

# Provincial Dental Board of Nova Scotia

## STANDARD OF PRACTICE

Use of Sedation and General Anesthesia in Dental Practice
January 31, 2020



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### Introduction

The Standards of Practice of the Provincial Dental Board of Nova Scotia describe the minimum requirements that all dentists must meet in an area of clinical practice to maintain patient safety. On a regular basis, the PDBNS 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 patients. This Standard is important because it literally concerns matters of life or death.

Sedation is a continuum ranging from minimal (i.e., the relief of anxiety) up to and including a state of unconsciousness (i.e., general anesthesia). The method of sedation is less important than the outcome. The American Dental Association (ADA) guide (see Table 1) will be used to classify levels of sedation.

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 PDBNS requires that a properly trained sedation 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 always be in the operatory when general anesthesia, deep sedation or parenteral moderate sedation is administered. Concerns for patient safety are always the 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 challenges when receiving sedation or general anesthesia. Children under 12 years of age — especially under 3 years of age — require even more diligent monitoring because they have reduced physical reserves and impairment may occur rapidly. It can be difficult to diagnose hypoventilation and airway obstruction quickly.

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

The Standard on the Use of Sedation and General Anesthesia in Dental Practice sets enhanced requirements and higher standards throughout. The PDBNS 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 PDBNS operates an 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 PDBNS is 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.

## Sedation and General Anesthesia in Dental Practice

#### Sedation or general anesthesia may be indicated to:

- 1 treat patients with fear or anxiety associated with dental treatment
- 2 enable treatment for patients who have cognitive impairment or motor dysfunction that prevents adequate dental treatment
- 3 treat patients below the age of reason
- 4 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.

#### **Levels of Sedation**

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. 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

- Nitrous oxide and oxygen sedation
- Oral administration of a sedative drug with or without nitrous oxide and oxygen sedation

#### Moderate sedation

- Oral moderate sedation with or without nitrous oxide and oxygen
- Parenteral administration of a sedative drug (intravenous, intramuscular, subcutaneous, submucosal or intranasal)

#### Deep sedation

General anesthesia

#### 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.

#### 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.



Table 1: Characteristics of the Levels of Sedation and General Anesthesia - American Dental Association (ADA) Guide

	MINIMAL SEDATION	MODERATE SEDATION	DEEP SEDATION	GENERAL ANESTHESIA
CONSCIOUSNESS	maintained	maintained	obtunded	unconscious
RESPONSIVENESS	to <b>either</b> verbal command <b>or</b> tactile stimulation	may require either one of or both verbal command and tactile stimulation	response to repeated painful stimuli	unarousable, even to pain
AIRWAY	no intervention required	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

### General Standards for All Modalities of Sedation or General Anesthesia

#### **Professional Responsibilites**

- 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, 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. This should be documented in the patient's chart. These findings will be used as a guide in determining the appropriate facility and technique used.
- 6 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) are not 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 practitioner with a higher level of training and qualifications.
- 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 12 years of age are not acceptable for the administration of oral sedation with 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 Nova Scotia.
- 9 Patients who are under 3 years of age 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 general anesthesia.
- 10 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.

- a) 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.
  - **b)** All dentists and clinical staff providing minimal and/or oral moderate sedation must, as a minimum, maintain current BLS certification (CPR Level HCP).
  - c) Dental offices are encouraged to be equipped with an automated external defibrillator (AED).
  - d) All dentists providing moderate sedation, using any modality, to patients under 12 years of age must also maintain current Pediatric Advanced Life Support (PALS) certification or current Pediatric Emergency Assessment, Recognition and Stabilization (PEARS) certification.
  - e) All dentists providing parenteral moderate sedation, deep sedation and/or general anesthesia must also maintain current Advanced Cardiac Life Support (ACLS) certification.
  - **f)** Dentists should establish written protocols for emergency procedures and review them with their staff regularly.

Table 2 outlines the 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.

Table 2: Basic Drugs for Medical Emergencies

DRUG	IG INDICATION INITIAL ADULT DOSE		RECOMMENDED CHILD DOSE
OXYGEN*	Most medical emergencies	100% inhalation	100% inhalation
	Anaphylaxis	0.3–0.5 mg i.m./Sublingual or 0.01–0.1 mg i.v.	0.01 mg/kg
EPINEPHRINE	Bronchospasm that 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
NITROGLYGERINE	Angina pectoris	o.3 mg or o.4 mg Sublingual	Not indicated
DIPHENHYDRAMINE	Allergic reactions	50 mg i.m./Sublingual or i.v.	1 puff
SALBUTAMOL INHALATION AEROSOL	Bronchospasm	2 puffs (100 micrograms/puff)	may be inadequate
ASA (NON-ENTERIC COATED)	Acute myocardial infarction	160-325 mg	Not indicated

<sup>\*</sup> 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 resuscitate ventilation.

