation is usually accomplished by the following modalities:

1. administration of nitrous oxide and oxygen
2. oral administration of a single sedative drug

Moderate sedation is usually accomplished by the following modalities:

3. oral administration of a sedative drug, with or without nitrous oxide and oxygen
4. parenteral administration of a sedative drug (intravenous, intramuscular, subcutaneous, submucosal or intranasal)

PROFESSIONAL RESPONSIBILITIES FOR ALL MODALITIES OF MINIMAL AND MODERATE SEDATION

In addition to the General Standards listed previously, the following professional responsibilities apply to all modalities of minimal and moderate sedation:

i) Successful completion of a training program designed to produce competency in the use of the specific modality of minimal or moderate sedation, including indications, contraindications, patient evaluation, patient selection, pharmacology of relevant drugs, and management of potential adverse reactions, is mandatory. The training program must be obtained from one or more of the following sources:

- Ontario Faculties of Dentistry undergraduate and post-graduate programs
- other Faculties of Dentistry undergraduate and post-graduate programs, approved by the RCDSO
- Ontario Faculties of Dentistry continuing education programs
- other continuing education courses approved by the RCDSO which follow the general principle that they must be:

- Organized and taught by dentists certified to administer anesthesia and sedation as they apply to dentistry, supplemented as necessary by persons experienced in the technique being taught.
- Held in a properly equipped dental environment which will permit the candidates to utilize the techniques being taught on patients during dental treatment.
- Followed by a recorded assessment of the competence of the candidates.

ii) Dentists whose training does not exceed that described as necessary for the administration of minimal or moderate sedation are cautioned not to exceed the level of depression for which they are authorized to administer. Administration of a single sedative drug in a carefully considered dose is a prudent approach to minimal or moderate sedation. Successful completion of additional training, as outlined elsewhere in this document, is required if more than one sedative drug is to be used.

iii) Should the administration of any drug produce a level of depression beyond that for which the dentist is authorized to administer, the dental procedures should be halted. Appropriate support procedures must be administered until the level of depression is no longer beyond that for which the dentist is authorized to administer or until additional emergency assistance is obtained.

iv) Sedation techniques require the patient to be discharged to the care of a responsible adult. Nitrous oxide and oxygen sedation is the only modality for which a dentist may exercise discretion as to whether a patient may be discharged unaccompanied. All patients must be specifically assessed for fitness for discharge as described elsewhere in this document.

(A) MINIMAL SEDATION

- administration of nitrous oxide and oxygen
- oral administration of a single sedative drug

In all cases where the intention is to achieve moderate sedation using any modality of sedation, including the oral administration of a single sedative drug, the dentist must adhere to the standards for moderate sedation.

[This includes the professional responsibilities of obtaining authorization and a facility permit from the RCDSO.](#)

1. NITROUS OXIDE AND OXYGEN SEDATION

In addition to the General Standards and professional responsibilities listed above, the following professional responsibilities apply when nitrous oxide and oxygen sedation is being administered:

Additional Professional Responsibilities

1. All dentists administering nitrous oxide and oxygen sedation must have authorization from the RCDSO to do so, effective April 1, 2020.
2. All facilities where nitrous oxide and oxygen sedation is administered are subject to random on-site inspections and evaluation by the RCDSO, effective April 1, 2020.
3. Gas delivery systems used for the administration of nitrous oxide and oxygen sedation:
 - a. Must have a fail-safe mechanism such that it will not deliver an oxygen concentration of less than 30% in the delivered gas mixture.
 - b. Must have pipeline inlet fittings, or pin-indexing, that do not permit interchange of connections with oxygen and nitrous oxide.
 - c. Must be checked regularly for functional integrity by appropriately trained personnel, function reliably and accurately, and receive appropriate care and maintenance according to manufacturer's instructions or annually, whichever is more frequent. **A written record of this annual maintenance/servicing must be kept on file for review by the RCDSO as required.**

- d. Must have a reserve supply of oxygen that is ready for immediate use. For a portable gas delivery system, the reserve supply of oxygen must be connected to the system (i.e. a "4-yoke" system). For a centrally plumbed gas delivery system, two oxygen cylinders must be connected to the system at all times.
- e. Must be equipped with a scavenging system installed per manufacturer's specifications.

In addition to installing a scavenging system, dentists must ensure adequate ventilation of the facility to minimize occupational exposure to nitrous oxide and maintain acceptable air quality.

4. In addition to the gas delivery system, an emergency supply of oxygen is required (i.e. a "wheel-out"), as described in the above table of six basic drugs that must be included in the emergency kit of every dental office.
5. Nitrous oxide and oxygen sedation must be administered by:
 - a. an appropriately trained dentist **OR**
 - b. an appropriately trained nurse practitioner acting under the direction of an appropriately trained dentist, or an appropriately trained registered nurse, respiratory therapist or registered practical nurse acting under the order of an appropriately trained dentist, provided that:
 - an appropriately trained dentist is present at all times in the facility and **immediately** available in the event of an emergency;
 - nitrous oxide and oxygen sedation has been previously administered for the patient by the dentist;
 - appropriate dosage levels have been previously determined and recorded by the dentist in the patient record.

IMPORTANT: The administration of nitrous oxide and oxygen sedation is a controlled act. Dental hygienists and dental assistants are NOT authorized to perform it.

6. Consent must be obtained prior to the administration of nitrous oxide and oxygen sedation, which should be documented.

7. Patients should be given instructions not to eat or drink for 2 hours prior to their appointment.

8. Patients receiving nitrous oxide and oxygen sedation must be supervised by an appropriately trained dentist, or an appropriately trained nurse practitioner acting under the direction of a dentist, or an appropriately trained registered nurse, respiratory therapist or registered practical nurse acting under the order of a dentist, and must never be left unattended during administration.

9. Patients must be monitored by an appropriately trained dentist, or an appropriately trained nurse practitioner acting under the direction of a dentist, or an appropriately trained registered nurse, respiratory therapist or registered practical nurse acting under the order of a dentist, by direct and continuous clinical observation for level of consciousness and assessment of vital signs, which may include heart rate, blood pressure and respiration pre-operatively, intra-operatively and post-operatively, as necessary.

10. The practitioner must not be alone while treating a sedated patient.

11. Recovery status post-operatively must be specifically assessed and recorded by the dentist, who must remain in the facility until that patient is fit for discharge. Only fully recovered patients can be considered for discharge unaccompanied. If discharge occurs with any residual symptoms, the patient must be accompanied by a responsible adult.

Nitrous oxide and oxygen sedation is the only modality for which a dentist may exercise discretion as to whether a patient may be discharged unaccompanied. All patients must be specifically assessed for fitness for discharge.

12. Records of the sedation procedure must be kept that, as a minimum, include the following information:

- pre-operative review of the patient's medical history for any changes;
- pre-operative blood pressure and pulse;
- total flow of nitrous oxide and oxygen;
- percentage and duration of administration of nitrous oxide;
- duration of administration of 100% oxygen at the end of the sedation procedure;
- notation regarding the patient's tolerance of the sedation procedure.

13. Any Tier One or Tier Two Event must be reported to the RCDSO in writing.

2. ORAL MINIMAL SEDATION

In addition to the General Standards and professional responsibilities listed above, the following professional responsibilities apply to the oral administration of a single sedative drug (which includes the sublingual route of administration) for minimal sedation.

Additional Professional Responsibilities

1. All dentists administering oral minimal sedation must have authorization from the RCDSO to do so, effective April 1, 2020.
2. All facilities where oral minimal sedation is administered are subject to random on-site inspections and evaluation by the RCDSO, effective April 1, 2020.
3. All dentists administering oral minimal sedation for patients under 12 years of age must provide care that meets all requirements for oral moderate sedation. This includes the professional responsibilities of [obtaining authorization and a facility permit from the RCDSO](#) to do so, regardless of whether minimal or moderate sedation is intended or achieved.
4. For the administration of oral minimal sedation for patients under 3 years of age **OR** under 15 kilograms, the following training is required:
 - dentists who qualify for the administration of deep sedation and general anesthesia, as outlined in Part II of this document; **OR**

- dentists who have successfully completed a formal post-graduate program in pediatric dentistry suitable for certification in the Province of Ontario, incorporating adequate training in sedation, such that the individual competence has been specifically evaluated and attested.

5. Oral administration of a **single** sedative drug, specifically a benzodiazepine, is a prudent approach to minimal sedation. No additional drugs with sedative properties (e.g. opioids, anti-histamines) are permitted to be administered by any route in the peri-operative period. Non-sedative agents may be administered as deemed appropriate.

Table 1

ADULT DOSE RANGES OF ORAL SEDATIVES FOR MINIMAL SEDATION

Appointment 2 hours or less

- triazolam 0.125 to 0.25 mg

Appointment longer than 2 hours

- triazolam 0.25 mg OR
- diazepam 10 to 15 mg OR
- temazepam 15 mg OR
- oxazepam 10 to 15 mg

Appointment longer than 3 hours

- lorazepam 0.50 to 1.0 mg OR
- alprazolam 0.25 mg

These dose ranges are approximations only. Reduced doses should be considered for elderly and medically compromised patients.

The maximum dose of an oral sedative for minimal sedation must not be exceeded, unless the dentist provides care that meets all requirements for oral moderate sedation. This includes the professional responsibilities of [obtaining authorization and a facility permit from the RCDSO](#) to do so, regardless of whether minimal or moderate sedation is intended or achieved.

