College of Chiropodists of Ontario

PRACTICE STANDARD

Administering Inhaled Substances and the Use of Sedation

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INDEX

Introduction

This document outlines the minimum standards of practice for administering inhaled substances and using sedation in practice. Any registrant who uses sedative agents or sedation modalities must:

- Be appropriately trained,
- Have an inhalation certification and/or prescribing privileges, as outlined below,
- Regulate their practice in accordance with this standard, the ***Chiropody Act, 1991***, its regulations, and the **College by-laws**.

This standard must be read in conjunction with Ontario Regulation 203/94, under the Chiropody Act, 1991, By-Law 5: Inhalation and Sedation, and the College's Office Medical Emergencies Guideline.

Defining Sedation Levels

Sedation and general anesthesia exist along a **continuum**, from mild anxiety relief with little or no drowsiness (minimal sedation) to complete unconsciousness (general anesthesia).

Patient responses to sedation can vary, and it may be difficult to clearly distinguish between levels — such as minimal versus moderate sedation, or the transition into deep sedation and general anesthesia. Given this variability, sedation must be used carefully and with a wide margin of safety to minimize the risk of unintended loss of consciousness.

In practice, minimal sedation can help reduce anxiety and make treatment more comfortable, with less physical and psychological stress.

Responsibilities of Registrants Administering Sedation

Registrants who administer sedation must be able to:

- Recognize and manage the physiological effects of sedation, and
- Rescue patients if sedation becomes deeper than the intended level (beyond minimal sedation).

This requires:

- Proper training and clinical skills,
- Access to emergency drugs and equipment, and
- The ability to manage the situations until the patient either:
    - Returns to the intended level of sedation without airway or cardiovascular complications, or
    - Is transferred to emergency medical services.

Conscious Sedation

- Conscious sedation is a minimally to moderately depressed level of consciousness that allows the patient to independently and continuously maintain their airway and respond appropriately to physical stimulation and verbal commands. It may be achieved through pharmacological, non-pharmacological, or combined methods.
- Conscious sedation is further classified into:
    - Minimal sedation
    - Moderate sedation

These classifications are defined in the document Characteristics of the Levels of Sedation and General Anesthesia (see **Appendix I**).

Minimal Sedation

Regardless of the sedation modality or combination used, **registrants must limit the depth of sedation to minimal sedation only**.

Minimal sedation is a **minimally depressed level of consciousness** induced by pharmacological means. Under minimal sedation:

- The patient retains the ability to **independently and continuously maintain their airway**.
- The patient can **respond normally to tactile stimulation and verbal commands**.
- **Cognitive function and coordination** may be mildly impaired.
- **Ventilatory and cardiovascular functions remain unaffected**.
- Minimal sedation is usually achieved using one of the following approaches:
    1. Administration of nitrous oxide and oxygen.
    2. Administration of nitrous oxide and oxygen with a [single][1] sedative drug.
    3. Oral administration of a [single][2] sedative drug.

[1] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug in combination with nitrous oxide and oxygen.
[2] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug.

Moderate Sedation

- **Moderate sedation** is a **drug-induced depression of consciousness** in 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**.

Moderate sedation is typically achieved using one of the following modalities:

- **Oral administration of multiple sedative drugs**, with or without **nitrous oxide and oxygen**.
- **Parenteral administration** of sedative drug(s), including:
    1. Intravenous (IV)
    2. Intramuscular (IM)
    3. Subcutaneous (SC)
    4. Submucosal
    5. Intranasal routes

Deep Sedation

- A controlled state of depressed consciousness, characterized by a partial loss of protective reflexes, including the inability to respond purposefully to verbal commands.
- During deep sedation:
    1. The ability to independently maintain ventilatory function may be impaired.
    2. Patients may require assistance in maintaining a patent airway.
    3. Spontaneous ventilation may be inadequate.
    4. Cardiovascular function is usually maintained.

General Anesthesia

General anesthesia is a **controlled state of unconsciousness** accompanied by a **partial or complete loss of protective reflexes**, including:

- The **inability to maintain an airway independently**, and
- The **inability to respond purposefully** to physical stimulation or verbal commands.

Part 1 – Administering Oxygen

When used alone, **oxygen is not considered a sedative agent**.

While oxygen administration is most associated with emergency situations—such as resuscitation, anaphylaxis, syncope, shock, or convulsions—it may also be appropriate in **non-emergent situations**, depending on the specific needs of the patient.