<sup>12</sup> All dentists who are licensed to provide sedation and/or general anesthesia must be able to satisfy the PDBNS 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 requirements outlined in Table 3.

FOR MINIMAL SEDATION USING NITROUS OXIDE	<ul> <li>a minimum of 5 cases must be performed per year and</li> <li>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</li> </ul>
FOR ORAL MODERATE SEDATION	<ul> <li>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</li> <li>a minimum of 5 cases** must be performed per year 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</li> </ul>
FOR PARENTERAL MODERATE SEDATION	<ul> <li>a minimum of 12 hours of continuing education (or 12 CE points) related to parenteral moderate sedation must be performed per 3-year period* and</li> <li>a minimum of 20 cases must be performed per year</li> </ul>
FOR DEEP SEDATION AND/OR GENERAL ANESTHESIA	<ul> <li>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</li> <li>a minimum of 24 cases must be performed per year and</li> <li>if patients under 12 years of age are treated, a minimum of 24 cases involving patients under 12 years of age must be performed per year</li> </ul>

For the purposes of fulfilling this requirement, courses in the management of medical emergencies and courses to acquire or maintain life-support certification (BLS, ACLS, PALS and PEARS) are accepted. Medical anesthesiologists are exempt from this requirement.

**13** All dentists providing sedation or general anesthesia must monitor and report any serious adverse event (Tier One Event) or another incident (Tier Two Event) to the PDBNS, as described in Table 4.

Table 4: Adverse Events

TIER ONE EVENTS: Serious adverse events must be reported to the PDBNS in writing within 24 hours of knowledge of the event.	<ul> <li>Death of a patient within the facility.</li> <li>Death of a patient within 10 days of a procedure performed at the facility.</li> <li>Transfer of a patient from the facility directly to the hospital for care.</li> </ul>
TIER TWO EVENTS: Other incidents must be reported to the PDBNS within 10 days of knowledge of the event.	<ul> <li>Unscheduled treatment of a patient in a hospital within 10 days of a procedure performed with sedation or general anesthesia</li> <li>Any use of a benzodiazepine or opioid antagonist.</li> <li>Any serious cardiac or respiratory adverse event requiring administration of a medication for its management.</li> </ul>

<sup>\*\*</sup> 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.

#### **Drug Storage and Dispensing**

Dentists using sedative and/or general anesthesia 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 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.

Dentists or their staff must not 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**

#### MINIMAL AND MODERATE SEDATION

#### Professional Responsibilities for 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:

- 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:
  - a) Dalhousie University Faculty of Dentistry undergraduate and post- graduate programs
  - b) Other Faculties of Dentistry undergraduate and postgraduate programs, approved by the PDBNS
  - c) Dalhousie Faculty of Dentistry continuing education programs
  - d) Other continuing education courses approved by the PDBNS 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.
- 2 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 sedation 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. If oral sedation is used with nitrous oxide and oxygen appropriate doses of the oral sedative drug must be used and nitrous oxide and oxygen appropriately titrated to achieve mild or moderate sedation.
- 3 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.
- 4 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.

#### MINIMAL SEDATION

- NITROUS OXIDE AND OXYGEN SEDATION
- ORAL ADMINISTRATION OF A SEDATIVE DRUG WITH OR WITHOUT NITROUS OXIDE AND OXYGEN SEDATION

Practitioners intending to produce a given level of sedation must be able to diagnose and manage the physiological consequences 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.

#### **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 PDBNS to do so.
- 2 All facilities where nitrous oxide and oxygen sedation is administered are subject to random onsite inspections and evaluation by the PDBNS.
- **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 PDBNS 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, 2 oxygen cylinders must always be connected to the system.
  - 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 Table 2: Basic Drugs for Medical Emergencies. This must be included in the emergency kit of every dental office.
- 5 Consent must be obtained prior to the administration of nitrous oxide and oxygen sedation, which should be documented.

- 6 Patients should be given instructions not to eat or drink for 2 hours prior to their appointment.
- 7 Patients must be monitored by an appropriately trained dentist, or an appropriately trained nurse practitioner, registered nurse or respiratory therapist acting under the order of a dentist. There must be direct and continuous clinical observation for level of consciousness and assessment of vital signs, which must include heart rate, blood pressure, Sp02 and respiration preoperatively, intraoperatively and postoperatively, as necessary. The patient must never be left unattended during administration.
- 8 The practitioner must not be alone while treating a sedated patient. Recovery status postoperatively 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.
- 9 Records of the sedation procedure must be kept that, as a minimum, include the following information:
  - a) preoperative review of the patient's medical history for any changes;
  - **b)** preoperative blood pressure, pulse, respiratory rate and oxygen saturation;
  - c) total flow of nitrous oxide and oxygen;
  - d) percentage and duration of administration of nitrous oxide; e. duration of administration of 100% oxygen at the end of the sedation procedure; and f. notation regarding the patient's tolerance of the sedation procedure.
- 10 Continuous monitoring with pulse oximetry is mandatory for patients when nitrous is used. The pulse oximeter 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.