For the purposes of minimal and/or moderate sedation, the oral administration of an opioid and/or chloral hydrate is NOT permitted.

6. A dose of an oral sedative used to induce minimal sedation should be administered to the patient in the dental office, taking into account the time required for drug absorption.

Elderly and medically compromised patients, including those who are taking prescribed medication with sedative properties, require appropriate adjustment of the dose of the oral sedative drug to ensure that the intended level of minimal sedation is not exceeded. Continuous monitoring with pulse oximetry is strongly recommended for these patients. If a pulse oximeter is used for continuous monitoring of sedated patients (including the immediate recovery phase), it must have a Health Canada medical device license and be used in accordance with the manufacturer's 'intended use' (i.e. for continuous monitoring). The pulse oximeter must have variable pitch tone, clearly audible alarms, appropriately set and NOT permanently silenced.

7. There are two rare situations in which the patient may need to take an oral sedative prior to arrival to the dental office. One indication is if the practitioner has determined that the patient requires an oral sedative to facilitate sleep the night prior to the dental procedure. The second indication is when the patient's anxiety is such that sedation is required to permit arrival to the dental office. Such situations, however, should be the exception and not common practice, and may be subject to scrutiny by the RCDSO. In addition to the requirements in paragraph 6 above, the following additional requirements apply in these two situations:

- Each patient must be screened by the dentist at a prior appointment, with an appropriate medical history, as described in the General Standards in this document.
- If a prescription sedative drug is required, only a benzodiazepine may be prescribed.

- The dose of the benzodiazepine must not exceed the maximum dose for minimal sedation (See TABLE 1).
- The patient must be instructed not to drive a vehicle and must be accompanied to and from the dental office by a responsible adult.
- In each case, clear written instructions must be given to the patient or guardian explaining how to take the medication, the need for accompaniment and listing the expected effects from this sedative drug.

8. Patients should be given instructions not to eat or drink for 2 hours prior to their appointment.

9. Consent must be obtained prior to the administration of any oral sedative, which should be documented.

10. Patients must be monitored by clinical observation of the level of consciousness and assessment of vital signs, which may include heart rate, blood pressure and respiration.

11. The patient may be discharged once he/she shows signs of progressively increasing alertness and has met the following criteria:

- conscious and oriented
- vital signs are stable
- ambulatory

12. The patient must be discharged to the care of a responsible adult.

13. The patient must be instructed to not drive a vehicle, operate hazardous machinery or make important decisions. In addition, the patient must be cautioned about consuming alcohol and other drugs with sedative properties for a minimum of 18 hours or longer if drowsiness or dizziness persists.

14. If a reversal agent is administered before discharge criteria have been met, the patient must be monitored beyond the expected duration of action of the reversal agent to guard against re-sedation, and a Tier Two Event must be reported to the RCDSO in writing.

15. Records of the sedation procedure must be kept that, as a minimum, include the following information:

- pre-operative review of the patient's medical history for any changes;
- verification of accompaniment for discharge;
- pre-operative blood pressure and pulse;
- name and dose of the oral sedative administered;
- time of administration of the oral sedative;
- time that discharge criteria are met;
- notation regarding the patient's tolerance of the sedation procedure.

16. The practitioner must not be alone while treating a sedated patient.

17. Any Tier One or Tier Two Event must be reported to the RCDSO in writing.

18. Emergency equipment and drugs must be available at all times. Drugs must be current and stored in readily identifiable and organized fashion (i.e. labelled trays or bags). It is the dentist's responsibility to ensure that the dental office in which oral minimal sedation is being performed is equipped with the following:

- full face masks of appropriate sizes and connectors
- current drugs in appropriate amounts for management of emergencies, including:
 - oxygen (an E-size cylinder is required)
 - 1:1,000 epinephrine (at least 2 doses are required, ampules or auto-injectors)
 - nitroglycerin
 - parenteral diphenhydramine
 - salbutamol
 - flumazenil
 - acetylsalicylic acid (ASA, non-enteric coated)

(B) MODERATE SEDATION

It is assumed that this will be accomplished by either:

- oral administration of a sedative drug, with or without nitrous oxide and oxygen;
- parenteral administration of a sedative drug (intravenous, intramuscular, subcutaneous, submucosal or intranasal).

However, in all cases where the intention is to achieve moderate sedation using any modality of sedation, including the oral administration of a single sedative drug, with or without nitrous oxide and oxygen, the dentist must adhere to the standards for moderate sedation. [This includes the professional responsibilities of obtaining authorization and a facility permit from the RCDSO.](#)

1. ORAL MODERATE SEDATION

In addition to the General Standards, this section outlines standards specific to any sedation technique utilizing the oral administration of a sedative drug, with or without nitrous oxide and oxygen, for moderate sedation.

Additional Professional Responsibilities

1. All dentists administering oral moderate sedation must have authorization from the RCDSO to do so.

2. All facilities where oral moderate sedation is administered must have a permit from the RCDSO. Such permit will be granted subject to training and conformance with all aspects of the Standard and subject to satisfactory on-site inspections and evaluation by the RCDSO.

3. The following training is required:

- dentists who qualify for the administration of deep sedation and general anesthesia, as outlined in Part II of this document; OR
- dentists who qualify for the administration of parenteral moderate sedation, as outlined later in this document; OR
- dentists with formal training in a post-graduate specialty program that has specifically incorporated the teaching of techniques using any modality to produce moderate sedation, as well as appropriate

airway management, and has evaluated and attested to the competency of the candidate; OR

- dentists who have successfully completed continuing education training that has specifically incorporated the teaching of techniques using any modality to produce moderate sedation, as well as appropriate airway management, followed by a formal evaluation of the competency of the candidate; OR
- dentists with other training and/or experience who received approval from the RCDSO prior to December 31, 2012.

4. Oral administration of a **single** sedative drug, specifically a benzodiazepine, is a prudent approach to moderate sedation. Successful completion of additional training, as outlined below, is required if more than one oral sedative drug is to be used. Otherwise, no additional oral drugs with sedative properties (e.g. opioids, anti-histamines) are permitted to be administered in the peri-operative period. Non-sedative agents may be administered as deemed appropriate.

5. If an oral sedative has been administered and nitrous oxide/oxygen is used, the latter must be slowly titrated to achieve the signs and symptoms of moderate sedation, with vigilant assessment of the level of consciousness.

6. For the oral administration of two sedative drugs, specifically a benzodiazepine and an anti-histamine, the following training is required:

- dentists who qualify for the administration of deep sedation and general anesthesia, as outlined in Part II of this document; OR
- dentists who qualify for the administration of parenteral moderate sedation, as outlined later in this document; OR
- dentists who have successfully completed a formal post-graduate program in pediatric dentistry suitable for certification in the Province of Ontario, incorporating adequate training in sedation, such that the individual competence has been specifically evaluated and attested.

7. For the administration of oral moderate sedation for patients under 3 years of age **OR** under 15 kilograms, the following training is required:

- dentists who qualify for the administration of deep sedation and general anesthesia, as outlined in Part II of this document; OR
- dentists who have successfully completed a formal post-graduate program in pediatric dentistry suitable for certification in the Province of Ontario, incorporating adequate training in sedation, such that the individual competence has been specifically evaluated and attested.

8. All dentists administering oral moderate sedation for patients under 3 years of age **OR** under 15 kilograms must be able to satisfy the RCDSO that they have appropriate training and experience to possess the knowledge, skills and judgment necessary for the care of such patients. In addition, current PALS or PEARS certification is required.

Table 2

ADULT DOSE RANGES OF ORAL SEDATIVES FOR MODERATE SEDATION

Appointment 2 hours or less	
• triazolam 0.375 to 0.50 mg	
Appointment longer than 2 hours	
• triazolam 0.50 mg	OR
• diazepam 20 to 30 mg	OR
• temazepam 30 mg	OR
• oxazepam 20 to 30 mg	
Appointment longer than 3 hours	
• lorazepam 2 to 3 mg	OR
• alprazolam 0.50 mg	

These dose ranges are approximations only. Reduced doses should be considered for elderly and medically compromised patients, and when nitrous oxide and oxygen will be administered.

In rare situations, the dentist may consider exceeding the maximum dose of triazolam for adults, described above, provided the dose does not exceed 0.75 mg

for 1 appointment. The dentist is expected to exercise reasonable professional judgment in determining when this is justified, and the rationale for doing so must be documented in the patient record. Such situations, however, should be the exception and not common practice, and may be subject to scrutiny by the RCDSO.

For the administration of oral moderate sedation to patients under 12 years of age, the use of oral midazolam, diazepam or hydroxyzine may be considered by those dentists who have successfully completed additional training in their use. The dose of the oral sedative drug must be calculated, based on the weight of the patient:

- For oral midazolam, the dose must not exceed 0.5 mg/kg, with a maximum dose of 15 mg for 1 appointment.
- For oral diazepam, the dose must not exceed 0.5 mg/kg, with a maximum dose of 15 mg for 1 appointment.
- For oral hydroxyzine, the dose must not exceed 1.0 mg/kg, with a maximum dose of 30 mg for 1 appointment.

