

College of Chiropodists of Ontario



Standard of Practice for the Administration of Inhaled Substances and the Use of Sedation in a Member's Practice*

INTRODUCTION

This document represents the **minimum** standards of practice for the administration of inhaled substances and the use of sedation in a member's practice.¹ Since contravention of this standard may be considered professional misconduct, a member utilizing any type of sedative agent(s) and/or sedation modality(ies) must adhere to this standard, be appropriately trained, and regulate his or her practice accordingly, to comply with this standard of practice, the *Chiropody Act, 1991*, its regulations, and the by-laws of the College of Chiropodists of Ontario ("**College**").

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* This standard must be read in conjunction with Ontario Regulation 203/94, made under the *Chiropody Act, 1991*, and the College's by-laws in relation to the administration of inhaled substances and the use of sedation in a member's practice.

¹ Where the term "member" is used in this standard, it means a member of the College of Chiropodists of Ontario, unless another meaning is clearly intended.

DEFINITIONS OF SEDATION LEVELS

*****REGARDLESS OF WHICH SEDATION MODALITY OR COMBINATION OF SEDATION MODALITIES IS EMPLOYED, A MEMBER MUST LIMIT THE DEPTH OF SEDATION TO *MINIMAL SEDATION*, AS DEFINED BELOW.*****

- **Minimal Sedation**

- Minimally depressed level of consciousness. With modalities aimed at producing minimal sedation, the patient responds normally to tactile stimulation and verbal commands. Although cognitive function and coordination may be modestly impaired, ventilator and cardiovascular functions are unaffected.
- Minimal sedation is usually accomplished by the use of one of the following modalities:
 1. Administration of nitrous oxide and oxygen.
 2. Oral administration of a single sedative drug.
 3. Oral administration of a single sedative drug with nitrous oxide and oxygen.

- **Conscious Sedation**

- Conscious sedation is a minimally to moderately depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal commands. It is produced by a pharmacological or non-pharmacological method or a combination thereof.
- Conscious sedation may be further divided into **minimal sedation** and **moderate sedation** as defined by the Characteristics of the Levels of Sedation and General Anesthesia (see **Appendix I**).

- **Moderate Sedation**

- Moderately depressed level of consciousness. With modalities aimed at producing moderate sedation, the patient responds 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.
- Moderate sedation is usually accomplished by the use of one of the following modalities:
 1. Oral administration of multiple sedative drugs, with or without nitrous oxide and oxygen.
 2. Parenteral administration of a sedative drug(s) (intravenous, intramuscular, subcutaneous, sub-mucosal, or intranasal).

- **Deep Sedation**

- A controlled state of depressed consciousness, accompanied by partial loss of protective reflexes, including inability to respond purposefully to verbal command.

- **General Anaesthesia**

- A controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes including inability to maintain an airway independently and respond purposefully to physical stimulation or verbal command.

It must be emphasized that the various levels of sedation and general anaesthesia are produced along a continuum, ranging from the relief of anxiety with little or no associated drowsiness (i.e. low level minimal sedation), up to and including a state of unconsciousness (i.e. general anaesthesia). 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-points of the various levels of conscious sedation (i.e. minimal sedation versus moderate sedation) and the starting points of deep sedation and general anaesthesia. Therefore, the agents and modalities used for conscious sedation must be used judiciously and carry a margin of safety wide enough to render unwanted loss of consciousness highly unlikely.

In a member's practice, sedation modalities targeting various levels of minimal sedation may be used to reinforce positive suggestion and reassurance in a way which allows treatment to be performed with minimal physiological and psychological stress, and enhanced physical comfort. However, members inducing sedation must be able to diagnose and manage the physiological consequences of sedation as well as be able to rescue patients whose level of sedation becomes deeper than initially intended. Members must have the training, skills, drugs, and equipment to identify and manage such an occurrence until either the patient returns to the intended level of sedation without airway or cardiovascular complications or assistance arrives (e.g. emergency medical service).

PART 1 – ADMINISTRATION OF OXYGEN

When used alone oxygen is not considered a sedative agent. While the administration of oxygen is most commonly associated with the management of emergency situations (resuscitation, anaphylaxis, syncope, shock, convulsions, etc.), the decision to administer oxygen may also be made in non-emergent situations and is highly dependent on the varied and specific needs of each patient. Therefore, the decision to administer oxygen to a patient in a practice setting is dictated by the specific circumstances surrounding that patient and is at the discretion of the member. So too, are the specific levels of oxygen concentration and flow deemed appropriate in each specific case with the goal of maintaining or re-establishing a patient's normal physiologic oxygen saturation levels (94–98% in most patients, or 88–92% in chronic obstructive pulmonary disease patients).