The decision to administer oxygen should be based on the **individual circumstances of the patient** and is at the **discretion of the registrant**. Registrants must also exercise clinical judgment in determining the **appropriate oxygen concentration and flow rate**, with the goal of maintaining or restoring normal physiological oxygen saturation levels:

- **94–98%** for most patients.
- **88–92%** for patients with **chronic obstructive pulmonary disease (COPD).**

Part 2 – General Standards for All Modalities of Sedation

This section outlines the general requirements for sedation that apply to any modality.

Sedation may be appropriate in the following situations:

- To manage patient anxiety and pain associated with treatment.
- To enable treatment for patients with cognitive impairment or motor dysfunction that prevents adequate care.
- To treat patients below the age of reason.
- To manage traumatic conditions.
- To alleviate anxiety and pain during invasive or prolonged procedures.

Sedation should only be used when clinically indicated and should serve as an adjunct to appropriate non-pharmacological methods of patient management. It is the registrant's responsibility to assess and determine which patients are suitable candidates for the various sedation modalities and pharmacological agents.

Any registrant who wishes to administer sedation must:

- Obtain **informed consent** from the patient, and
- Ensure compliance with the requirements outlined below, including those related to:
    - **Office and facility requirements**, and
    - **Sedation protocols** applicable to **all sedation modalities**

These requirements are essential to ensure safe, ethical, and compliant practice.

Office and Facility Requirements

Before treating a patient who is to be sedated, the registrant must:

1. Ensure that their office is equipped with all required sedation and emergency equipment and drugs necessary to meet the requirements of this standard of practice.
2. Ensure that the facility complies with all applicable building codes, including:
    - Fire safety regulations,
    - Electrical standards
    - Access requirements.
3. The size and layout of the facility must be sufficient to:

- Support the safe performance of all procedures
- Allow for the safe evacuation of patients in the event of an emergency.

4. Make sure the clinical setting is suitably staffed and equipped for the specific type of sedation being used.

Emergency Drug and Equipment Requirements

Emergency equipment and medications must **always be available** when sedation is performed.

A) DRUGS

All drugs must be:

1. **Current** (i.e., not expired)
2. **Clearly labeled** and
3. **Stored in an organized and easily identifiable manner** (e.g., in labeled trays or bags)

Registrants using sedation should include and be prepared to use the following medications/agents in an emergency kit:

- **Oxygen** – For most medical emergencies. This should include an adjustable regulator capable of delivering oxygen at flow rates up to 15 liters per minute.
- **Epinephrine (for parenteral emergency use)** – For:
  - Severe allergic reactions (anaphylaxis)
  - Asthma attacks not responding to inhalers
  - Cardiac arrest
- **Diphenhydramine (for parenteral emergency use)** – For allergic reactions
- **Aspirin (325 mg chewable) –** For suspected heart attacks
- **Glucose tablets –** For low blood sugar in conscious patients

Additional recommendations (only to be used by practitioners trained and comfortable with their administration)**:**

- **Aromatic ammonia** – For fainting
- **Midazolam (Versed)** – For seizures
- **Hydrocortisone** or equivalent agent (E.g. Dexamethasone 4 mg PO, IM, IV) – For allergic reactions or adrenal crisis
- **50% Dextrose solution (IV) or Glucagon (IM) –** For low blood sugar in unconscious patients
- **Salbutamol/Albuterol (Ventolin/Proventil) –** For asthma attacks
- **Nitroglycerin (Nitrostat/Nitromist) –** For chest pain (angina)

Safeguarding Sedative Agents

A registrant who uses sedative agents in their practice must take reasonable precautions to prevent any unauthorized access and use of these substances for recreational or other improper purposes by office staff or any individuals with access to the premises or equipment. Preventative strategies must include the following:

- **Inventory Management**: Maintain a written log of all monitored and controlled drugs in the clinic. These include, but are not limited to, sedative agents (e.g. benzodiazepines), narcotics, and nitrous oxide. The log must include:
    - The specific substance acquired
    - Supplier name
    - Date of acquisition
    - Name of the individual confirming receipt
    - Total amount acquired
    - Expiry date (if applicable)
- This inventory must be reconciled regularly and kept on file for review by the College upon request by the Registrar or the College's Sedation Committee.
- **Secure Storage**: These agents must be stored safely in a locked cupboard or secure storage unit, with access only available to authorized staff.
- **Usage Log**: Maintain a separate log that accurately records the use of these agents within the practice. This log must include:
    - The specific substance used
    - Date of use
    - Total amount administered
    - Correlating patient identifier
    - Name of the individual who administered the substance.