In rare situations, an appropriately trained specialist in pediatric dentistry may consider exceeding the maximum dose of oral midazolam for patients under 12 years of age, described above, when used as a single oral sedative (i.e. no additional oral sedatives are administered), provided the dose does not exceed 0.75 mg/kg, with a maximum dose of 20 mg for 1 appointment. Similarly, in rare situations, an appropriately trained specialist in pediatric dentistry may consider exceeding the maximum dose of oral hydroxyzine for patients under 12 years of age, described above, when used as a single oral sedative (i.e. no additional oral sedatives are administered), provided the dose does not exceed 2.0 mg/kg, with a maximum dose of 50 mg for 1 appointment. The pediatric dentist is expected to exercise reasonable professional judgment in determining when this is justified, and the rationale for doing so must be documented in the patient record. Such situations, however, should be the exception and not common practice, and may be subject to scrutiny by the RCDSO.

With the exceptions noted above, the maximum dose of an oral sedative must NOT be exceeded, unless the dentist is authorized by the RCDSO to administer deep sedation or general anesthesia.

For the purposes of minimal and/or moderate sedation, the oral administration of an opioid and/or chloral hydrate is NOT permitted.

The administration of a single dose of an oral sedative is a prudent approach to either minimal or moderate sedation. **The administration of multiple doses of an oral sedative until a desired effect is reached (i.e. “incremental dosing”) is strongly discouraged and if used, must be carried out with great caution.** Knowledge of the oral sedative’s time of onset, peak response and duration of action is essential to avoid over-sedation. Before administering an additional dose of an oral sedative, the dentist must ensure that the previous dose has taken full effect. **The maximum dose of an oral sedative must not be exceeded at any one appointment.**

Children, elderly and medically compromised patients, including those who are taking prescribed medication with sedative properties, require appropriate adjustment of the dose(s) of the oral sedative drug(s) to ensure that the intended level of moderate sedation is not exceeded.

Dentists, who use the services of another dentist who is qualified to administer oral moderate sedation, share the responsibility of complying with the Standard. However, the ultimate responsibility rests with the facility permit holder to ensure that:

- the dentist administering oral moderate sedation is authorized by the RCDSO to do so;
- the dentist has no term, condition or limitation on his or her certificate of registration relevant to the administration of sedation or general anesthesia; and
- all required emergency and other equipment is available and emergency drugs are on-site and current.

With the exception of oxygen, EITHER the facility permit holder OR the dentist administering oral moderate sedation MUST provide all required emergency equipment and drugs. The shared provision of emergency equipment and drugs is NOT allowed.

OFFICE PROTOCOL AND FACILITIES

The facility must permit adequate access for emergency stretchers and have auxiliary powered backup for suction, lighting and monitors for use in the event of a power or system failure.

1. Patient Selection

An adequate, clearly recorded current medical history, including present and past illnesses, hospital admissions, current medications and dose, allergies (in particular to drugs), and a functional inquiry or review of systems (ROS), along with an appropriate physical examination must be completed for each patient and must form a permanent part of each patient’s record. For medically compromised patients, consultation with their physician may be indicated. This assessment should be consistent in content with Appendix I.

The patient’s ASA Classification (see Appendix II) and risk assessment must then be determined. These findings will be used to determine the appropriate facility and technique used.

2. Sedation Protocol

1. The medical history must be reviewed for any changes at each sedation appointment. Such a review must be documented in the sedation record for the appointment.
2. The patient must have complied with the minimum duration of fasting prior to appointments that is consistent with the following minimum requirements:
 - 8 hours after a meal that includes meat, fried or fatty foods;
 - 6 hours after a light meal (such as toast and a clear fluid), or after ingestion of infant formula or nonhuman milk;
 - 4 hours after ingestion of breast milk; and
 - 2 hours after clear fluids (such as water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee, but NOT alcohol).

Possible exceptions to this are usual medications or pre-operative medications, which may be taken as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their pre-operative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of eight hours, and that they may ingest clear fluids up until two hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

3. Consent must be obtained prior to the administration of any oral sedative, which should be documented.

4. A dose of an oral sedative used to induce moderate sedation should be administered to the patient in the dental office, taking into account the time required for drug absorption.

5. There are two rare situations in which the patient may need to take an oral sedative prior to arrival to the dental office. One indication is if the practitioner has determined that the patient requires an oral sedative to facilitate sleep the night prior to the dental procedure. The second indication is when the patient's anxiety is such that sedation is required to permit arrival to the dental office. Such situations, however, should be the exception and not common practice, and may be subject to scrutiny by the RCDSO. In addition to the requirements in paragraph 4 above, the following additional requirements apply in these two situations:

- Each patient must be screened by the dentist at a prior appointment, with an appropriate medical history, as described in the General Standards in this document.
- If a prescription sedative drug is required, only a benzodiazepine may be prescribed.
- The dose of the benzodiazepine must not exceed the maximum dose for minimal sedation (See TABLE 1).
- The patient must be instructed not to drive a vehicle and must be accompanied to and from the dental office by a responsible adult.
- For patients under 12 years of age, it is strongly recommended that the patient be accompanied to and from the dental office by two responsible adults, so that one adult can focus on the patient during transport.

- In each case, clear written instructions must be given to the patient or guardian explaining how to take the medication, the need for accompaniment and listing the expected effects from this sedative drug.

6. Clinical observation must be supplemented by the following means of monitoring throughout the sedation administration, including into recovery:

- continuous pulse oximeter monitoring of oxyhemoglobin saturation, recorded at a minimum of 15 minute intervals;
- blood pressure and pulse must be taken and recorded pre-operatively and throughout the sedation period at appropriate intervals, not greater than every 15 minutes;
- continuous observation of respiration, with rate recorded at a minimum of 15 minute intervals.

7. [A sedation record](#) must be kept that includes the recording of vital signs as listed above.

8. Alarm settings and their audio component on monitoring equipment must be used at all times.

In cases where the dentist has determined that the use of a blood pressure cuff and/or pulse oximeter would be an impediment to the management of an individual patient, and the patient is clearly conscious throughout the procedure, a decision may be made not to use these monitors. In these isolated cases, a notation explaining the reason for not using these monitors must be recorded in the chart. Furthermore, these monitors (pulse oximeter, stethoscope and sphygmomanometer) must be present in the office and readily available for use.

9. The patient may be discharged once he/she shows signs of progressively increasing alertness and has met the following criteria:

- conscious and oriented
- vital signs are stable
- ambulatory

10. The patient must be discharged to the care of a responsible adult.

For patients under 12 years of age, it is strongly recommended that the patient be discharged to the care of two responsible adults, so that one adult can focus on the patient during transport. Alternatively, the patient should not be discharged until the patient has demonstrated the ability to remain awake for at least 20 minutes in a quiet environment.

11. Written post-sedation instructions must be given and explained to both the patient and accompanying adult. The patient must be instructed to not drive a vehicle, operate hazardous machinery or make important decisions. In addition, the patient must be cautioned about consuming alcohol and other drugs with sedative properties for a minimum of 18 hours or longer if drowsiness or dizziness persists.

12. If a reversal agent is administered before discharge criteria have been met, the patient must be monitored beyond the expected duration of action of the reversal agent to guard against re-sedation, and a Tier Two Event must be reported to the RCDSO in writing.

13. The practitioner must not be alone while treating a sedated patient.

14. Any Tier One or Tier Two Event must be reported to the RCDSO in writing.

3. Sedation Equipment

Emergency equipment and drugs must be available at all times. Drugs must be current and stored in readily identifiable and organized fashion (i.e. labelled trays or bags). All automated monitors must receive regular service and maintenance by qualified personnel according to the manufacturer's specifications or annually, whichever is more frequent. **A written record of this annual maintenance/servicing must be kept on file for review by the RCDSO as required.**

Equipment that is used for continuous monitoring of sedated patients (including the immediate recovery phase) must have a Health Canada medical device license and be used in accordance with the manufacturer's 'intended use' (i.e. for continuous monitoring). All equipment must have audible alarms, appropriately set and NOT permanently silenced.

It is the dentist's responsibility to ensure that the dental office in which oral moderate sedation is being performed is equipped with the following:

- portable apparatus for intermittent positive pressure resuscitation
- pulse oximeter with clearly audible, variable pitch tone
- stethoscope and sphygmomanometers of appropriate sizes
- full face masks of appropriate sizes and connectors
- portable auxiliary systems for light, suction and oxygen
- current drugs in appropriate amounts for management of emergencies, including:
 - oxygen (an E-size cylinder is required)
 - 1:1,000 epinephrine (at least 2 doses are required, ampules or auto-injectors)
 - nitroglycerin
 - parenteral diphenhydramine
 - salbutamol
 - flumazenil
 - acetylsalicylic acid (ASA, non-enteric coated)

2. PARENTERAL MODERATE SEDATION

Parenteral moderate sedation may be accomplished using any one of the following routes of administration: intravenous, intramuscular, subcutaneous, submucosal or intranasal. For the purposes of this document, these standards also apply when the rectal route of administration is utilized.

In addition to the General Standards, this section outlines standards specific to any sedation technique utilizing the parenteral administration of a sedative drug for moderate sedation.

Additional Professional Responsibilities

1. All dentists administering parenteral moderate sedation must have authorization from the RCDSO to do so.
2. All facilities where parenteral moderate sedation is administered must have a permit from the RCDSO. Such permit will be granted subject to training and conformance with all aspects of the Standard and subject to satisfactory on-site inspections and evaluation by the RCDSO.
3. The following training is required:
 - Dentists who qualify for the administration of deep sedation and general anesthesia, as outlined in Part II of this document.
 - If not qualified for the administration of deep sedation or general anesthesia, then the following training is required:
 - Successful completion of a course of instruction in parenteral moderate sedation that is held where adequate facilities are available for proper patient care, including drugs and equipment for the handling of emergencies, and meeting the didactic and clinical requirements outlined below. A certificate or other evidence of satisfactory completion of the course and a description of the program signed by the course director must be submitted to the RCDSO for consideration. Completion of such a course will be entered onto the dentist's record.