## Oral administration of a sedative drug with or without nitrous oxide and oxygen sedation

In addition to the General Standards and professional responsibilities listed previously, the following professional responsibilities apply to the oral administration of a single sedative drug (which includes the sublingual route of administration) with or without nitrous oxide and oxygen for minimal sedation.

#### **Additional Professional Responsibilities**

- 1 All dentists administering minimal sedation with nitrous oxide and oxygen must have authorization from the PDBNS to do so.
- 2 All facilities where oral minimal sedation is administered are subject to random onsite inspections and evaluation by the PDBNS.
- 3 Patients who are under 12 years of age are not acceptable for the administration of oral sedation with nitrous oxide and oxygen, except by those practitioners who are qualified to administer deep sedation or general anesthesia and by those practicitioners who have completed a formal post-graduate program in pediatric dentistry suitable for certification in the province of Nova Scotia.
- 4 For the administration of oral minimal sedation for patients under 3 years of age OR under 15 kilograms, the following training is required:
  - a) dentists who qualify for the administration of deep sedation and general anesthesia; OR
  - b) dentists who have successfully completed a formal post- graduate program in pediatric dentistry suitable for certification in the Province of Nova Scotia, incorporating adequate training in sedation, such that the individual competence has been specifically evaluated and attested.
- 5 Patients who are under 2 years of age are not acceptable for the administration of oral sedation with nitrous oxide and oxygen, except by those practitioners who are qualified to administer general anesthesia.
- 6 Oral administration of a single sedative drug with or without nitrous oxide and oxygen, 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.

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

- 7 A dose of an oral sedative used to induce minimal sedation should be administered to the patient in the dental office, considering the time required for oral absorption. There are 2 rare situations in which the patient may need to take an oral sedative prior to the 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 of the PDBNS. In addition to the requirements in paragraph 6 above, the following additional requirements apply in these 2 situations:
  - a) 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.
  - b) If a prescription sedative drug is required, only a benzodiazepine may be prescribed.
  - c) The dose of the benzodiazepine must not exceed the maximum dose for minimal sedation.
  - d) The patient must be instructed not to drive a vehicle and must be accompanied to and from the dental office by a responsible adult.
  - e) 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.

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 mandatory for these patients. The pulse oximeter 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 and clearly audible alarms, appropriately set and NOT permanently silenced.

- 8 Patients should be given instructions not to eat or drink for 2 hours prior to their appointment.
  - Consent must be obtained prior to the administration of any oral sedative, which should be documented.
- 9 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.
- 10 The patient may be discharged once they show signs of progressively increasing alertness and has met the following criteria:
  - a) conscious and oriented
  - b) stable vital signs
  - c) ambulatory
- 11 The patient must be discharged to the care of a respon sible adult.
- 12 The patient must be instructed to not drive a vehicle, op erate hazardous machinery or make important decisions. In addition, the patient must be cautioned about consum ing alcohol and other drugs with sedative properties for a minimum of 18 hours or longer if drowsiness or dizzi ness persists.
- 13 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 PDBNS in writing.

- **14** Records of the sedation procedure must include the following information:
  - a) preoperative review of the patient's medical history for any changes;
  - b) verification of accompaniment for discharge;
  - c) preoperative blood pressure and pulse;
  - d) name and dose of the oral sedative administered;
  - e) time of administration of the oral sedative;
  - f) time that discharge criteria are met; and
  - **g)** notation regarding the patient's tolerance of the sedation procedure.
- **15** The practitioner must not be alone while treating a se dated patient.
- 16 Any Tier One or Tier Two Event must be reported to the PDBNS in writing.
- 17 Emergency equipment and drugs must always be available. 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:
  - a) full face masks of appropriate sizes and connectors
  - **b)** 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
    - acetylsalicylic acid (ASA, non-enteric coated)

#### **MODERATE SEDATION**

It is assumed that this will be accomplished by either:

- 1 ORAL MODERATE SEDATION WITH OR WITHOUT NITROUS OXIDE AND OXYGEN
- 2 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 PDBNS.

Practitioners intending to produce a given level of sedation must be able to diagnose and manage the physiological consequences 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.

Should the administration of any drug produce sedation beyond the intended level, the dental procedures should be stopped. Appropriate support must be administered until the intended level of sedation is regained.