This usage log must also be kept on file and made available for review by the College upon request.

- **Prescription Pad Security:** Exercise strict control over blank prescription pads. Never pre-sign blank prescriptions.
- **Staff Education and Awareness**: Conduct and document regular staff training sessions to:
    - Discuss the dangers of drug and substance misuse
    - Reinforce office safeguards and protocols
    - Provide information on wellness resources available to staff
    - Reporting procedures for errors or misuse

Record the dates and duration of these sessions to demonstrate compliance if requested by the College.

B) EQUIPMENT

It is the **registrant's responsibility** to ensure that the practice setting where sedation is administered is equipped with the required emergency supplies, including:

- Pulse oximeter, approved by Health Canada;
- Appropriately sized sphygmomanometers and stethoscopes;
- Appropriately sized full-face masks and connectors; and
- An **Automated External Defibrillator (AED)**, which can be lifesaving in the event of a sudden cardiac arrest and is designed to be used by non-medical personnel with minimal training. Having one readily available significantly improves the chances of survival while waiting for emergency medical services to arrive.

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

Sedation Protocol (Applicable to All Modalities)

1. Obtain and document informed consent before giving any oral sedative drug and/or nitrous oxide and oxygen.
2. Take an adequate, clearly recorded, current medical history for each patient before administering any form of sedation. This history must include:
    - Present and past illnesses,
    - Hospital admissions,
    - Current prescription and non-prescription medication
    - Herbal supplements (including dosage)
    - Allergies, particularly to medications
    - Functional inquiry and a physical examination
3. For medically compromised patients, it may be necessary to consult their primary healthcare provider. If a consultation occurs, it must be documented in the patient record, consistent with the requirements in **Appendix II**.
4. At every sedation appointment, review the patient's medical history for any changes and record it in their chart. This will help the registrant decide if the patient is a suitable candidate for in-office use of a particular sedation modality or agent.
5. Before giving any sedation, determine the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (see **Appendix III**) and record it in their chart. Also evaluate any other factors that could affect whether the patient is a good candidate for sedation must be conducted.
6. Patients classified as ASA IV and higher (see **Appendix III**) are not candidates for sedation outside of a hospital. Oxygen can be given at the registrant's discretion. If a patient is ASA III or higher, registrants must consult with their primary healthcare provider before administering sedation.

7. Registrants must always ensure sedation stay at a minimal level (see **Definitions of Sedation Levels**). Using one drug at a well-planned dose is the safest way to achieve this.
8. If the patient becomes more than mildly sedated (overly drowsy or unresponsive), stop treatment right away. Support the patient until they return to mild sedated or call emergency services if needed.
9. Always consider the maximum safe dose of local anaesthetic, especially for children, older adults, and people with health issues. If sedation is also being used, the maximum safe dose may need to be lowered even more to ensure patient safety.
10. Registrants must not be alone when treating a sedated patient.
11. After minimal sedation, the patient must leave with a responsible adult. The only time a registrant can decide if someone can leave alone is when nitrous oxide and oxygen were the only sedation used. No matter what type of sedation was given, the registrant who administered the sedation must confirm and document that the patient is safe and ready to go before discharge.

Part 3 – Specific Standards for Particular Modalities

Registrants must follow the College's standard of practice when providing minimal sedation to a patient using any modality, including:

- the administration of nitrous oxide and oxygen alone or the administration of nitrous oxide and oxygen with a [single][3] sedative drug; and
- the oral administration of a [single][4] sedative drug; and
- the oral administration of a [single][5] sedative drug.

Administering Nitrous Oxide and Oxygen OR Nitrous Oxide and Oxygen with a Single Sedative Drug

In addition to the requirements listed in **PART 2**, the following standards of practice apply when nitrous oxide and oxygen sedation or nitrous oxide and oxygen sedation with a [single] sedative drug are being used to induce minimal sedation.