Didactic requirement: The training must include a minimum of 40 hours of lecture and seminar time presented by dental anesthesiologists, dentists/dental specialists formally trained at the post-graduate level in anesthesia and sedation as they apply to dentistry or physicians formally trained in anesthesia. Dentists in a hospital internship or general practice residency program, recognized by RCDSO, may be given credit for one-half of this didactic requirement, provided that documentation of formal training is obtained from the program director.

Clinical Requirement: The training must include supervised application of parenteral moderate sedation concurrent with dental treatment, performed on a minimum of 20 individually managed patients. Active participation in the above is required. Observation alone is not sufficient.

4. All dentists administering parenteral moderate sedation must maintain current ACLS certification.
5. Parenteral administration of a **single** sedative drug, specifically a benzodiazepine (e.g. midazolam or diazepam), is a prudent approach to moderate sedation. Accordingly, intravenous titration of a single **benzodiazepine** alone may be used by those with the training specified immediately above. No additional drugs with sedative properties (e.g. opioids, anti-histamines) are permitted to be administered by **any** route in the peri-operative period. Non-sedative agents may be administered as deemed appropriate.

For the purposes of moderate sedation, the parenteral administration of two benzodiazepines (e.g. midazolam and diazepam) is NOT permitted. For the purposes of moderate sedation, the parenteral administration of an opioid is NOT permitted, except by those dentists described immediately below.

Other than the single parenteral sedative, specifically a benzodiazepine, no additional sedative agents are permitted to be used by any route of administration unless the dentist:

- qualifies for the administration of deep sedation or general anesthesia, as outlined in Part II or this document; **OR**
- received approval from the RCDSO prior to December 31, 2004 **AND** meets the following additional professional responsibilities:
 - only 2 sedative drugs are permitted, specifically:
 - + parenteral administration of a benzodiazepine with nitrous oxide and oxygen; **OR**
 - + parenteral administration of a benzodiazepine and an opioid;
 - the sedation team must meet the same requirements as for an anesthetic team, including at least 2 individuals with current ACLS certification;
 - the sedation equipment and emergency drugs must meet the same requirements as for deep sedation or general anesthesia.

There are two rare situations in which the patient may need to take an oral sedative prior to arrival to the dental office. One indication is if the practitioner has determined that the patient requires an oral sedative to facilitate sleep the night prior to the dental procedure. The second indication is when the patient's anxiety is such that sedation is required to permit arrival to the dental office. Such situations, however, should be the exception and not common practice, and may be subject to scrutiny by the RCDSO. The following requirements apply in these two situations:

- Each patient must be screened by the dentist at a prior appointment, with an appropriate medical history, as described in the General Standards in this document.
- If a prescription sedative drug is required, only a benzodiazepine may be prescribed.
- The dose of the benzodiazepine must not exceed the maximum dose for minimal sedation (See TABLE 1).
- The patient must be instructed not to drive a vehicle and must be accompanied to and from the dental office.
- In each case, clear written instructions must be given to the patient or guardian explaining how to take the medication, the need for accompaniment and listing the expected effects from this sedative drug.

In order to assist with venipuncture, it is permissible to administer EITHER an oral sedative OR nitrous oxide and oxygen:

- For an oral sedative: ONLY a benzodiazepine, preferably triazolam, may be administered for this purpose. The dose of the benzodiazepine must not exceed the maximum dose for minimal sedation.
- For nitrous oxide and oxygen: Once the intravenous line is established and BEFORE the first administration of the parenteral sedative, the nitrous oxide and oxygen must be discontinued.

Patients who are under 12 years of age are not acceptable for the administration of parenteral moderate sedation in out-of-hospital dental facilities, except by those practitioners who are qualified to administer deep sedation or general anesthesia.

Table 3

ADULT DOSE RANGES OF PARENTERAL SEDATIVES FOR MODERATE SEDATION

Midazolam

Appointment 1 hour or less:

- midazolam 1 to 5 mg, administered in 1 to 2 mg increments with 2 to 3 minutes between doses and titrated for effect

Appointment longer than 1 hour:

- additional 1 to 5 mg per hour

OR

Diazepam

- diazepam 2 to 20 mg at one appointment, administered in increments with 2 to 3 minutes between doses and titrated for effect

These dose ranges are approximations only. Reduced doses should be considered for elderly and medically compromised patients.

In rare situations, the dentist may consider exceeding the dose of 5 mg midazolam during the first hour of an appointment for adults, described above, provided the dose does not exceed 10 mg. The dentist is expected to exercise reasonable professional judgment in determining when this is justified, and the rationale for doing so must be documented in the patient record. Such situations, however, should be the exception and not common practice, and may be subject to scrutiny by the RCDSO.

The following **maximum doses** of a parenteral sedative must NOT be exceeded, unless the dentist is authorized by the RCDSO to administer deep sedation or general anesthesia:

Midazolam: • for an appointment 1 hour or less = 10 mg
• for an appointment longer than 1 hour = additional 5 mg per hour, up to a **cumulative maximum dose** of 20 mg for that appointment

Diazepam: • **cumulative maximum dose** not to exceed 20 mg for 1 appointment

6. Pre-operative instructions must be given in writing to the patient or responsible adult. Patients should be given instructions regarding the minimum duration of fasting prior to appointments that is consistent with the following minimum requirements:

- 8 hours after a meal that includes meat, fried or fatty foods;
- 6 hours after a light meal (such as toast and a clear fluid), or after ingestion of infant formula or nonhuman milk;
- 4 hours after ingestion of breast milk; and
- 2 hours after clear fluids (such as water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee, but NOT alcohol).

Possible exceptions to this are usual medications or pre-operative medications which may be taken as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their pre-operative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of eight hours, and that they may ingest clear fluids up until two hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

7. Written consent must be obtained prior to the administration of any parenteral sedative.

8. The patient must never be left unattended following administration of the sedative until fit for discharge.

9. Sedation and monitoring equipment must conform to current appropriate standards for functional safety.

10. A dentist qualified for this sedative technique and responsible for the patient must not leave the facility until that patient is fit for discharge.

THE SEDATION TEAM

Parenteral moderate sedation for ambulatory dental patients must be administered through the combined efforts of the sedation team. This team is composed of a minimum of 3 individuals, who must be in the operatory at all times during the administration of parenteral moderate sedation. There are 2 common formats of this team, as follows:

In one format, the sedation team includes, as a minimum:

- a dentist, who is qualified and responsible for the sedation and dental procedures
- a sedation assistant
- an operative assistant

In the other format, the sedation team includes, as a minimum:

- a dentist, who is responsible for the dental procedures only
- another dentist or a physician, who is qualified and responsible for the sedation procedures only
- an operative assistant

In addition to the dentist or physician who is qualified and responsible for the sedation procedures, the sedation team must include at least 1 individual who has successfully completed a provider course in ACLS and maintains current BLS certification (CPR Level HCP), as a minimum.

Sedation Team for Format 1:

The use of this sedation team allows a qualified dentist to provide sedation services simultaneously with dental procedures. The sedation team must consist of the following individuals:

The **dentist**, who is qualified and directly responsible for the sedation, the sedation team and the dental procedures.

The **sedation assistant**, who must be a nurse practitioner currently registered with the College of Nurses of Ontario, a registered nurse currently registered with the College of Nurses of Ontario, a respiratory therapist currently registered with the College of Respiratory Therapists of Ontario, or a dentist or physician currently registered in Ontario. In addition, the sedation assistant must provide evidence of successful completion of a provider course in ACLS and maintain current BLS certification (CPR Level HCP), as a minimum.

It is the responsibility of the dentist to ensure that the sedation assistant is adequately trained to perform their

duties. The dentist must ensure that this assistant has or develops the skills necessary for their responsibilities, as described below. This assistant's primary function is to provide assistance, under the direction of the dentist, by:

- assessing and maintaining a patent airway
- monitoring vital signs
- keeping appropriate records
- venipuncture
- administering medications as directed
- assisting in emergency procedures

The **operative assistant**, whose primary function is to keep the operative field free of blood, mucous and debris.

The **recovery supervisor**, who under the dentist's supervision has the primary function of supervising and monitoring patients in the recovery area, as well as determining, under the direction and responsibility of the dentist, if the patient meets the criteria for discharge, as outlined below. This person must have the same qualifications as described for the sedation assistant. **The sedation assistant may act as recovery supervisor if not required concurrently for other duties. One cannot perform both duties simultaneously.**

In addition, an **office assistant** should be available to attend to office duties, so the sedation team is not disturbed.

Sedation Team for Format 2:

The use of this sedation team requires a qualified dentist or physician to provide sedation services. The sedation team must consist of the following individuals:

- a **dentist**, who is responsible for the dental procedures only
- another **dentist or a physician**, who is qualified and responsible for the sedation procedures only
- an **operative assistant**, whose primary function is to keep the operative field free of blood, mucous and debris.

Where there is a separate dentist or physician solely providing the parenteral moderate sedation, then a sedation assistant or a recovery supervisor is not required, provided that this individual fulfills these duties. **This dentist or physician may act as a recovery supervisor if not required concurrently for other duties. One cannot perform both duties simultaneously.**

In addition, an **office assistant** should be available to attend to office duties, so the sedation team is not disturbed.