#### Oral Moderate Sedation With or Without Nitrous Oxide and Oxygen

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 facilities where oral moderate sedation with or without nitrous oxide and oxygen is administered must have a permit from the PDBNS. 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 PDBNS.
- 2 The following training is required:
  - a) Dentists who qualify for the administration of deep sedation and general anesthesia,
    OR
  - b) Dentists who qualify for the administration of parenteral moderate sedation, as outlined later in this document, OR
  - c) 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

- d) 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.
- 3 Oral administration of a single sedative drug, specifically a benzodiazepine, is a prudent approach to moderate sedation.
- 4 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.

- 5 For the administration of oral moderate sedation with or without nitrous oxide and oxygen for patients under 12 years of age, the following training is required:
  - a) Dentists who qualify for the administration of deep sedation and general anesthesia, as outlined in Part II of this document; OR
  - b) Dentists who have successfully completed a formal post- graduate program in pediatric dentistry suitable for certification in the province of Nova Scotia, incorporating adequate training in sedation such that the individual competence has been specifically evaluated and attested.
- 6 Patients who are under 3 years of age 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 general anesthesia.
- 7 All dentists administering oral moderate sedation for patients under 12 years of age must be able to satisfy the PDBNS 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.
- 8 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.
  - 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 have qualified practitioners come into their office to provide sedation to patients share the responsibility of complying with the Standard. However, the ultimate responsibility rests with the facility permit holder to ensure that:

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

All required emergency equipment and drugs must be present within the facility while patients are being treated under sedation.

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

#### 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**

- a) 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.
- **b)** 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 non-human milk, and
  - 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 preoperative medications as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their preoperative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of 8 hours and that they may ingest clear fluids up until 2 hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

- c) Consent must be obtained prior to the administration of any oral sedative, which should be documented.
- d) A dose of an oral sedative used to induce moderate sedation should be administered to the patient in the dental office, considering the time required for drug absorption.
- e) There are 2 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. This dose should not exceed the minimal dose. 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 PDBNS. The following additional requirements apply in these 2 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 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 2 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.
- f) 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 preoperatively 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.
- g) A sedation record must be kept that includes the recording of vital signs as listed above.
- h) Alarm settings and their audio component on monitoring equipment must always be used.

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.

- i) The patient may be discharged to the care of a responsible adult once they show signs of progressively increasing alertness and have met the following criteria:
  - conscious and oriented
  - vital signs are stable
  - ambulatory
- j) 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.
- k) 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 PDBNS in writing.
- 1) The practitioner must not be alone while treating a sedated patient.
- m) Any Tier One or Tier Two Event must be reported to the PDBNS in writing.

#### **3 SEDATION EQUIPMENT**

Emergency equipment and drugs must always be available. 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 PDBNS 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:

- a) portable apparatus for intermittent positive pressure ventilation
- b) pulse oximeter with clearly audible, variable pitch tone
- c) stethoscope and sphygmomanometers of appropriate sizes
- d) full face masks of appropriate sizes and connectors
- e) portable auxiliary systems for light, suction and oxygen
- f) 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)

## Parenteral administration of a sedative drug (intravenous, intramuscular, subcutaneous, submucosal or intranasal)

Parenteral moderate sedation may be accomplished using any one of the following routes of administration: intravenous, intramuscular, subcutaneous, submucosal, intranasal or rectal. 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 PDBNS.
- 2 All facilities where parenteral moderate sedation is administered must have a permit from the PDBNS. 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 PDBNS.
- **3** The following training is required:
  - **a)** Dentists who qualify for the administration of deep sedation and general anesthesia.
  - **b)** 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 PDBNS 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 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 PDBNS, may be given credit for this didactic requirement if documentation of formal training is obtained from the dentist/physician responsible for providing the training.

**Clinical Requirement**: The training must include supervised application of parenteral moderate seda-

- tion concurrent with dental treatment, performed on a minimum of 20 individually managed patients. For patients under 12 years of age, the training must include supervised application of parenteral moderate sedation concurrent with dental treatment performed on a minimum of 25 individually managed patients under 12 years of age. 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) 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 2 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:

- a) Qualifies for the administration of deep sedation or general anesthesia, as outlined in Part II or this document; OR
- b) Additional professional responsibilities:
  - the sedation team must meet the same requirements as for deep sedation or general anesthesia;
  - 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 PDBNS. The following requirements apply in these two situations:

- a) 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.
- b) The patient must be instructed not to drive a vehicle and must be accompanied to and from the dental office.
- c) In each case, clear written instructions must be given to the patient or guardian explaining how to take the medication, where appropriate; 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.

- d) 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.
- e) For nitrous oxide and oxygen, once the intravenous line is established and BEFORE the first administration of the parenteral sedative, the nitrous oxide must be discontinued.
- f) 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.
- **g)** Written consent must be obtained prior to the administration of any parenteral sedative.
- h) The patient must never be left unattended following administration of the sedative until fit for discharge.
- Sedation and monitoring equipment must conform to current appropriate standards for functional safety.
- j) 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 always be in the operatory during the administration of parenteral moderate sedation.