PART 2 – GENERAL STANDARDS FOR ALL MODALITIES OF SEDATION

Sedation may be indicated to:

- Treat patient anxiety and pain associated with treatment.
- Enable treatment for patients who have cognitive impairment or motor dysfunction which prevents adequate treatment.
- Treat patients below the age of reason.
- Treat traumatic conditions.
- Treat patient anxiety and pain during invasive and/or prolonged treatment or procedures.

Sedation is to be used only when indicated, as an adjunct to appropriate non-pharmacological means of patient management. It is the responsibility of the member to determine which patients are suitable candidates for the various sedative modalities and agents.

A member wishing to administer sedation must, of course, have informed consent to do so and ensure the requirements related to the following are met: I. The Sedation Team, II. Member's Qualifications, III. Office Protocol and Facilities, and IV. Sedation Protocol (Applicable to All Modalities).

I. THE SEDATION TEAM

Due to the inherent difficulties in safely providing foot care while simultaneously administering nitrous oxide and oxygen sedation, **there must be a minimum of two individuals present during the administration of nitrous oxide and oxygen, whether or not the modality being used involves the concurrent use of an oral sedative drug.**²

A member inducing sedation must recognize he or she cannot adequately and responsibly monitor the patient while treating the feet and therefore must have the assistance of another person.

Individual One:

The first individual focuses principally on the foot care needs of the patient and must be a member currently registered with the College who is authorized by the College to administer the specific sedation agent or modality.³

Individual Two:

The second individual administers the sedation on the order of the member and must be continually monitoring the patient with regard to the sedation. This individual is able to dedicate his or her full attention to the sedation needs of the patient and also immediately attend to any issues arising from the sedation.

² Please note that this standard of practice has not been designed for the circumstance where a member arranges for a physician to provide sedation as the member tends to the foot care needs of the patient.

³ Individual One would not be required to be authorized by the College to administer sedation where Individual Two was a member currently registered with the College who is authorized by the College to administer sedation.

Only the following persons (“**Authorized Sedation Monitors**”) may assist a member where the member intends to induce sedation for a patient⁴:

- Another member currently registered with the College and authorized by the College to administer the specific sedation agent or modality;
- A nurse currently registered with the College of Nurses of Ontario in the general class in the RN category acting under the required order and the direct control and supervision of a member currently registered with the College and authorized by the College to administer the specific sedation agent or modality;
- A nurse currently registered with the College of Nurses of Ontario in the general class in the RPN category, who has obtained a two-year diploma in Practical Nursing from a Community College of Applied Arts or completed an enhanced medication course in the administration and monitoring of minimal sedation, acting under the required order and the direct control and supervision of a member currently registered with the College and authorized by the College to administer the specific sedation agent or modality.

It is of course also incumbent on the member to ensure the Authorized Sedation Monitor is competent to perform the tasks being assigned to him or her.

II. MEMBER’S QUALIFICATIONS

In order for a member to administer sedation, the member is required to meet the following requirements:

1. Successful completion of a sedation training program, approved by the College, designed to produce competency in the specific modality or modalities of sedation utilized.⁵
2. Successful completion of a comprehensive pharmacologic training program, approved by the College, designed to produce competency in general clinical pharmacological principles and overall systems pharmacology, and meet the requirements needed to prescribe the relevant sedative and emergency drugs as set forth in the current regulations or as may otherwise be required for appropriate patient care.
3. Successful completion of the College’s Inhaled Substances and Sedation Examination.
4. Obtain an Inhalation and Sedation Certificate from the College (for details, see the College’s by-laws in relation to the administration of inhaled substances and the use of sedation in a member’s practice).

⁴ Please note that this standard of practice has not been designed for the circumstance where a member arranges for a physician to provide sedation as the member tends to the foot care needs of the patient.

⁵ This program will include: indications, contraindications, patient evaluation, patient selection, pharmacology of relevant drugs, administration of sedation agents and modalities, and management of potential adverse reactions, as they relate to the relevant sedation agents and modalities.

5. Maintain competence by including ongoing training, courses, and/or other educational programs related to these modalities in professional continuing education planning.
6. Ensure that a member's clinical staff (which includes Authorized Sedation Monitors) are prepared to recognize and treat adverse responses using appropriate emergency equipment and appropriate drugs, when necessary. A member will be required to establish written protocols for emergency procedures and review them with staff regularly.

A written record of this must be kept on file and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

7. Ensure that a member's clinical staff (which includes Authorized Sedation Monitors) have the training and ability to perform basic life support (BLS) techniques. A member providing sedation must maintain current BLS certification (CPR Level HCP – CPR Level for Health Care Providers) as a minimum.⁶

III. OFFICE PROTOCOL AND FACILITIES

1. Before a member treats a patient who is to be sedated, the member must ensure that the member's office has present all of the sedation equipment and emergency drugs and equipment needed to meet the requirements of this standard of practice.
2. The following table outlines the basic drugs that must be included in the emergency kit immediately available, where a member is treating a patient who is to be sedated.