Dentists, who use the services of another dentist or a physician who is qualified to administer parenteral moderate sedation, share the responsibility of complying with the Standard. However, the ultimate responsibility rests with the facility permit holder to ensure that:

- the dentist or physician administering parenteral moderate sedation is authorized by or has approval from the RCDSO to do so;
- this dentist or physician has no term, condition or limitation on his or her certificate of registration with his or her respective regulatory College, relevant to the administration of sedation or general anesthesia; and
- all required emergency and other equipment is available and emergency drugs are on-site and current.

With the exception of oxygen, EITHER the facility permit holder OR the dentist / physician administering parenteral moderate sedation MUST provide all required emergency equipment and drugs. The shared provision of emergency equipment and drugs is NOT allowed.

OFFICE PROTOCOL AND FACILITIES

The facility must permit adequate access for emergency stretchers and have auxiliary powered backup for suction, lighting and monitors for use in the event of a power or system failure.

1. Patient Selection

An adequate, clearly recorded current medical history, including present and past illnesses, hospital admissions, current medications and dose, allergies (in particular to drugs), and a functional inquiry or review of systems (ROS), along with an appropriate physical examination must be completed for each patient and must form a permanent part of each patient's record. For medically compromised patients, consultation with their physician may be indicated. This assessment should be consistent in content with Appendix I.

The patient's ASA Classification (see Appendix II) and risk assessment must then be determined. These findings will be used to determine the appropriate facility and technique used.

2. Sedation Protocol

1. The medical history must be reviewed for any changes at each sedation appointment. Such review must be documented in the sedation record for the appointment.
2. The patient must have complied with the minimum duration of fasting prior to appointments that is consistent with the following minimum requirements:
 - 8 hours after a meal that includes meat, fried or fatty foods;
 - 6 hours after a light meal (such as toast and a clear fluid), or after ingestion of infant formula or nonhuman milk;
 - 4 hours after ingestion of breast milk; and
 - 2 hours after clear fluids (such as water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee, but NOT alcohol).

Possible exceptions to this are usual medications or pre-operative medications, which may be taken as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their pre-operative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of eight hours, and that they may ingest clear fluids up until two hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

3. Laboratory investigations may be used at the discretion of the dentist or physician responsible for the sedation procedures.
4. Clinical observation must be supplemented by the following means of monitoring throughout the sedation administration:
 - continuous pulse oximeter monitoring of oxyhemoglobin saturation, recorded at a minimum of 5 minute intervals;
 - blood pressure and pulse must be taken and recorded pre-operatively and throughout the sedation period at appropriate intervals, not greater than every 5 minutes;

- continuous observation of respiration, with rate recorded at a minimum of 15 minute intervals.

5. [A sedation record](#) must be kept consistent with Appendix IV.

6. When intravenous sedation is used, an intravenous needle or indwelling catheter must be *in situ* and patent at all times during the procedure. An intermittent or continuous fluid administration must be used to ensure patency.

7. Alarm settings and their audio component on monitoring equipment must be used at all times.

3. Recovery Protocol

1. As described below, recovery accommodation and supervision is **mandatory** when parenteral sedation is administered.

2. The recovery area or room must be used to accommodate the post-sedation patient from the completion of the procedure until the patient meets the criteria for discharge. Oxygen and appropriate suction and lighting must be readily available. The operatory can act as a recovery room.

3. A sufficient number of such recovery areas must be available to provide adequate recovery time for each case. Caseload must be governed accordingly.

4. Continuous supervision and appropriately recorded monitoring by the recovery supervisor must occur throughout the recovery period, until the patient meets the criteria for discharge. **The minimum ratio of recovery supervisors to patients is one to two.** Pulse oximeter monitoring of oxyhemoglobin saturation, blood pressure and heart rate must be recorded at a minimum of 15 minute intervals.

5. The patient may be discharged once he/she shows signs of progressively increasing alertness and has met the following criteria:

- conscious and oriented
- vital signs are stable
- ambulatory

6. The patient must be discharged to the care of a responsible adult.

7. Written post-sedation instructions must be given and explained to both the patient and accompanying adult. The patient must be instructed to not drive a vehicle, operate hazardous machinery or make important decisions. In addition, the patient must be cautioned about consuming alcohol and other drugs with sedative properties for a minimum of 18 hours, or longer if drowsiness or dizziness persists.

8. If a reversal agent is administered before discharge criteria have been met, the patient must be monitored beyond the expected duration of action of the reversal agent to guard against re-sedation, and a Tier Two Event must be reported to the RCDSO in writing.

9. Any Tier One or Tier Two Event must be reported to the RCDSO in writing.

4. Sedation Equipment

Emergency equipment and drugs must be available at all times. Drugs must be current and stored in readily identifiable and organized fashion (i.e. labelled trays or bags). All automated monitors must receive regular service and maintenance by qualified personnel according to the manufacturer's specifications or annually, whichever is more frequent. **A written record of this annual maintenance/ servicing must be kept on file for review by the RCDSO as required.**

Equipment that is used for continuous monitoring of sedated patients (including the immediate recovery phase) must have a Health Canada medical device license and be used in accordance with the manufacturer's 'intended use' (i.e. for continuous monitoring). All equipment must have audible alarms, appropriately set and NOT permanently silenced.

It is the dentist's responsibility to ensure that the dental office in which parenteral moderate sedation is being performed is equipped with the following:

- portable apparatus for intermittent positive pressure resuscitation
 - pulse oximeter with clearly audible variable pitch tone
 - stethoscope and sphygmomanometers of appropriate sizes
 - automated blood pressure monitor with programmable alarm settings and audio component
 - tonsil suction (Yankauer) adaptable to the suction outlet
 - full face masks of appropriate sizes and connectors
 - adequate selection of endotracheal tubes or laryngeal mask airways and appropriate connectors
 - laryngoscope with an adequate selection of blades, spare batteries and bulbs
 - Magill forceps
 - adequate selection of oral airways
 - portable auxiliary systems for light, suction and oxygen
 - apparatus for emergency tracheotomy or cricothyroid membrane puncture
 - defibrillator (either an automated external defibrillator [AED] or one with synchronous cardioversion capabilities)
 - intravenous indwelling catheters and needles
- current drugs in appropriate amounts for management of emergencies, including:
 - oxygen (an E-size cylinder is required)
 - epinephrine (at least 4 sources are required, such as 4 ampules 1:1000 epinephrine, 4 syringes 1:10,000 epinephrine or a combination of ampules and syringes)
 - nitroglycerin
 - parenteral diphenhydramine
 - salbutamol
 - parenteral vasopressor (e.g. ephedrine)
 - parenteral atropine
 - parenteral corticosteroid
 - flumazenil
 - appropriate intravenous fluids
 - acetylsalicylic acid (ASA, non-enteric coated)

Part II – Deep Sedation and General Anesthesia

DEFINITION

In addition to the General Standards, this section outlines standards specific to any technique that has depressed the patient beyond moderate sedation, as defined in Part I.

ADDITIONAL PROFESSIONAL RESPONSIBILITIES

In addition to the General Standards listed in Part I, the following responsibilities apply:

1. All dentists administering deep sedation or general anesthesia must have authorization from the RCDSO to do so. All physicians administering deep sedation or general anesthesia must have approval from the RCDSO to do so.
2. All facilities where deep sedation or general anesthesia is administered must have a permit from the RCDSO. Such permit will be granted subject to training and conformance with all aspects of the Standard and subject to satisfactory onsite inspections and evaluation by the RCDSO.
3. Deep sedation or general anesthesia must only be performed in the dental office by a professional qualified according to the following standards.
 - Dentists who hold a specialty certificate in Dental Anesthesiology in Ontario.
 - Dentists who have successfully completed a post-graduate anesthesia program in a university and/or teaching hospital over a minimum of 24 consecutive months. The program must have specifically evaluated and attested to the competency of the individual.
 - Dentists who had successfully completed a post-graduate anesthesia program in a university and/or teaching hospital over a minimum of 12 consecutive months prior to 1993 and have continued to practice these modalities since that time. The program must have specifically evaluated and attested to the competency of the individual.
 - Dentists who have successfully completed a formal post-graduate program in oral and maxillofacial surgery suitable for certification in the Province of Ontario.
- Physicians currently registered with the College of Physicians and Surgeons of Ontario (CPSO) who can provide evidence satisfactory to the RCDSO that they hold a designation as a specialist in anesthesia with the Royal College of Physicians and Surgeons of Canada (RCPSC) **OR** one of the following:
 - Completion of a 12-month rotation in a program accredited by the College of Family Physicians of Canada (CFPC) under the category of "Family Medicine Anesthesia".
 - Recognition by the CPSO as a specialist in anesthesia.
 - Satisfactory completion of all CPSO requirements for a physician requesting a change in their scope of practice **AND** active privileges to support similar procedures at a hospital.
4. All dentists and physicians administering deep sedation or general anesthesia must maintain current ACLS certification.
5. All dentists and physicians administering deep sedation or general anesthesia for patients under 12 years of age must be able to satisfy the RCDSO that they have appropriate training and experience to possess the knowledge, skills and judgment necessary for the care of such patients. In addition, current PALS certification is required.
6. When the operating dentist is not administering the anesthetic, they share the responsibility to ensure that these standards are followed.
7. All facilities where deep sedation or general anesthesia is administered must have written policies and procedures, including checklists for the management of emergencies. The facility's written policies and procedures must be reviewed with staff regularly, which must be documented.
8. Pre-operative instructions must be given in writing to the patient or responsible adult. Patients should be given instructions regarding the minimum duration of fasting prior to appointments that is consistent with the following minimum requirements:

- 8 hours after a meal that includes meat, fried or fatty foods;
- 6 hours after a light meal (such as toast and a clear fluid), or after ingestion of infant formula or nonhuman milk;
- 4 hours after ingestion of breast milk; and
- 2 hours after clear fluids (such as water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee, but NOT alcohol).