REGISTRANT QUALIFICATIONS

Registrants must meet the following requirements to administer nitrous oxide and oxygen sedation or nitrous oxide and oxygen sedation with a [single] sedative drug:

1. Obtain an Inhalation Certificate from the College (for details, see the College's By-law 5: Inhalation and Sedation).

[3] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug in combination with nitrous oxide and oxygen.
[4] This standard does not anticipate any circumstance in which a registrant would administer more than one sedative drug concurrently
[5] This standard does not anticipate any circumstance in which a registrant would administer more than one sedative drug concurrently

2. Successfully complete a training program, approved by the College, that teaches how to competently administer nitrous oxide and oxygen, with or without a [single][6] sedative drug.[7]
3. Successfully complete a comprehensive pharmacology course, approved by the College, that covers general clinical pharmacological principles and overall systems pharmacology, and gives the registrant the ability to prescribe the relevant sedative and emergency drugs in the *Ontario Regulation 203/94*: General or as may otherwise be required for appropriate patient care.[8]
4. Maintain competence by completing ongoing training, courses, and/or other educational programs.
5. Make sure all clinical staff, including Authorized Sedation Monitors, know how to recognize and manage adverse reactions to sedation and have access to the necessary emergency equipment and drugs.
6. Establish written emergency protocols s and review them regularly with staff. Keep a record of these protocols on file. **You must provide this record to the College if requested by the Registrar or the College's Sedation Committee.**
7. All clinical staff, including Authorized Sedation Monitors, must be trained and able to perform basic life support (BLS). Registrants who provide sedation must maintain BLS certification (CPR Level HCP – CPR Level for Health Care Providers) as a minimum and renew it at least every three years.

AUTHORIZED SEDATION MONITOR

Because it is difficult to safely provide foot care and administer nitrous oxide and oxygen sedation, **there must always be at least two people present when nitrous oxide and oxygen are used, whether or not an oral sedative drug is being administered at the same time**[9].

Individual One: The first person in the room during sedation is mainly responsible for providing foot care to the patient. They must be registered with the College and must also be authorized by the College to administer a substance to a patient by inhalation (nitrous oxide and oxygen).[10]

Individual Two: The second person in the room is the Authorized Sedation Monitor. This person administers the sedation under the direction of the registrant and must closely monitor the patient to make sure the sedation is working safely. This person must be ready to respond to any problems or side effects from the sedation.

To be an **Authorized Sedation Monitor**[11], a person must meet specific qualifications:

- Another College registrant who is authorized to administer a substance to a patient by inhalation, or;
- A Registered Nurse (RN) currently registered with the College of Nurses of Ontario acting under an order from a registrant, or;

[6] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug in combination with nitrous oxide and oxygen.
[7] 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.
[8] The registrant must meet the standard of practice set out in Ontario Regulation 203/94, made under the *Chiropody Act, 1991*, for prescribing sedative drugs.
[9] Please note that this standard of practice has not been designed for the circumstance where a registrant arranges for a physician to provide sedation as the registrant provides foot care.
[10] Individual One would not be required to be authorized by the College to administer a substance by inhalation where Individual Two was a registrant currently registered with the College who is authorized by the College to do so.
[11] This standard does **not** apply where a registrant arranges for a physician to provide sedation while the registrant provides foot care.

- A Registered Practical Nurse (RPN) currently registered with the College of Nurses of Ontario, 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 an order from a registrant.

The registrant must ensure the Authorized Sedation Monitor has current BLS certification (CPR Level HCP – CPR Level for Health Care Providers) and is competent to perform the tasks being assigned.

In the case of a nurse, the registrant performing foot care must always be present in the office suite and available **immediately** in the event of an emergency.

GAS DELIVERY SYSTEM REQUIREMENTS

Gas delivery systems used for nitrous oxide and oxygen sedation must meet the following standards:

1. **Fail-safe oxygen:** The system must have a fail-safe feature, so it never delivers less than 30% oxygen in the gas mixture.
2. **Secure connections:** Pipeline inlet fittings or pin-indexing, must prevent mixing up oxygen and nitrous oxide connections.
3. **Regular maintenance:** The system must be checked regularly by trained staff, work reliably and accurately, and maintained according to manufacturer's instructions or annually, whichever is more frequent. A written record of this maintenance must be kept and provided to the College if requested.
4. **Standard outlet:** The system must have a common gas outlet that fits.
5. **Backup oxygen supply:** A portable "E" size oxygen cylinder must be ready for immediate use. It should include a regulator (capable of delivering oxygen at flow rates up to 15 liters per minute), flowmeter, connectors, tubing, and a reservoir bag for positive pressure resuscitative ventilation with 100% oxygen using a full-face mask.
6. **Disposable masks:** Only single use disposable masks with scavenging capability should be used to prevent cross-contamination and safely remove exhaled gases.
7. **Scavenging system:** The system must include a properly functioning scavenging setup installed per manufacturer's specifications. It should have an accurate flowmeter, scavenging masks, and a vacuum system that removes gases at a rate of at least **45 L per minute,** venting them in compliance with local regulations.
8. **Single-patient components:** All components that touch the patient must be single-use. Parts that do not touch the patient must be cleaned and disinfected in accordance with the manufacturer's instructions.