<p>Mandatory Emergency Agents for Facilities in Which a Member Administers One or More Sedation Modalities</p>

Generic Agent	Proprietary Agent	Indications	Initial Adult Dose	Pediatric Dose
Oxygen	Oxygen	Most medical emergencies	100% inhalation	100% inhalation
Epinephrine 1:1000 Solution	Adrenalin	Anaphylaxis	0.1 mg IV or 0.3-0.5 mg IM	0.01 mg/kg (total pediatric dose not to exceed adult dose of 0.3 mg/kg)
		Asthmatic bronchospasm unresponsive to salbutamol/albuterol	0.1 mg IV or 0.3-0.5 mg IM	0.01 mg/kg (total pediatric dose not to exceed adult dose of 0.3 mg/kg)
		Cardiac arrest	1 mg IV	0.01 mg/kg (total

⁶ It is strongly recommended that all members, whether or not intending to induce sedation, maintain current BLS certification (CPR Level HCP – CPR Level for Health Care Providers).

				pediatric dose not to exceed adult dose of 0.3 mg/kg)
Diphenhydramine	Benadryl	Allergic reactions	50 mg IV or IM	1 mg/kg (total pediatric dose not to exceed adult dose of 50 mg)
Nitroglycerin	Nitrostat Nitromist	Angina pectoris	0.3 or 0.4 mg sublingual tablet or metered spray	No pediatric dose
Salbutamol (<i>Int</i>) Albuterol (<i>US</i>)	Ventolin Proventil	Asthmatic bronchospasm	2 puffs (100 micrograms per puff)	1 puff (100 micrograms per puff)
Acetylsalicylic acid (Aspirin)	Many	Acute myocardial infarction	325 mg non-enteric coated tablet to be chewed	Not indicated
Hydrocortisone	Many	Allergic reactions and/or adrenal insufficiency crisis	Hydrocortisone 100 mg or equivalent dose IM or IV	Hydrocortisone 1-5 mg/kg
Glucose Tablets	Dex4 Glucose Tablets	Hypoglycemic event (conscious patient)	1-2 tablets chewed prn in conscious patient	1-2 tablets chewed prn in conscious patient
Aromatic ammonia or other respiratory stimulant	Aromatic ammonia or other respiratory stimulant	Syncope episode	Inhaled as needed	Inhaled as needed
Midazolam	Versed	Seizures/convulsions	5 mg IM	0.1-0.25 mg/kg IM (not to exceed adult dose of 5 mg)
Naloxone	Narcan	Opioid antagonism for opioid overdose	0.4-2 mg IV (may repeat every 2-3 minutes prn)	0.01-0.1 mg/kg IV or IM (may repeat every minute, not to exceed 2 mg/dose)
Flumazenil	Romazicon	Benzodiazepine antagonism for benzodiazepine overdose	0.2 mg IV infused over 30 seconds; may repeat with additional doses of 0.5 mg over 30 seconds at 1 minute intervals; not to exceed a total cumulative dose of 3 mg	0.01 mg/kg IV infused over 15 seconds (not to exceed 0.2 mg/dose); may repeat every minute; not to exceed total cumulative dose of 0.05 mg/kg or 1 mg (whichever is lower)

3. A member utilizing sedative agents in his or her practice must take reasonable precautions to prevent the unauthorized use of these substances for recreational or other improper purposes, by office staff and other individuals with access to the office and equipment. To do this, preventative strategies must include the following:

- Maintaining an inventory (written log) of all sedative agents including narcotics, other controlled drugs and substances, and nitrous oxide acquired by the practice. This log must record the procurement of these substances, including specific

substance acquired, supplier, date, and name of individual confirming receipt of substance, and total amount of substance acquired.

This log must be kept on file and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

- Keeping all sedative agents in a locked storage cupboard.
- Keeping a log that accurately accounts for the use in the practice of all narcotics, other controlled drugs and substances, and nitrous oxide. This log must record the specific utilization of these substances, including specific substance utilized, date and total amount of substance utilized with correlating patient identifier, and name of individual who administered the substance.

This log must be kept on file and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

- Keeping careful control of blank prescription pads and never pre-signing prescription blanks.
- Using 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 office and clinical staff to assist with wellness issues. The dates and length of the training sessions should be recorded so that the member can establish that this training has been done, if requested by the College.

4. Before a member treats a patient who is to be sedated, the member must ensure that the facility in which these modalities are utilized 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 as well as to provide for the safe evacuation of patients, in case of an emergency.
5. Before a member treats a patient who is to be sedated, the member must ensure that the office in which these modalities are utilized is suitably staffed and equipped for the specific modality or modalities being utilized, as required in this standard.