Possible exceptions to this are usual medications or pre-operative medications, which may be taken as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their pre-operative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of eight hours, and that they may ingest clear fluids up until two hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

9. Written consent must be obtained prior to the administration of any parenteral sedative or general anesthetic.

10. Anesthetic and monitoring equipment must conform to current appropriate standards for functional safety.

11. The patient must never be left unattended by a dentist or physician qualified for this sedative/anesthetic technique during the administration of the sedative or general anesthetic.

12. A dentist or physician qualified for this sedative/anesthetic technique and responsible for the patient must not leave the facility until that patient is fit for discharge.

THE ANESTHETIC TEAM

General anesthesia or deep sedation for ambulatory dental patients must be administered through the combined efforts of the anesthetic team. This team is composed of a minimum of 3 individuals, who must be in the operatory at all times during the administration of general anesthesia or deep sedation. There are 2 common formats of this team, as follows:

In one format, the anesthetic team includes, as a minimum:

- a dentist, who is qualified and responsible for the anesthesia and dental procedures
- an anesthetic assistant
- an operative assistant

In the other format, the anesthetic team includes, as a minimum:

- a dentist, who is responsible for the dental procedures only
- another dentist or a physician, who is qualified and responsible for the anesthesia procedures only
- an operative assistant

In addition, the anesthetic team must include at least 2 individuals with current ACLS certification and, if providing care for patients under 12 years of age, current PALS certification.

Anesthetic Team for Format 1:

The use of this anesthetic team allows a qualified dentist to provide anesthesia services simultaneously with dental procedures. The anesthetic team must consist of the following individuals:

The **dentist**, who is qualified and directly responsible for the anesthesia, the anesthetic team and the dental procedures.

The **anesthetic assistant**, who must be a nurse practitioner currently registered with the College of Nurses of Ontario, a registered nurse currently registered with the College of Nurses of Ontario, a respiratory therapist currently registered with the College of Respiratory Therapists of Ontario, or a dentist or physician currently registered in Ontario. In addition, the anesthetic assistant must maintain current ACLS certification and, if providing care for patients under 12 years of age, current PALS certification.

It is the responsibility of the dentist to ensure that the anesthetic assistant is adequately trained in peri-operative care (e.g. documented work experience in emergency care, ICU, PACU and/or the operating room environment or training to a similar level) and able to perform their duties. The dentist must ensure that this assistant has and further develops the skills necessary for their responsibilities, as described below. This assistant's primary function is to provide assistance, under the direction of the dentist, by:

- assessing and maintaining a patent airway
- monitoring vital signs
- keeping appropriate records
- venipuncture
- administering medications as directed
- assisting in emergency procedures

The **operative assistant**, whose primary function is to keep the operative field free of blood, mucous and debris.

The **recovery supervisor**, who under the dentist's supervision has the primary function of supervising and monitoring patients in the recovery area, as well as determining, under the direction and responsibility of the dentist, if the patient meets the criteria for discharge, as outlined below. This person must have the same qualifications as described for the anesthetic assistant. **The anesthetic assistant may act as recovery supervisor if not required concurrently for other duties. One cannot perform both duties simultaneously.**

In addition, an **office assistant** should be available to attend to office duties, so the anesthetic team is not disturbed.

IMPORTANT: Patients under 12 years of age have reduced physical reserves and impairment may occur rapidly. In particular, it can be difficult to diagnose hypoventilation and airway obstruction in a timely manner. The supervision of such a patient must be vigilant throughout the recovery period and utilize appropriate monitoring, including capnography. The recovery supervisor for such a patient must be adequately trained in peri-operative care, have both current ACLS certification and current PALS certification, and possess the knowledge, skills and judgment to recognize and respond to an emergency. Continuous supervision and appropriately recorded monitoring by the recovery supervisor must occur throughout the recovery period, until the patient meets the criteria for discharge.

Anesthetic Team for Format 2:

The use of this anesthetic team requires a qualified dentist or physician to provide anesthesia services. The anesthetic team must consist of the following individuals:

- a **dentist**, who is responsible for the dental procedures only
- another **dentist or a physician**, who is qualified and responsible for the anesthesia procedures only
- an **operative assistant**, whose primary function is to keep the operative field free of blood, mucous and debris.

Where there is a separate dentist or physician solely providing the deep sedation or general anesthetic, then an anesthetic assistant or a recovery supervisor is not required, provided that this individual fulfills these duties. **This dentist or physician may act as a recovery supervisor if not required concurrently for other duties. One cannot perform both duties simultaneously.**

In addition, an **office assistant** should be available to attend to office duties, so the anesthetic team is not disturbed.

Dentists, who use the services of another dentist or a physician who is qualified to administer deep sedation or general anesthesia, share the responsibility of complying with the Standard. However, the ultimate responsibility rests with the facility permit holder to ensure that:

- the dentist or physician administering deep sedation or general anesthesia is authorized by or has approval from the RCDSO to do so;
- this dentist or physician has no term, condition or limitation on their certificate of registration with their respective regulatory College, relevant to the administration of sedation or general anesthesia; and
- all required emergency and other equipment is available and emergency drugs are on-site and current.

With the exception of oxygen, EITHER the facility permit holder OR the dentist / physician administering deep sedation or general anesthesia MUST provide all required emergency equipment and drugs. The shared provision of emergency equipment and drugs is NOT allowed.

OFFICE PROTOCOL AND FACILITIES

The facility must permit adequate access for emergency stretchers and have auxiliary powered backup for suction, lighting and monitors for use in the event of a power or system failure.

1. Patient Selection

An adequate, clearly recorded current medical history, including present and past illnesses, hospital admissions, current medications and dose, allergies (in particular to drugs), and a functional inquiry or review of systems (ROS), along with an appropriate physical examination must be completed for each patient and must form a permanent part of each patient's record, prior to the administration of deep sedation or general anesthesia. For medically compromised patients, consultation with their physician may be indicated. This assessment should be consistent in content with Appendix I.

The patient's ASA Classification (see Appendix II) and risk assessment must be determined. These findings will be used to determine the appropriate facility and technique to be used.

2. Anesthesia Protocol

1. The medical history must be reviewed for any changes at each deep sedation or general anesthetic appointment. Such review must be documented in the anesthetic record for the appointment.
2. The patient must have complied with the minimum duration of fasting prior to appointments that is consistent with the following minimum requirements:
 - 8 hours after a meal that includes meat, fried or fatty foods;
 - 6 hours after a light meal (such as toast and a clear fluid), or after ingestion of infant formula or nonhuman milk;
 - 4 hours after ingestion of breast milk; and
 - 2 hours after clear fluids (such as water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee, but NOT alcohol).

Possible exceptions to this are usual medications or pre-operative medications, which may be taken as deemed necessary by the professional responsible for the administration of the sedation or general anesthetic.

To avoid confusion, some dentists may wish to simplify their pre-operative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of eight hours, and that they may ingest clear fluids up until two hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

3. Laboratory investigations may be used at the discretion of the dentist or physician responsible for the anesthesia procedures.
4. Clinical observation must be supplemented by the following means of monitoring performed at a minimum of 5 minute intervals throughout the deep sedation or general anesthetic administration and until the patient is no longer deeply sedated, including into recovery, if necessary:
 - continuous pulse oximeter monitoring of oxyhemoglobin saturation
 - blood pressure and pulse

- continuous observation of respiration
- continuous electrocardiogram monitoring
- continuous capnography monitoring
- if non-intubated, a pre-tracheal/pre-cordial stethoscope is also recommended
- if intubated or a laryngeal mask airway is used, monitoring by oxygen analyzer is required
- if a volatile inhalational anesthetic agent is used to maintain anesthesia (e.g. isoflurane, sevoflurane, desflurane), an anesthetic agent analyzer is required

5. If triggering agents for malignant hyperthermia are being used (volatile inhalational general anesthetics or succinylcholine), measurement of temperature and appropriate emergency drugs, as outlined below, must be readily available.

6. [An anesthetic record](#) must be kept consistent with Appendix VI.

7. An intravenous needle or indwelling catheter must be *in situ* and patent at all time during the procedure. An intermittent or continuous fluid administration must be used to ensure patency.

8. Alarm settings and their audio component on monitoring equipment must be used at all times.

3. Recovery Protocol

1. As described below, recovery accommodation and supervision is mandatory where deep sedation or general anesthesia is administered.
2. The recovery area or room must be used to accommodate the patient from the completion of the procedure until the patient meets the criteria for discharge. Oxygen and appropriate suction and lighting must be readily available. The operatory can act as a recovery room.
3. A sufficient number of such recovery areas must be available to provide adequate recovery time for each case. Caseload must be governed accordingly.
4. Continuous supervision and appropriately recorded monitoring by the recovery supervisor must occur throughout the recovery period, until the patient meets the criteria for discharge. In addition to continuous pulse oximetry, monitors must be immediately available for recovery use, including sphygmomanometer, electrocardiogram and capnograph. Requirements for monitoring during recovery are as follows:

RECOVERY PERIOD MONITORING

Patient meets criteria for deep sedation/general anesthesia

The minimum ratio of recovery supervisors to patients is one to one. Continuous pulse oximetry and capnography is required and must be recorded at a minimum of 5 minute intervals. In addition, blood pressure and heart rate must be recorded at a minimum of 5 minute intervals.