SEDATION PROTOCOL

1. The patient's medical history (as described in **Part 2** and **Appendix II**) must be reviewed for any changes at each sedation appointment.
2. Pre-operative and written post-operative instructions must be provided to the patient or their guardian.
3. No fasting is necessary before (minimal) sedation using nitrous oxide and oxygen or sedation using the administration of a [single] sedative drug with or without nitrous oxide and oxygen. Registrants may, however, recommend that the patient only eat a light meal within two hours of nitrous oxide being administered.

4. A flow rate of 5 to 6 liters per minute is generally acceptable for most patients. The flow rate should be adjusted by observing the reservoir bag.
5. Start with 100% oxygen for 1 to 2 minutes, then gradually add nitrous oxide in 10% intervals.
6. Nitrous oxide and oxygen should be increased slowly to achieve **minimal** sedation, with continuous and careful monitoring of the patient's level of consciousness, unless there is a justified reason to do otherwise.[12]
7. The concentration of nitrous oxide should not exceed 50% when aiming for minimal sedation, except in justifiable circumstances.[13]
8. Increase nitrous oxide during more stimulating procedures (e.g. injection of local anaesthetic) and/or decreased during periods of less stimulation (e.g. ongoing anxiolysis once local anaesthetic has had effect). Adjusting to the patient's needs helps prevent overmedication, reduces adverse side effects, and improves the overall sedation experience.
9. Patients receiving nitrous oxide and oxygen sedation must never be left unattended and must be continuously monitored by an **Authorized Sedation Monitor**. Monitoring must include:
    - Continuous observation of consciousness and vital signs (heart rate, blood pressure, respiration) before, during and after the procedures.
    - Use a pulse oximetry throughout.
    - Record monitoring details at least **every 15 minutes.**
10. After stopping nitrous oxide, **100% oxygen must be delivered for 3 to 5 minutes.**
11. The patient's recovery status must be **assessed and documented** following the administration of sedation. The decision to discharge a patient after receiving **nitrous oxide and oxygen sedation** must be made by a **registrant of the College** who is:
    - **Currently registered** with the College, and
    - **Authorized** to administer the specific sedation agent or modality.
12. This registrant must **remain on-site** until the patient is deemed **fit for discharge**.
13. Only patients who are fully recovered may be considered for unaccompanied discharge. If a patient exhibits any residual symptoms, they must be discharged with a responsible adult to ensure their safety and continued recovery.
14. The patient record must include:
    - **Indication(s) for the use of sedation.**
    - **Rationale for the choice of sedative agent administered.**
15. In cases where **nitrous oxide and oxygen** are administered, the record must also include:
    - Name of the **Authorized Sedation Monitor.**
    - **Dosage details**: percentage of nitrous oxide and oxygen, and flow rate.
    - **Duration** of administration.
    - **Post-treatment oxygenation procedures.**
    - **Monitoring records**: pre-operative, intra-operative, and post-operative.

[12] In these cases, the patient record must reflect the reasons for these circumstances.
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- **Discharge summary.**
- Documentation of **any adverse effects.**

ADDITIONAL SEDATION PROTOCOLS – [SINGLE] USE DRUG

1. For the purposes of this standard, the administration of an oral sedative intended to induce sedation refers to a single oral dose administered to the patient while in the registrant's office. The administration of this dose must consider:
    - The time required for drug absorption.
    - The potential interactions with other concurrently used medications that may influence the clinical effects of the sedative.

It is recommended that the full effect of the administered oral sedative be realized before initiating treatment or beginning any procedure.

2. There are two exceptions to the recommendation that the oral sedative be administered in the registrant's office:
    - If the registrant decides the patient needs an oral sedative to sleep the night before treatment or a procedure.
    - If the patient's anxiety is so high that sedation is needed before arriving at the registrant's office.