IV. SEDATION PROTOCOL (APPLICABLE TO ALL MODALITIES)

1. Informed consent must be obtained from a patient, or his or her legal guardian, and must be documented in the patient's record, prior to the administration of any oral sedative drug and/or nitrous oxide and oxygen.
2. An adequate, clearly recorded, current medical history, including present and past illnesses, hospital admissions, current medications and/or non-prescription drugs and/or herbal supplements, as well as dose, allergies (in particular to drugs), and a functional inquiry, along with an appropriate physical examination must be completed for each patient prior to the administration of any form of sedation. For medically compromised patients, consultation with their primary healthcare practitioner may be indicated. This must form a permanent part of each patient's record, consistent in content with **Appendix II.**

Additionally, the medical history must be reviewed for any changes at each appointment at which sedation is to be utilized and it must be documented in the permanent record of the patient. This medical history will assist the member in determining whether the patient is a suitable candidate for in-office use of a particular sedation modality or agent.

3. A determination of the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (see **Appendix III**), as well as careful evaluation of any other factors which may affect the patient's suitability for a sedation modality or modalities must be made prior to administration of the modality or modalities.

This ASA status must be documented in the permanent record. This ASA status will assist the member in determining whether the patient is a suitable candidate for in-office use of a particular sedation modality or agent.

4. Patients who are determined to be ASA IV and higher (as per **Appendix III**) are not considered acceptable candidates for the administration of any sedation modality outside of a hospital facility. The administration of oxygen is permissible to these patients at the member's discretion.
5. A member must at all times be vigilant not to exceed minimal sedation levels (see **Definitions of Sedation Levels**). Single agent choice in a carefully considered dose is a prudent approach to achieving this level of sedation.
6. Should the administration of any modality produce depression beyond that of minimal sedation level, the treatment or procedure must be halted and appropriate support procedures administered until the level of depression is no longer beyond that of minimal sedation, or if necessary, until additional emergency assistance is available.
7. A member must take into account the maximum dose of local anaesthetic that may be safely administered, especially for children, the elderly, and the medically compromised. Whenever sedation is used, the calculated maximum dose of local anaesthetic may need to be further adjusted to provide a greater margin of safety.
8. In order to avoid allegations of sexual or other impropriety, the Authorized Sedation Monitor, in the case of sedation involving the use of nitrous oxide and oxygen, or another person must be present in the treatment room at all times whenever the patient is sedated.
9. Minimal sedation techniques require the patient to be discharged to the care of a responsible adult. The only situation in which a member may exercise discretion as to whether a patient may be discharged unaccompanied is that in which nitrous oxide and oxygen sedation **alone** is the modality used. Regardless of the modality used to induce sedation, all patients must be specifically assessed for fitness for discharge by the member responsible for the administration of the sedation.

PART 3 - SPECIFIC STANDARDS FOR PARTICULAR MODALITIES

The member must adhere to the College's standard of practice where providing sedation to a patient using any modality including:

- the administration of nitrous oxide and oxygen alone;
- the oral administration of a single sedative drug; and
- the oral administration of a single sedative drug in combination with the administration of nitrous oxide and oxygen.

*****REGARDLESS OF WHICH SEDATION MODALITY OR COMBINATION OF SEDATION MODALITIES IS EMPLOYED, A MEMBER MUST LIMIT THE DEPTH OF SEDATION TO *MINIMAL SEDATION*, AS DEFINED IN THIS STANDARD.*****

The member must adhere to the professional responsibilities of initial and ongoing member authorization by the College in conjunction with the requirements specific to the modality the member wishes to administer. The requirements for each modality are set out below.

A. ADMINISTRATION OF NITROUS OXIDE AND OXYGEN

In addition to the requirements listed in **Part 2**, the following standard of practice applies when nitrous oxide and oxygen sedation are being used to induce sedation.

USE OF AN AUTHORIZED SEDATION MONITOR

Nitrous oxide and oxygen sedation **must** be administered by an Authorized Sedation Monitor, as defined in **Part 2**. In the case of a nurse, the member performing the treatment must be present at all times in the office suite and **immediately** available in the event of an emergency.