Patient meets criteria for moderate or minimal sedation

The minimum ratio of recovery supervisors to patients is one to two, provided both patients meet the criteria for moderate sedation or lighter. Pulse oximetry, blood pressure and heart rate must be recorded at a minimum of 15 minute intervals. Consideration should be given to continuous capnography for patients who are under 12 years of age, as well as patients who are obese or have a history of sleep apnea.

IMPORTANT: Patients under 12 years of age have reduced physical reserves and impairment may occur rapidly. In particular, it can be difficult to diagnose hypoventilation and airway obstruction in a timely manner. The supervision of such a patient must be vigilant throughout the recovery period and utilize appropriate monitoring, including capnography. The recovery supervisor for such a patient must be adequately trained in peri-operative care, have both current ACLS certification and current PALS certification, and possess the knowledge, skills and judgment to recognize and respond to an emergency. Continuous supervision and appropriately recorded monitoring by the recovery supervisor must occur throughout the recovery period, until the patient meets the criteria for discharge.

5. The patient may be discharged once he/she shows signs of progressively increasing alertness and has met the following criteria:

- conscious and oriented
- vital signs are stable
- ambulatory

6. The patient must be discharged to the care of a responsible adult.

For patients under 12 years of age, it is strongly recommended that the patient be discharged to the care of two responsible adults, so that one adult can focus on the patient during transport. Alternatively, the patient should not be discharged until the patient has demonstrated the ability to remain awake for at least 20 minutes in a quiet environment.

7. Written post-sedation/anesthetic instructions must be given and explained to both the patient and accompanying adult. The patient must be instructed to not drive a vehicle, operate hazardous machinery or make important decisions. In addition, the patient must be cautioned about consuming alcohol and other drugs with sedative properties for a minimum of 18 hours or longer if drowsiness or dizziness persists.

8. If a reversal agent is administered before discharge criteria have been met, the patient must be monitored beyond the expected duration of action of the reversal agent to guard against re-sedation, and a Tier Two Event must be reported to the RCDSO in writing.

9. Any Tier One or Tier Two Event must be reported to the RCDSO in writing.

4. Deep Sedation/General Anesthetic Equipment

Emergency equipment and drugs must be available at all times. Drugs must be current, in sufficient supply for caseload and stored in readily identifiable and organized fashion (i.e. labelled trays or bags). All anesthetic and monitoring equipment must receive regular service and

maintenance by qualified personnel according to the manufacturer's specifications, or annually, whichever is more frequent. **A written record of this annual maintenance/ servicing must be kept on file for review by the RCDSO as required.**

Equipment that is used for continuous monitoring of sedated or anesthetized patients (including the immediate recovery phase) must have a Health Canada medical device license and be used in accordance with the manufacturer's 'intended use' (i.e. for continuous monitoring). All equipment must have audible alarms, appropriately set and NOT permanently silenced.

1. Gas delivery systems used for the administration of nitrous oxide and oxygen must meet the following requirements:

- a nitrous oxide and oxygen gas delivery system that meets the requirements for such equipment as described in the previous section of this document under Minimal Sedation; **OR**
- a general anesthesia gas delivery system that has been approved by Health Canada and:
 - must be equipped with connectors and tubing which allow use of a full face mask for resuscitative ventilation with 100% oxygen;
 - must have readily available a reserve supply of oxygen ready for immediate use. This should be portable, an "E" size cylinder as a minimum and attached with appropriate regulator, flowmeter and connectors as described previously;
 - must be equipped with a scavenging system installed per manufacturer's specifications.

2. If a vaporizer is fitted to the gas delivery system, then:

- It must have an agent-specific, keyed filling device.
- The connection of the inlet and outlet ports of the vaporizer to the gas machine must be such that an inadvertent incorrect attachment cannot be made.
- All vaporizer control knobs must open counterclockwise and be marked to indicate vapour concentration in volume percent. It must mark and lock the control in the "off" position.

- The vaporizer must be connected to the scavenging system. Where multiple vaporizers are used, an Interlock System must be installed.
3. If the patient is intubated or a laryngeal mask airway is used, an oxygen analyzer is required.
4. If a volatile inhalational anesthetic agent is used to maintain anesthesia (e.g. isoflurane, sevoflurane, desflurane), an anesthetic agent analyzer is required.
5. It is the dentist's responsibility to ensure that the dental office in which deep sedation or general anesthesia is being performed is equipped with the following:
- portable apparatus for intermittent positive pressure resuscitation
 - pulse oximeter with clearly audible variable pitch tone
 - stethoscope and sphygmomanometers of appropriate sizes
 - automated blood pressure monitor with programmable alarm settings and audio component
 - tonsil suction (Yankauer) adaptable to the suction outlet
 - full face masks of appropriate sizes and connectors
 - adequate selection of laryngeal mask airways and appropriate connectors
 - adequate selection of endotracheal tubes and appropriate connectors
 - laryngoscope with an adequate selection of blades, spare batteries and bulbs
 - Magill forceps
 - adequate selection of oral airways
 - portable auxiliary systems for light, suction, and oxygen
 - apparatus for emergency tracheotomy or cricothyroid membrane puncture
 - electrocardiogram monitor with programmable alarm settings and audio component
 - defibrillator (either an automated external defibrillator [AED] or one with synchronous cardioversion capabilities)
 - capnometer/capnograph with programmable alarm settings and audio component
 - intravenous indwelling catheters and needles
- current drugs in appropriate amounts for management of emergencies, including:
 - oxygen (an E-size cylinder is required)
 - epinephrine (at least 4 sources are required, such as 4 ampules 1:1000 epinephrine, 4 syringes 1:10,000 epinephrine or a combination of ampules and syringes)
 - nitroglycerin
 - parenteral diphenhydramine
 - salbutamol
 - parenteral vasopressor (e.g. ephedrine)
 - parenteral atropine
 - parenteral corticosteroid
 - flumazenil
 - naloxone
 - appropriate intravenous fluids
 - parenteral muscle relaxant to support the management of laryngospasm
 - succinylcholine, if inhalation induction is used
 - parenteral amiodarone
 - parenteral beta-blocker
 - parenteral morphine or fentanyl
 - dantrolene, if triggering agents for malignant hyperthermia are being used (consistent with MHAUS guidelines)
 - insulin and D50W
 - acetylsalicylic acid (ASA, non-enteric coated)

APPENDIX I

Medical History and Patient Evaluation

An adequate, current, clearly recorded and signed medical history must be made for each patient. The history is part of the patient's permanent record. It forms a database upon which appropriate sedation or anesthetic modality is determined. The medical history must be kept current. This information may be organized in any format that each dentist prefers provided that the scope of the content contains the **minimum information described in this section**.

Vital Statistics

This includes the patient's full name, date of birth, weight in kilograms and the name of the person to be notified in the event of an emergency. In case of a minor or a mentally disadvantaged patient, the name of the parent or guardian must be recorded.

Core Medical History

The core medical history must fulfill the following two basic requirements:

- It must elicit the core medical information to enable the dentist to assign the correct ASA Classification (see Appendix II) in order to assess risk factors in relation to sedation or anesthetic choices.
- It must provide written evidence of a logical process of patient evaluation.

This core information should be a system-based review of the patient's past and current health status. It can be developed from the RCDSO's sample medical history questionnaire, supplemented with questions relevant to the use of sedation or general anesthesia (e.g. family history of adverse anesthetic outcomes, alcohol and other substance use, screening for sleep apnea).

Core Physical Examination

A current, basic physical examination, suitable for determining information that may be significant to sedation and anesthesia and appropriate to the modality being used, must be carried out for each patient. At a minimum, all modalities of sedation or general anesthesia require the evaluation and recording of significant positive findings related to:

- general appearance, noting obvious abnormalities;
- an appropriate airway assessment;
- the taking and recording of vital signs, i.e. heart rate and blood pressure.

This can be carried out by most general practitioners and specialists.

If a more in-depth physical examination is required involving:

- auscultation (cardiac or pulmonary)
- examination of other physiologic systems, or,
- other assessments

This examination **must be performed** by a physician or by a dentist who has received formal training in a post-graduate anesthesiology program or an oral and maxillofacial surgery program.

The core physical examination may include an order for and assessment of laboratory data if indicated.