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 must be:

- a) A dentist currently registered with the Provincial Dental Board of Nova Scotia (PDBNS) who is qualified and responsible for the sedation procedures only;
- b) A physician currently registered with the College of Physicians and Surgeons of Nova Scotia (CPSNS) who is qualified and responsible for the sedation procedures only;
- c) A nurse practitioner (NP) currently registered with the Nova Scotia College of Nursing (NSCN) who is qualified and responsible for the sedation procedures only acting under the direction of a dentist or a physician currently registered in Nova Scotia;
- d) A registered nurse (RN) currently registered with the Nova Scotia College of Nursing (NSCN) acting under the order of a dentist or a physician currently registered in Nova Scotia to administer sedation;
- e) A respiratory therapist (RT) currently registered with the Nova Scotia College of Respiratory Therapists (NSCRT) who is qualified and acting under the required order and the direct control and supervision of a dentist or a physician currently registered in Nova Scotia;

f) A paramedic currently registered with the College of Paramedics of Nova Scotia (CPNS) who is qualified and acting under the required order and the direct control and supervision of a dentist or a physician currently registered in Nova Scotia.

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 the skills necessary for their responsibilities as described below. The sedation 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.

An additional staff member should be available to attend to office duties so the sedation team is not disturbed.

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.

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

- a) this dentist or physician is qualified and 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
- b) all required emergency and other equipment is available and emergency drugs are on site and current.

#### 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**

a) 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.

- **b)** 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 non-human 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 preoperative medications as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their preoperative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of 8 hours, and that they may ingest clear fluids up until 2 hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

- c) Laboratory investigations may be used at the discretion of the dentist or physician responsible for the sedation procedures.
- d) 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 preoperatively and throughout the sedation period at appropriate intervals, not greater than every 5 minutes;
  - continuous capnography
- e) A sedation record must be kept consistent with Appendix III.
- f) 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.
- g) Alarm settings and their audio component on monitoring equipment must be used all the time.

#### **3 RECOVERY PROTOCOL**

- a) As described below, recovery accommodation and supervision is mandatory when parenteral sedation is administered.
- b) 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.
- c) A sufficient number of such recovery areas must be available to provide adequate recovery time for each case. Caseload must be governed accordingly.
- d) 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 1 to 2. Pulse oximeter monitoring of oxyhemoglobin saturation, blood pressure and heart rate must be recorded at a minimum of 15-minute intervals.
- **e)** The patient may be discharged to the care of a responsible adult once they show signs of progressively increasing alertness and have met the following criteria:
  - · conscious and oriented
  - vital signs are stable
  - ambulatory

- f) 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 for a minimum of 18 hours. The patient must also be cautioned about consuming alcohol and other drugs with sedative properties for a minimum of 18 hours or longer if drowsiness or dizziness persists.
- g) 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 PDBNS 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 PDBNS 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:

- a) portable apparatus for intermittent positive pressure ventilation
- **b)** pulse oximeter with clearly audible variable pitch tone
- c) stethoscope and sphygmomanometers of appropriate sizes
- automated blood pressure monitor with programmable alarm settings and audio component
- e) tonsil suction (Yankauer) adaptable to the suction outlet
- f) full face masks of appropriate sizes and connectors
- g) adequate selection of endotracheal tubes or laryngeal mask airways and appropriate connectors
- h) laryngoscope with an adequate selection of blades, spare batteries and bulbs
- i) Magill forceps

- j) adequate selection of oral airways and nasopharyngeal airways
- k) portable auxiliary systems for light, suction and oxygen
- I) apparatus for emergency tracheotomy or cricothyroid membrane puncture
- m) defibrillator (either an automated external defibrillator [AED] or one with synchronous cardioversion capabilities)
- n) intravenous indwelling catheters and needles
- o) capnography
- p) 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 1:1,000 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
  - acetylsalicylic acid (ASA, non-enteric coated

#### **DEEP SEDATION AND GENERAL ANESTHESIA**

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

#### **Additional Professional Responsibilities**

In addition to the General Standards listed previously, the following responsibilities apply:

- 1 All dentists administering deep sedation must have authorization from the PDBNS.
- 2 All facilities where deep sedation or general anesthesia is administered must have a permit from the PDBNS. 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 PDBNS.
- 3 Deep sedation must only be performed in the dental office by a professional qualified according to the following standards.
  - a) Dentists who have successfully completed a formal post- graduate program in oral and maxillofacial surgery suitable for certification in the Province of Nova Scotia.
  - b) Dentists who have successfully completed a postgraduate 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.
  - c) Physicians currently registered with the College of Physicians and Surgeons of Nova Scotia who can provide evidence satisfactory to the PDBNS that they hold a designation as a specialist in anesthesia with the Royal College of Physicians and Surgeons of Canada (RCPSC).
- 4 General Anesthesia must only be performed in the dental office by a Physician currently registered with the College of Physicians and Surgeons of Nova Scotia who can provide evidence satisfactory to the PDBNS that they hold a designation as a specialist in anesthesia with the Royal College of Physicians and Surgeons of Canada (RCPSC).
- 5 All dentists and physicians administering deep sedation or general anesthesia must maintain current ACLS certification.
- 6 All dentists and physicians administering deep sedation or general anesthesia for patients under 12 years of age must be able to satisfy the PDNS 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.
- 7 When the operating dentist is not administering the anesthetic, they share the responsibility to ensure that these standards are followed.
- 8 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.
- 9 Preoperative 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:
  - a) 8 hours after a meal that includes meat, fried or fatty foods;
  - b) 6 hours after a light meal (such as toast and a clear fluid), or after ingestion of infant formula or nonhuman milk;
  - c) 4 hours after ingestion of breast milk; and
  - d) 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 preoperative medications, which may be taken as deemed necessary by the dentist.

To avoid confusion, some dentists may wish to simplify their preoperative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of 8 hours, and that they may ingest clear fluids up until 2 hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

- 10 Written consent must be obtained prior to the administration of any parenteral sedative or general anesthetic.
- 11 Anesthetic and monitoring equipment must conform to current appropriate standards for functional safety.
- **12** 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.
- 13 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 Sedation Team

Deep sedation and general anesthesia 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. The team formats for these 2 levels of sedation are as follows:

- 1 The anesthetic team for deep sedation includes, as a minimum:
  - a) a dentist who is qualified and responsible for the anesthesia and dental procedures
  - b) a sedation assistant
  - c) 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.

The sedation assistant must be:

- a) A dentist currently registered with the Provincial Dental Board of Nova Scotia (PDBNS) who is qualified and responsible for the sedation procedures only
- b) A physician currently registered with the College of Physicians and Surgeons of Nova Scotia (CPSNS) who is qualified and responsible for the sedation procedures only;
- c) A nurse practitioner (NP) currently registered with the Nova Scotia College of Nursing (NSCN) who is qualified and responsible for the sedation procedures only acting under the direction of a dentist or a physician currently registered in Nova Scotia;
- d) A registered nurse (RN) currently registered with the Nova Scotia College of Nursing (NSCN) acting under the order of a dentist or a physician currently registered in Nova Scotia to administer sedation;

- e) A respiratory therapist (RT) currently registered with the Nova Scotia College of Respiratory Therapists (NSCRT) who is qualified and acting under the required order and the direct control and supervision of a dentist or a physician currently registered in Nova Scotia;
- f) A paramedic currently registered with the College of Paramedics of Nova Scotia (CPNS) who is qualified and acting under the required order and the direct control and supervision of a dentist or a physician currently registered in Nova Scotia.

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 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 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:

- a) assessing and maintaining a patent airway
- b) monitoring vital signs
- c) keeping appropriate records
- d) venipuncture
- e) administering medications as directed
- f) 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.

An additional staff member should be available to attend to office duties so that the sedation team is not disturbed.

Important: Patients under 12 years of age have reduced physical reserves and impairment may occur rapidly. 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.

- 2 The anesthetic team for general anesthesia includes, as a minimum:
  - a) a dentist, who is responsible for the dental procedures only
  - b) an anesthesiologist who is currently registered with the College of Physicians and Surgeons of Nova Scotia (CPSNS) as an anesthesiologist and whom is responsible for the anesthetic only
  - c) an operative assistant

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

An additional staff member should be available to attend to office duties so that the sedation team is not disturbed.

Dentists who have a qualified practitioner administer deep sedation or general anesthesia in their office share the responsibility of complying with the Standard. However, the ultimate responsibility rests with the facility permit holder to ensure that:

- a) the dentist or physician administering deep sedation or general anesthesia is authorized by or has approval from the PDBNS to do so
- b) 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
- c) all required emergency and other equipment is available and emergency drugs are on site and current.

The dentist/physician administering the deep sedation/anesthetic MUST ensure all the required emergency equipment and drugs are present within the facility during the procedure.

#### 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 (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**

- a) 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.
- b) The patient must have complied with the minimum duration of fasting prior to appointments.

Possible exceptions to this are usual medications or preoperative 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 preoperative instructions to patients regarding fasting requirements. For example, patients might be instructed not to have any solid food for a minimum of 8 hours, and that they may ingest clear fluids up until 2 hours before the appointment. Such instructions would be consistent with the minimum fasting requirements.