GAS DELIVERY SYSTEM REQUIREMENTS

1. **Must** have a fail-safe mechanism such that it will not deliver an oxygen concentration of less than 30% in the delivered gas mixture.
2. **Must** have pipeline inlet fittings, or pin-indexing, that do not permit interchange of connections with oxygen and nitrous oxide.
3. **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 and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

4. **Must** be equipped with a common gas outlet compatible with 15mm male and 22mm female conical connectors.
5. **Must** have readily available a reserve supply of oxygen ready for immediate use. This must be a portable "E" size cylinder attached with an appropriate oxygen regulator and flowmeter, as well as connectors, tubing, and a reservoir bag which allows the use of a full face mask for positive pressure resuscitative ventilation with 100% oxygen.
6. **Must** be used with only single use disposable masks with scavenging capabilities to prevent nosocomial cross contamination between patients and allow for the evacuated gas being exhaled by the patient.
7. **Must** be equipped with a properly functioning scavenging system installed per manufacturer's specifications. Such a system must include an accurate flowmeter, scavenging masks, and a vacuum system able to eliminate gases at a rate of at least **45 L per minute**. These gases must be vented to the outside.

8. **Must** allow for the sterilization (or for single patient use) of all components which come into contact with a patient's body fluids and exhaled gases. The manufacturer's instructions must be consulted and followed regarding the appropriate sterilization of sedation equipment.

EMERGENCY EQUIPMENT AND DRUG REQUIREMENTS

1. Emergency equipment and drugs must be available at all times. Drugs must be current (not expired) and stored in a readily identifiable and organized fashion (i.e. labelled trays or bags). It is the member's responsibility to ensure that the office in which sedation is being performed is equipped with the following:
 - Pulse oximeter
 - Sphygmomanometers and stethoscopes of appropriate sizes
 - Full face masks of appropriate sizes and connectors
 - Current (unexpired) drugs for management of emergencies as detailed in the table, *Mandatory Emergency Agents for Facilities in Which a Member Administers One or More Sedation Modalities* (see **Part 2**)

A written record of the equipment's annual maintenance/servicing and emergency drugs must be kept on file and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

SEDATION PROTOCOL

1. Review of the patient's medical history (as described in **Part 2** and **Appendix II**) must be performed prior to the decision to use any form of sedation.
2. Appropriate pre-operative and written post-operative instructions must be provided to or for the patient.
3. No fasting requirements are necessary prior to (minimal) sedation using nitrous oxide and oxygen. The member, however, may recommend that only a light meal be consumed by the patient within 2 hours of the administration of nitrous oxide.
4. A flow rate of 5 to 6 liters/minute generally is acceptable for most patients. The flow rate can be adjusted upon observation of the reservoir bag.
5. 100% oxygen for 1 to 2 minutes followed by titration of nitrous oxide in 10% intervals is recommended.

6. The administration of nitrous oxide and oxygen must be slowly titrated to achieve the signs and symptoms of minimal sedation, with continuous and vigilant assessment of the level of consciousness, except in justifiable circumstances.⁷
7. The concentration of nitrous oxide administered with the intent of achieving (minimal) sedation must not exceed 50%, except in justifiable circumstances.⁸
8. Nitrous oxide concentration may be increased during periods of increased stimulation (e.g. injection of local anaesthetic) and/or decreased during periods of less stimulation (e.g. ongoing anxiolysis once local anaesthetic has had effect). Tailoring the administration of nitrous oxide to the patient's needs will assist in preventing over-medication of the patient, reduce adverse effects, and provide a more positive overall sedation experience.
9. Patients receiving nitrous oxide and oxygen sedation must never be left unattended during the administration of these inhaled substances and must be continuously monitored by an Authorized Sedation Monitor.
10. Monitoring must consist of direct and continuous clinical observation for level of consciousness and assessment of vital signs which may include heart rate, blood pressure, and respiration pre-operatively, intra-operatively, and post-operatively, as necessary. It must also include the use of pulse oximetry pre-operatively, intra-operatively, and post-operatively.⁹ The medical record must include details of this monitoring.
11. Once the nitrous oxide flow is terminated, 100% oxygen must be delivered for 3 to 5 minutes.
12. The patient's recovery status post-operatively must be specifically assessed and recorded. The decision to discharge a patient following the administration of nitrous oxide and oxygen sedation must be made by a member currently registered with the College and authorized by the College to administer the specific sedation agent or modality, who must remain in the office until that patient is fit for discharge.
13. Only fully recovered patients can be considered for discharge unaccompanied. If the patient has residual symptoms, the patient must be accompanied by a responsible adult.
14. Specific to sedation, the patient's record must include the indication(s) for use of sedation and the rationale for the choice of sedation administered. In these situations where nitrous oxide and oxygen have been administered, the record must also include the following information: the name of the Authorized Sedation Monitor, the nitrous oxide dosage (i.e., percentage of nitrous oxide and oxygen and flow rate), the duration of

⁷ In these cases, the member's records must reflect the reasons for these circumstances.

⁸ In these cases, the member's records must reflect the reasons for these circumstances.

⁹ Children, the elderly, and the medically compromised including patients who are taking prescribed medication with sedative properties require more vigilant monitoring to ensure that the intended level of sedation is not exceeded.

administration of the nitrous oxide and oxygen, post-treatment oxygenation procedure(s), record of pre-operative, intra-operative, and post-operative monitoring, discharge summary, and any adverse effects.