APPENDIX II

American Society of Anesthesiology Physical Status Classification System

ASA I: A normal healthy patient

ASA II: A patient with mild systemic disease

ASA III: A patient with severe systemic disease that limits activity but is not incapacitating

ASA IV: A patient with incapacitating systemic disease that is a constant threat to life

ASA V: A moribund patient not expected to survive 24 hours with or without operation

ASA VI: A declared brain-dead patient whose organs are being removed for donor purposes

ASA E: Emergency operation of any variety; E precedes the number, indicating the patient's physical status

APPENDIX III

Characteristics of the Levels of Sedation and General Anesthesia

	MINIMAL SEDATION	MODERATE SEDATION	DEEP SEDATION	GENERAL ANESTHESIA
CONSCIOUSNESS	maintained	maintained	obtunded	unconscious
RESPONSIVENESS	to either verbal command or tactile stimulation	may require either one of or BOTH verbal command and tactile stimulation	response to repeated or painful stimuli	unarousable, even to pain
AIRWAY	maintained	no intervention required	intervention may be required	intervention usually required
PROTECTIVE REFLEXES	intact	intact	partial loss	assume absent
SPONTANEOUS VENTILATION	unaffected	adequate	may be inadequate	frequently inadequate
CARDIOVASCULAR FUNCTION	unaffected	usually maintained	usually maintained	may be impaired
REQUIRED MONITORING	basic	increased	advanced	advanced

APPENDIX IV

Sedation Record for Oral Moderate Sedation

A sedation record must contain the following information:

- patient's name, date of birth, weight in kilograms
- date of procedure
- review of medical history, including allergies and medications
- verification of NPO status
- verification of accompaniment for discharge
- pre-operative blood pressure, heart rate, oxygen saturation, respiration rate
- ASA status
- names of all drugs administered
- doses of all drugs administered
- time of administration of all drugs
- names and doses of all local anesthetics administered
- record of systolic and diastolic blood pressure, heart rate, oxygen saturation and respiration rate at a minimum of 15 minute intervals. If the monitors used provide an automated printout, this printout may be attached in lieu of handwritten recording of these signs
- record of level of sedation (LOS) at a minimum of 15 minute intervals
- time of the start and completion of the dental procedure
- recovery period must be clearly documented
- discharge criteria met: oriented, ambulatory, vital signs stable (record of blood pressure, heart rate, oxygen saturation)
- time that discharge criteria are met
- name and designation of the professional responsible for the case
- a notation of any Tier One or Tier Two Event

APPENDIX V

Sedation Record for Parenteral Moderate Sedation

An anesthetic/sedation record must contain the following information:

- patient's name, date of birth, weight in kilograms
- date of procedure
- review of medical history, including allergies and medications
- verification of NPO status
- verification of accompaniment for discharge
- pre-operative blood pressure, heart rate, oxygen saturation, respiration rate
- ASA status
- names of all drugs administered
- doses of all drugs administered
- time of administration of all drugs
- names and doses of all local anesthetics administered
- if used: intravenous type, location of venipuncture, type and volume of fluids administered
- list of monitors used
- record of systolic and diastolic blood pressure, heart rate and oxygen saturation at a minimum of 5 minute intervals. If the monitors used provide an automated printout, this printout may be attached in lieu of handwritten recording of these signs
- record of respiration rate at 15 minute intervals
- record of level of sedation (LOS) at a minimum of 5 minute intervals
- time of the start and completion of the administration of the sedation
- time of the start and completion of the dental procedure
- recovery period must be clearly documented
- discharge criteria met: oriented, ambulatory, vital signs stable (record of blood pressure, heart rate, oxygen saturation)
- time that discharge criteria are met
- names and designations of all members of the sedation team
- a notation of any Tier One or Tier Two Event

APPENDIX VI

Anesthetic Record for Deep Sedation or General Anesthesia

An anesthetic record must contain the following information:

- patient's name, date of birth, weight in kilograms
- date of procedure
- review of medical history, including allergies and medications
- verification of NPO status
- verification of accompaniment for discharge
- pre-operative blood pressure, heart rate, oxygen saturation, respiration rate
- ASA status
- names of all drugs administered
- doses of all drugs administered
- time of administration of all drugs
- names and doses of all local anesthetics administered
- if used: intravenous type, location of venipuncture, type and volume of fluids administered
- list of monitors used
- record of systolic and diastolic blood pressure, heart rate, oxygen saturation and end-tidal carbon dioxide levels (ETCO₂) at a minimum of 5 minute intervals. If the monitors used provide an automated printout, this printout may be attached in lieu of handwritten recording of these signs
- record of respiration rate at 15 minute intervals
- confirmation of continuous electrocardiogram monitoring
- if triggering agents for malignant hyperthermia are being used (volatile inhalational general anesthetics or succinylcholine), record of temperature at a minimum of 15 minute intervals
- time of the start and completion of the administration of the deep sedation/general anesthetic
- time of the start and completion of the dental procedure
- recovery period must be clearly documented
- discharge criteria met: oriented, ambulatory, vital signs stable (record of blood pressure, heart rate, oxygen saturation)
- time that discharge criteria are met
- names and designations of all members of the anesthetic team
- a notation of any Tier One or Tier Two Event

APPENDIX VII

Safe Handling of Injectable Drugs

The transmission of blood-borne viruses and other microbial pathogens to patients may occur due to unsafe and improper handling of injectables (e.g. local anesthetics, drugs and solutions for sedation).

The following practices should be adhered to when preparing and administering injectable drugs.

Aseptic Technique

- Perform hand hygiene prior to accessing supplies, handling vials and IV solutions, and preparing or administering drugs.
- Prepare drugs and supplies in a clean area on a clean surface.
- Use aseptic technique in all aspects of parenteral drug administration, drug vial use and injections. Limit access to select trained individuals, if possible.
- Never administer a drug from the same syringe to more than one patient, even if the needle is changed between patients.
- Never store needles and syringes unwrapped, as sterility cannot be assured.
- If an administration set is prepared ahead of time, all drugs should be drawn up as close to use as possible to prevent contamination. Once set up, an administration set should be covered.
- Do not use intravenous solution bags as a common source of supply for multiple patients.

Single Dose Vials

Single dose vials, intended for single patient use, typically lack preservatives. The use of these vials for multiple patients carries substantial risk for bacterial contamination and infection.

- Do not reuse single dose vials.
- Always use a sterile syringe and needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been used on a patient.
- Never combine or pool the leftover contents of single dose vials.

Multi-dose Vials

Any error in following protocols for the correct use of multi-dose vials can result in the transmission of both bacterial and blood-borne viral pathogens. Transmission of HBV, HCV and HIV has been associated with the use of multi-dose vials.

The use of multi-dose vials for injectable drugs increases the risk of transmission of blood-borne pathogens and bacterial contamination of the vial **and should be avoided**. Patient safety should be prioritized over cost when choosing between multi-dose and single dose vials.

If multi-dose vials are used, the following practices must be followed each time the multi-dose vial is used:

- NEVER re-enter a vial with a used needle OR used syringe.
- Once medication is drawn up, the needle should be IMMEDIATELY withdrawn from the vial. A needle should NEVER be left in a vial to be attached to a new syringe.
- Use a multi-dose vial for a single patient whenever possible and mark the vial with the patient's name.
- Mark the multi-dose vial with the date it was first used and ensure that it is discarded at the appropriate time.
- Adhere to aseptic technique when accessing multi-dose vials. Multi-dose vials should be accessed on a surface that is clean and where no dirty, used or potentially contaminated equipment is placed or stored. Scrub the access diaphragm of vials using friction and 70% alcohol. Allow to dry before inserting a new needle and new syringe into the vial.
- Discard the multi-dose vial immediately if sterility is questioned or compromised or if the vial is not marked with the patient's name and original entry date.
- Review the product leaflet for recommended duration of use after entry of the multi-dose vial. Discard opened multi-dose vials according to the manufacturer's instructions or within 28 days, whichever is shorter.

The use of multi-dose vials increases the risk of transmission of blood-borne pathogens and bacterial contamination. Single dose vials are ALWAYS preferred.

APPENDIX VIII

Sample Pre- / Post-Operative Instructions for Oral Minimal Sedation

Pre-Operative Instructions:

1. You will not be able to drive home. You must be accompanied by a responsible adult, and may travel by private vehicle or taxi.
2. Do not eat or drink for 2 hours prior to your appointment.
3. Take all regular medications at their usual time with sips of water, unless you have been instructed otherwise by your dentist or physician.
4. Wear loose comfortable clothing. Do not wear nail polish.
5. Report any health changes prior to your appointment.

Post-Operative Instructions

1. After your appointment, you must not operate a motor vehicle or hazardous machinery for at least 18 hours. You may be drowsy for the remainder of the day and should not consume alcohol and other drugs with sedative properties or make important decisions.
2. Depending on your dental treatment, you may need to modify your diet. This will be reviewed with you prior to leaving the office.
3. If you have any concerns following the appointment, contact the office for advice.

APPENDIX IX

Sample Pre- / Post-Operative Instructions for Oral Moderate Sedation, Parenteral Moderate Sedation, Deep Sedation and General Anesthesia

Pre-Operative Instructions:

1. You will not be able to drive home. You must be accompanied by a responsible adult, and may travel by private vehicle or taxi.
2. Do not eat for 8 hours prior to your appointment. Clear fluids may be taken up to 2 hours before the appointment. This includes water, clear juice and black coffee or tea (no dairy). For afternoon appointments, a light meal may be consumed 6 hours prior to the appointment.
3. Take all regular medications at their usual time with sips of water, unless you have been instructed otherwise by your dentist or physician.
4. Wear loose comfortable clothing. Do not wear nail polish.
5. Report any health changes prior to your appointment.

Post-Operative Instructions

1. After your appointment, you must not operate a motor vehicle or hazardous machinery for at least 18 hours. You may be drowsy for the remainder of the day and should not consume alcohol and other drugs with sedative properties or make important decisions.
2. Depending on your dental treatment, you may need to modify your diet. This will be reviewed with you prior to leaving the office.
3. If you have any concerns following the appointment, contact the office for advice.



Royal College of
Dental Surgeons of Ontario

6 Crescent Road
Toronto, ON Canada M4W 1T1
T: 416.961.6555 F: 416.961.5814
Toll Free: 800.565.4591 www.rcdso.org