- c) Laboratory investigations may be used at the discretion of the dentist or physician responsible for the anesthesia procedures.
- d) Clinical observation must be supplemented by the following monitoring methods. These must be 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. The monitoring methods are: continuous pulse oximeter monitoring of oxyhemoglobin saturation
  - blood pressure and pulse
  - continuous observation of respiration
  - continuous electrocardiogram monitoring
  - continuous capnography monitoring
  - 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
- e) 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.
- f) An anesthetic record must be kept consistent with Appendix IV.
- g) 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.
- h) Alarm settings and their audio component on monitoring equipment must be used at all times.

#### **3 RECOVERY PROTOCOL**

- a) As described below, recovery accommodation and supervision is mandatory where deep sedation or general anesthesia is administered.
- b) 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.
- **c)** A sufficient number of such recovery areas must be available to provide adequate recovery time for each case. Caseload must be governed accordingly.
- d) 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 recovery period monitoring are in Table 5.

Table 5: Recovery Period Monitoring

Patient meets criteria for DEEP SEDATION or GENERAL ANESTHESIA.	<ul> <li>The minimum ratio of recovery supervisors to patients is 1:1.</li> <li>Continuous pulse oximetry is required and must be recorded at a minimum of 5-minute intervals.</li> <li>In addition, blood pressure and heart rate must be recorded at a minimum of 5-minute intervals.</li> </ul>
Patient meets criteria for MODERATE SEDATION or MINIMAL SEDATION.	<ul> <li>The minimum ratio of recovery supervisors to patients is 1:2, provided both patients meet the criteria for moderate sedation or lighter.</li> <li>Pulse oximetry, blood pressure and heart rate must be recorded at a minimum of 15 minute intervals.</li> <li>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.</li> </ul>

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.

- e) The patient may be discharged to the care of a responsible adult once they show signs of progressively increasing alertness and has met the following criteria:
  - · conscious and oriented
  - stable vital signs
  - ambulatory
- f) 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 for a minimum of 18 hours. The patient must also be cautioned about consuming alcohol and other drugs with sedative properties for a minimum of 18 hours or longer if drowsiness or dizziness persists.

- g) 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.
- h) A Tier Two Event must be reported to the PDBNS in writing.

IMPORTANT: For patients under 12 years of age, it is strongly recommended that the patient be discharged to the care of 2 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.

#### 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 PDBNS as required.

IMPORTANT: 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) 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
  - b) a general anesthesia gas delivery system that has been approved by Health Canada; and
  - c) must be equipped with connectors and tubing which allow use of a full face mask for resuscitative ventilation with 100% oxygen;
  - d) 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;
  - e) must be equipped with a scavenging system installed per manufacturer's specifications.
- 2 If a vaporizer is fitted to the gas delivery system, then:
  - a) it must have an agent-specific, keyed filling device.
  - b) 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.
  - c) 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.
  - d) 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:
  - a) portable apparatus for intermittent positive pressure resuscitation
  - b) pulse oximeter with clearly audible variable pitch tone
  - c) stethoscope and sphygmomanometers of appropriate sizes
  - d) automated blood pressure monitor with programmable alarm settings and audio component
  - e) tonsil suction (Yankauer) adaptable to the suction outlet
  - f) full face masks of appropriate sizes and connectors
  - g) adequate selection of laryngeal mask airways and appropriate connectors
  - adequate selection of endotracheal tubes and appropriate connectors
  - i) laryngoscope with an adequate selection of blades, spare batteries and bulbs
  - j) Magill forceps
  - k) adequate selection of oral airways and nasopharyngeal airways
  - portable auxiliary systems for light, suction, and oxygen
  - **m)** apparatus for emergency tracheotomy or cricothyroid membrane puncture
  - n) electrocardiogram monitor with programmable alarm settings and audio component
  - o) defibrillator (either an automated external defibrillator [AED] or one with synchronous cardioversion capabilities)
  - p) capnometer/capnograph with programmable alarm settings and audio component

- q) intravenous indwelling catheters and needles
- r) 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
- s) appropriate intravenous fluids
- t) parenteral muscle relaxant to support the management of laryngospasm
- u) succinylcholine, if inhalation induction is used
- v) parenteral amiodarone
- w) parenteral beta-blocker
- x) parenteral morphine or fentanyl
- y) dantrolene, if triggering agents for malignant hyperthermia are being used (consistent with MHAUS guidelines)
- z) insulin and D50W
- aa) 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 2 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 PDBNS'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; and
- the taking and recording of vital signs (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**

#### SEDATION RECORD FOR ORAL MODERATE SEDATION

A sedation record must contain the following information:

- 1 Patient's name, date of birth, weight in kilograms
- 2 Date of procedure
- 3 Review of medical history, including allergies and medications
- 4 Verification of NPO status
- 5 Verification of accompaniment for discharge
- 6 Preoperative blood pressure, heart rate, oxygen saturation, respiration rate
- 7 ASA status
- 8 Names and doses of all drugs administered
- 9 Time of administration of all drugs
- 10 Names and doses of all local anesthetics administered
- 11 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
- 12 Record of level of sedation (LOS) at a minimum of 15-minute intervals
- 13 Time of the start and completion of the dental procedure
- 14 Recovery period must be clearly documented
- 15 Discharge criteria met: oriented, ambulatory, vital signs stable (record of blood pressure, heart rate, oxygen saturation)
- 16 Time that discharge criteria are met
- 17 Name and designation of the professional responsible for the case
- 18 A notation of any Tier One of Tier Two Event