B. ORAL ADMINISTRATION OF A SINGLE SEDATIVE DRUG (NO NITROUS OXIDE IS USED)

In addition to the requirements listed in **Part 2**, the following standard of practice applies when the oral route of administration is used to induce sedation. This also applies to the sublingual route of administration.

EMERGENCY EQUIPMENT AND DRUG REQUIREMENTS

1. Emergency equipment and drugs must be available at all times. Drugs must be current (unexpired) and stored in a readily identifiable and organized fashion (i.e. labelled trays or bags). It is the member's responsibility to ensure that the office in which sedation is being performed is equipped with the following:
 - Sphygmomanometers and stethoscopes of appropriate sizes
 - Full face masks of appropriate sizes and connectors
 - Current (unexpired) drugs for management of emergencies as detailed in the table, *Mandatory Emergency Agents for Facilities in Which a Member Administers One or More Sedation Modalities* (see **Part 2**)

A written record of the equipment's annual maintenance/servicing and emergency drugs must be kept on file and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

SEDATION PROTOCOL

1. Review of the patient's medical history (as described in **Part 2** and **Appendix II**) must be performed prior to the decision to use any form of sedation.
2. For the purposes of this document, the administration of an oral sedative intended to induce sedation refers to a single oral dose administered to the patient while in the member's office. The administration of this single oral dose must take into account the time required for drug absorption as well as the concurrent use of other medications which may impact the clinical effects of the administered dose. It is recommended that the full effect of the administered oral sedative has occurred prior to initiating treatment or beginning a procedure.
3. There are two possible exceptions to the recommendation that the oral sedative be administered in the member's office. One indication is if the member has determined that the patient requires an oral sedative to facilitate sleep the night prior to the member's treatment or procedure. The second indication is when the patient's anxiety is such that sedation is required to permit arrival to the member's office. In these two situations, the following additional requirements apply:

- Each patient must be screened by the member at a prior appointment, with an appropriate medical history (as described in **Part 2** and **Appendix II**).
 - Only one sedative drug should be prescribed at any one time, preferably a benzodiazepine or an antihistamine. Opioids must not be used as pre-operative or intra-operative sedative drugs.
 - The patient must be instructed not to drive a vehicle and must be accompanied to and from the member's office.
 - In each case, clear written instructions must be given to the patient, or his or her legal guardian, explaining how to take the medication, the need for accompaniment, and listing the expected effects from this drug.
4. Knowledge of the administered oral sedative's time of onset, peak response, and duration of action is essential to avoid over-sedation.
 5. The maximum recommended dose of an oral sedative must not be exceeded at any one appointment.
 6. Patients must be continuously monitored. However, an Authorized Sedation Monitor is not required. Monitoring may be performed by other clinical staff.
 7. Children, the elderly, and the medically compromised including patients 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 sedation is not exceeded. Continuous monitoring, including the use of pulse oximetry pre-operatively, intra-operatively, and post-operatively, and the inclusion of an Authorized Sedation Monitor, while not required, is strongly recommended for these patients. The medical record must include details of this monitoring if done.
 8. The patient's recovery status post-operatively must be specifically assessed and recorded. The decision to discharge a patient following the administration of a single oral sedative drug must be made by a member currently registered with the College and authorized by the College to administer the specific sedation agent or modality.
 9. The patient must be discharged to the care of a responsible adult. Before doing so, the patient must be oriented i.e. to time, place, and person relative to the pre-anaesthetic condition, ambulatory, with stable vital signs, and showing signs of increasing alertness.
 10. Written post-sedation instructions must be given. The patient must be instructed to not drive a vehicle, operate hazardous machinery, or consume alcohol for a minimum of 18 hours or longer if drowsiness or dizziness persists.
 11. Specific to sedation, the patient's record must include the indication(s) for use of sedation, the rationale for the choice of sedation administered, doses of all sedative drugs, time of administration of all sedative drugs, record of pre-operative, intra-operative, and post-operative monitoring, discharge summary, and any adverse effects.

C. ORAL ADMINISTRATION OF A SINGLE SEDATIVE DRUG WITH NITROUS OXIDE AND OXYGEN

In addition to the requirements listed in **Part 2**, the following standard of practice applies when an oral route of administration of a single sedative drug is used in combination with nitrous oxide and oxygen to induce sedation.

USE OF AN AUTHORIZED SEDATION MONITOR

Nitrous oxide and oxygen sedation **must** be administered by an Authorized Sedation Monitor, as defined in **Part 2**. In the case of a nurse, the member performing the treatment must be present at all times in the office suite and **immediately** available in the event of an emergency.