    In these two situations, additional requirements apply:
    - The reason a registrant instructed a patient to take a sedative drug prior to arriving at the office must be clearly documented in the patient record.
    - The patient must be screened at a prior appointment, including a comprehensive medical history, as outlined in **Part 2** and **Appendix II**).
    - Only **one sedative drug** should be prescribed at a 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 and must be accompanied to and from the registrant's office by a responsible adult.
    - Clear written instructions must be provided to the patient or their legal guardian. The instructions must include: how to take the medication; the need to be accompanied to the appointment, and the expected effects from the drug.
3. It is essential to understand the oral sedative's onset time, peak response, and duration to avoid over-sedation.
4. Never exceed the maximum recommended dose during any single appointment, as outlined in **Appendix IV**. Because sedation occurs on a continuum, patient responses can vary. Registrants are encouraged to administer the lowest effective dose necessary to achieve the desired sedative effect.
5. If an oral sedative is given, make sure its full clinical effect has occurred before administering nitrous oxide.

6. When combining nitrous oxide and oxygen after an oral sedative, increase slowly to reach minimal sedation. Monitor the patient's level of consciousness continually, unless there is a justified reason not to.[14]
7. The patient must be discharged into the care of a responsible adult. Prior to discharge, the patient must demonstrate: orientation to time, place, and person, relative to their pre-anesthetic condition; ability to ambulate independently; stable vital signs; increasing alertness.
8. Written post-sedation instructions must be provided to the patient. The patient must be advised not to drive a vehicle, operate hazardous machinery, or consume alcohol for a minimum of 18 hours, or longer if symptoms such as drowsiness or dizziness persist.
9. When oral sedation is administered, the patient record must include:
    - **Indication(s)** for the use of sedation.
    - **Rationale** for the choice of sedative agent(s).
    - **Dosage** of all oral sedative drugs.
    - **Time of administration** of all oral sedative drugs.
10. In cases where **nitrous oxide and oxygen** are administered, the record must also include:
    - Name of the **Authorized Sedation Monitor.**
    - **Dosage details**: percentage of nitrous oxide and oxygen, and flow rate.
    - **Duration** of administration.
    - **Post-treatment oxygenation procedures.**
    - **Monitoring records**: pre-operative, intra-operative, and post-operative.
    - **Discharge summary.**
    - Documentation of **any adverse effects.**

Oral Administration of a Single Sedative Drug (no Nitrous Oxide is Used)

In addition to the requirements listed in **Part 2**, the following standards of practice apply when a [single][15] oral dose of a sedative drug is administered via the oral route. This also applies to medication taken under the tongue (sublingual).

REGISTRANT QUALIFICATIONS

Registrants must meet the following requirements to administer a [single][16] sedative drug:

1. Successfully complete a pharmacology course, approved by the College, that covers general clinical pharmacological principles and overall systems pharmacology. They must also meet the requirements to prescribe the relevant sedative and emergency drugs in Ontario Regulation 203/94: General or as may otherwise be required for appropriate patient care.
2. Maintain competence by completing ongoing training, courses, and/or other educational programs.

[14] In these cases, the patient record must reflect the circumstances.
[15] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug.
[16] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug.

3. Ensure that clinical staff are prepared to recognize and treat adverse responses using emergency equipment and drugs.
4. Establish written protocols for emergency procedures and review them regularly with staff. **A written record must be kept on file and presented to the College when requested by the Registrar or the College's Sedation Committee.**
5. Ensure that clinical staff have the training and ability to perform basic life support (BLS) techniques. A registrant providing sedation must maintain BLS certification (CPR Level HCP – CPR Level for Health Care Providers) as a minimum.[17] BLS certification must be renewed at least every three years.

SEDATION PROTOCOL

The patient's medical history (as described in **Part 2** and **Appendix II**) must be reviewed for any changes at each sedation appointment.

- For the purposes of this standard, the administration of an oral sedative intended to induce sedation refers to a [single][18] oral dose administered to the patient while in the registrant's office. The administration of this dose must consider:
    - the time required for drug absorption.
    - potential interactions with other concurrently used medications that may impact the clinical effects of the sedative.

It is recommended that the full effect of the administered oral sedative be realized before initiating treatment or beginning a procedure.

- There are two exceptions to the recommendation that the oral sedative be administered in the registrant's office:
    - If the registrant determines the patient requires an oral sedative to sleep the night before treatment or a procedure.
    - If the patient's anxiety is so high that sedation is needed before arriving at the registrant's office.