## **Appendix IV**

#### SEDATION RECORD FOR PARENTERAL MODERATE SEDATION

An anesthetic/sedation record must contain the following information:

- 1 Patient's name, date of birth, weight in kilograms
- 2 Date of procedure
- 3 Review of medical history, including allergies and medications
- 4 Verification of NPO status
- 5 Verification of accompaniment for discharge
- 6 Preoperative blood pressure, heart rate, oxygen saturation, respiration rate
- 7 ASA status
- 8 Names and doses of all drugs administered
- 9 Time of administration of all drugs
- 10 Names and doses of all local anesthetics administered, if used: intravenous type, location of venipuncture, type and volume of fluids administered
- 11 List of monitors used
- 12 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
- 13 Record of respiration rate at 15-minute intervals
- 14 Record of level of sedation (LOS) at a minimum of 5-minute intervals
- 15 Time of the start and completion of the administration of the sedation
- 16 Time of the start and completion of the dental procedure
- 17 Recovery period must be clearly documented
- 18 Discharge criteria met: oriented, ambulatory, vital signs stable (record of blood pressure, heart rate, oxygen saturation)
- 19 Time that discharge criteria are met
- 20 Names and designations of all members of the sedation team
- 21 A notation of any Tier One or Tier Two Event

## **Appendix V**

#### ANESTHETIC RECORD FOR DEEP SEDATION OR GENERAL ANESTHESIA

An anesthetic record must contain the following information:

- 1 Patient's name, date of birth, weight in kilograms
- 2 Date of procedure
- 3 Review of medical history, including allergies and medications
- 4 Verification of NPO status
- 5 Verification of accompaniment for discharge
- 6 Preoperative blood pressure, heart rate, oxygen saturation, respiration rate
- 7 ASA status
- 8 Names and doses of all drugs administered
- 9 Time of administration of all drugs
- 10 Names and doses of all local anesthetics administered
- 11 If used: intravenous type, location of venipuncture, type and volume of fluids administered
- 12 List of monitors used
- 13 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
- 14 Record of respiration rate at 15-minute intervals
- 15 Confirmation of continuous electrocardiogram monitoring
- 16 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
- 17 Time of the start and completion of the administration of the deep sedation/general anesthetic
- 18 Time of the start and completion of the dental procedure 1
- 19 Recovery period must be clearly documented
- 20 Discharge criteria met: oriented, ambulatory, vital signs stable (record of blood pressure, heart rate, oxygen saturation)
- 21 Time that discharge criteria are met
- 22 Names and designations of all members of the anesthetic team
- 23 A notation of any Tier One or Tier Two Event

## **Appendix VI**

#### 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.
- **2** Prepare drugs and supplies in a clean area on a clean surface.
- 3 Use aseptic technique in all aspects of parenteral drug administration, drug vial use and injections. Limit access to select trained individuals, if possible.
- 4 Never administer a drug from the same syringe to more than one patient, even if the needle is changed between patients.
- 5 Never store needles and syringes unwrapped, as sterility cannot be assured.
- 6 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.
- **7** 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.

- 1 Do not reuse single-dose vials.
- 2 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.
- **3** Never combine or pool the leftover contents of single-dose vials.

#### **Multi-Dose Vials**

Any error in following protocols for the correct use of multidose 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:

- 1 NEVER re-enter a vial with a used needle OR used syringe.
- **2** 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.
- **3** Use a multi-dose vial for a single patient whenever possible and mark the vial with the patient's name.
- 4 Mark the multi-dose vial with the date it was first used and ensure that it is discarded at the appropriate time.
- 5 Adhere to aseptic technique when accessing multidose 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.
- 6 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.
- 7 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.

## **Appendix VII**

#### SAMPLE PRE- / POSTOPERATIVE INSTRUCTIONS FOR ORAL MINIMAL SEDATION

#### **Preoperative 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.

#### **Postoperative 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 VIII**

#### SAMPLE PRE- / POSTOPERATIVE INSTRUCTIONS FOR ORAL MODERATE SEDATION

#### **Deep Sedation and General Anesthesia Preoperative 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.

#### **Postoperative 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.

The Provincial Dental Board of Nova Scotia kindly acknowledges the Royal College of Dental Surgeons of Ontario for allowing the use of their resource material in the creation of this Standard. The Provincial Dental Board of Nova Scotia also acknowledges the contributions of the Review Committee.