GAS DELIVERY SYSTEM AND EMERGENCY EQUIPMENT AND DRUG REQUIREMENTS

1. It is the member's responsibility to ensure that all gas delivery equipment, including all required fail-safe features, are well maintained and in proper working order. All sedation equipment necessary for the safe administration of the sedative agent(s) must be present and in compliance with the College's standard of practice (see **Section A of Part 3**).
2. Emergency equipment and drugs must be available at all times. Drugs must be current (unexpired) and stored in a readily identifiable and organized fashion (i.e. labelled trays or bags). It is the member's responsibility to ensure that the office in which sedation is being performed is equipped with the following:
 - Pulse oximeter
 - Sphygmomanometers and stethoscopes of appropriate sizes
 - Full face masks of appropriate sizes and connectors
 - Current (unexpired) drugs for management of emergencies as detailed in the table, *Mandatory Emergency Agents for Facilities in Which a Member Administers One or More Sedation Modalities* (see **Part 2**)

A written record of the equipment's annual maintenance/servicing and emergency drugs must be kept on file and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

3. All automated monitors (in addition to the gas delivery system as previously outlined) 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 and presented for review by the College when requested by the Registrar or the College's Inhalation and Sedation Committee.

SEDATION PROTOCOL

1. Review of the patient's medical history (as described in **Part 2** and **Appendix II**) must be performed prior to the decision to use any form of sedation.
2. No fasting requirements are necessary prior to (minimal) sedation using nitrous oxide and oxygen or oral administration of a single sedative drug with or without nitrous oxide and oxygen. The member, however, may recommend that only a light meal be consumed by the patient within 2 hours of the administration of nitrous oxide.
3. For the purposes of this document, the administration of an oral sedative intended to induce sedation refers to a single oral dose administered to the patient while in the member's office. The administration of this single oral dose must take into account the time required for drug absorption as well as the concurrent use of other medications which may impact the clinical effects of the administered dose. It is recommended that the full effect of the administered oral sedative has occurred prior to initiating treatment or beginning a procedure.
4. Knowledge of the administered oral sedative's time of onset, peak response, and duration of action is essential to avoid over-sedation.
5. The maximum recommended dose of an oral sedative must not be exceeded at any one appointment.
6. If an oral sedative has been administered, the practitioner must ensure that the full effect of the oral sedative has occurred before administering nitrous oxide.
7. If an oral sedative has been administered, nitrous oxide and oxygen must be slowly titrated to achieve the signs and symptoms of minimal sedation with continuous and vigilant assessment of the level of consciousness, except in justifiable circumstances.¹⁰
8. A flow rate of 5 to 6 liters/minute generally is acceptable for most patients. The flow rate can be adjusted after observation of the reservoir bag.
9. 100% oxygen for 1 to 2 minutes followed by titration of nitrous oxide in 10% intervals is recommended.
10. The concentration of nitrous oxide administered with the intent of achieving (minimal) sedation must not exceed 50%, except in justifiable circumstances.¹¹
11. Nitrous oxide concentration may be increased during periods of increased stimulation (e.g. injection of local anaesthetic) and/or decreased during periods of less stimulation (e.g. ongoing anxiolysis once local anaesthetic has had effect). Tailoring the administration of nitrous oxide to the patient's needs will assist in preventing over-

¹⁰ In these cases, the member's records must reflect the reasons for these circumstances.

¹¹ In these cases, the member's records must reflect the reasons for these circumstances.

medication of the patient, reduce adverse effects, and provide a more positive overall sedation experience.

12. Patients receiving this combination of sedative agents and modalities must never be left unattended during the administration of these inhaled substances and must be continuously monitored by an Authorized Sedation Monitor.
13. Monitoring must consist of direct and continuous clinical observation for level of consciousness and assessment of vital signs which may include heart rate, blood pressure, and respiration pre-operatively, intra-operatively, and post-operatively, as necessary. It must also include the use of pulse oximetry pre-operatively, intra-operatively, and post-operatively.¹² The medical record must include details of this monitoring.
14. Once the nitrous oxide flow is terminated, 100% oxygen must be delivered for 3 to 5 minutes.
15. The patient's recovery status post-operatively must be specifically assessed and recorded. The decision to discharge a patient following the administration of nitrous oxide and oxygen sedation, with or without the administration of an oral sedative drug, must be made by a member currently registered with the College and authorized by the College to administer the specific sedation agent or modality, who must remain in the office until that patient is fit for discharge.
16. The patient must be discharged to the care of a responsible adult. Before doing so, the patient must be oriented i.e. to time, place, and person relative to the pre-anaesthetic condition, ambulatory, with stable vital signs, and showing signs of increasing alertness.
17. Written post-sedation instructions must be given. The patient must be instructed to not drive a vehicle, operate hazardous machinery, or consume alcohol for a minimum of 18 hours or longer if drowsiness or dizziness persists.
18. Specific to sedation, the patient's record must include the indication(s) for use of sedation, the rationale for the choice of sedation administered, doses of all oral sedative drugs, and time of administration of all oral sedative drugs. In situations where nitrous oxide and oxygen have been administered, the record must also include the following information: the name of the Authorized Sedation Monitor, the nitrous oxide dosage (i.e., percentage of nitrous oxide and oxygen and flow rate), the duration of administration of the nitrous oxide and oxygen, post-treatment oxygenation procedure(s), record of pre-operative, intra-operative, and post-operative monitoring, discharge summary, and any adverse effects.

¹² Children, the elderly, and the medically compromised including patients who are taking prescribed medication with sedative properties require more vigilant monitoring to ensure that the intended level of sedation is not exceeded.

APPENDIX I

Characteristics of the Levels of Sedation and General Anesthesia¹³

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

¹³ As adapted by the Royal College of Dental Surgeons of Ontario in its *Standard of Practice: Use of Sedation and General Anesthesia in Dental Practice*, April 2015. Members are responsible for ensuring updates to information.

APPENDIX II

Medical History and Patient Evaluation

An adequate, current, clearly recorded, and signed (by the member who will be inducing sedation) medical history must be made for each patient. The history is part of the patient's permanent record. It forms a database from which the member can determine the appropriate sedation modality or modalities. The medical history must be kept current. This information must be organized and contain the **minimum information described in this section**.

- **Vital Statistics:** This includes the patient's full name, date of birth, sex, and the name of the person to be notified in the event of an emergency. In the 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 be a system-based review of the patient's past and current health status and must specifically fulfill the following two basic requirements:
 - 1) It must elicit the core medical information to enable the member to assign the correct ASA Physical Status Classification (see **Appendix III**) in order to assess risk factors in relation to sedation choices.
 - 2) It must provide written evidence of a logical process of patient evaluation.
- **Core Physical Examination:** A current, basic physical examination, suitable for determining information that may be significant to sedation and appropriate to the modality or modalities being used, must be carried out for each patient.

At a minimum, all modalities of sedation require the evaluation and recording of significant positive findings related to:

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

This core physical examination can be carried out by the member.

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

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

this examination **must be performed** by a physician or a nurse practitioner.

APPENDIX III

American Society of Anesthesiologists Physical Status Classification System¹⁴

- ASA I:** A normal healthy patient
- ASA II:** A patient with mild systemic disease
- ASA III:** A patient with severe systemic disease
- ASA IV:** A patient with severe systemic disease that is a constant threat to life
- ASA V:** A moribund patient who is not expected to survive without operation
- ASA VI:** A declared brain-dead patient whose organs are being removed for donor purposes
- ASA E:** The addition of E preceding the Roman numeral denotes emergency surgery (where an emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

¹⁴ This is the current version as of October 15, 2014. Members are responsible for ensuring updates to information.

APPENDIX IV

Guidelines, Standards, and Other Available Statements

Anaesthesia Organizations

American Society of Anesthesiologists

www.asahq.org

Association of Anaesthetists of Great Britain and Ireland

www.aagbi.org/publications

Australian and New Zealand College of Anaesthetists

www.anzca.edu.au/resources

Australian Society of Anaesthetists

www.asa.org.au

Canadian Anaesthesiologists' Society

www.cas.ca

European Society of Anaesthesiology

www.euroanesthesia.org

European Society for Paediatric Anaesthesiology

www.euroespa.com

Royal College of Anaesthetists

www.rcoa.ac.uk

Société Française d'Anesthésie et de Réanimation

www.sfar.org

Society for Pediatric Anesthesia

www.pedsanesthesia.org

World Federation of Societies of Anaesthesiologists

www.anaesthesiologists.org

Other Organizations

Royal College of Dental Surgeons of Ontario

www.rcdso.org

National Guideline Clearinghouse

<http://www.guideline.gov/content.aspx?id=15256>

American Dental Association

www.ada.org

American Academy of Pediatrics and the American Academy of Pediatric Dentistry

www.aapd.org/media/Policies_Guidelines/G_Sedation.pdf

Canadian Institute for Health Information

www.cihi.ca

CSA Group

www.csagroup.org

College of Physicians and Surgeons of Ontario

www.cpso.on.ca

Health Canada

www.hc-sc.gc.ca

Public Health Agency of Canada

www.phac-aspc.gc.ca

Royal College of Physicians and Surgeons of Canada

www.royalcollege.ca

Patient Safety Organizations

Anesthesia Patient Safety Foundation

www.apsf.org

Canadian Patient Safety Institute

www.patientsafetyinstitute.ca

National Patient Safety Foundation (USA)

www.npsf.org