In these two situations, additional requirements apply:

- The reason a registrant instructed a patient to take a sedative drug prior to arriving at the office must be clearly documented in the patient record.
- The patient must be screened at a prior appointment, including a comprehensive medical history, as outlined 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 and must be accompanied to and from the registrant's office by a responsible adult.

[17] It is strongly recommended that all registrants, whether or not intending to induce sedation, maintain current BLS certification (CPR Level HCP – CPR Level for Health Care Providers).
[18] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug.

- Clear written instructions must be provided to the patient or their legal guardian. The instructions must include how to take the medication, the need to be accompanied to the appointment, and the expected effects from the drug.
- Knowing the oral sedative's time of onset, peak response, and duration of action is essential to avoid over-sedation.
- Never go over the maximum recommended dose of an oral sedative during any single appointment as outlined in **Appendix IV**. Because sedation works on a continuum, patient responses can vary. Registrants are encouraged to administer the lowest effective dose necessary to achieve the desired sedative effect
- Patients must be monitored at all times. However, an Authorized Sedation Monitor is not required - other qualified clinical staff may perform the monitoring.
- Children, older adults, and medically compromised individuals, including patients taking prescribed medication with sedative properties, require appropriate dose adjustments to ensure the intended level of sedation is not exceeded. For these patients, the following practices are strongly recommended:
    - Continuous monitoring, including the use of pulse oximetry during the pre-operative, intra-operative, and post-operative phase.
    - Inclusion of an Authorized Sedation Monitor, while not required, is strongly recommended for these patients.
- If monitoring is conducted, documentation must include recorded observations at a minimum of every 15 minutes.
- The patient's post-operative recovery status must be assessed and recorded. The decision to discharge a patient following the administration of a [single][19] oral sedative drug must be made by a registrant.
- The patient must be discharged to the care of a responsible adult. Prior to discharge, the patient must demonstrate: orientation to time, place, and person, relative to their pre-anesthetic condition; ability to ambulate independently; stable vital signs; increasing alertness.
- Written post-sedation instructions must be provided to the patient. The patient must be advised not to drive a vehicle, operate hazardous machinery, or consume alcohol for a minimum of 18 hours or longer if drowsiness or dizziness persists.
- Specific to sedation, the patient record must include the following:
    - Indication(s) for the use of sedation,
    - Rationale for the choice of sedation agent administered,
    - Dosage of all oral sedative drugs,
    - Time of administration of all oral sedative drugs,
    - Monitoring records: pre-operative, intra-operative, and post-operative monitoring,
    - Discharge summary,
    - Documentation of any adverse effects.

[19] This standard does not anticipate any circumstance where a registrant would use more than one sedative drug.

Appendix I

Characteristics of the Levels of Sedation and General Anesthesia[20]

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

Appendix II

Medical History and Patient Evaluation

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

- **Vital Statistics:** This includes the patient's full name, date of birth, sex, and emergency contact. In the case of a minor or a patient who requires a substitute decision maker, 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 basic requirements:
    1) It must elicit the core medical information to enable the registrant to assign the correct ASA Physical Status Classification (see **Appendix III**) 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.

[20] This information is based on the Royal College of Dental Surgeons of Ontario's *Standard of Practice: Use of Sedation and General Anesthesia in Dental Practice* (November 2018). Registrants are responsible for checking and following any updates to this information.

This physical examination can be carried out by the registrant.

Appendix III

American Society of Anesthesiologists Physical Status Classification System[21]

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 the operation.

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

ASA 2: Although pregnancy is not a disease, the parturient' s physiologic state is significantly altered from when the woman is not pregnant, hence the assignment of ASA 2 for a woman with uncomplicated pregnancy.

ASA E: The addition of **E** denotes emergency surgery (an emergency surgery 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).

Appendix IV

Benzodiazepines for Oral Use[22]: for the purpose of treatment of anxiety before and during surgical procedures and to provide minimal sedation during surgical procedures:

- **Diazepam** — individual dosing range of 2.5-10 mg, with 10 mg being the maximum individual dose, every 6-12 hours. Maximum total dosage not to exceed 40 mg within 24 hours. Maximum total duration not to exceed 24 hours
- **Lorazepam** – individual dosing range of 0.5-1 mg, with 1 mg being the maximum individual dose, every 12 hours. Maximum total dosage not to exceed 2 mg within 24 hours. Maximum total duration not to exceed 24 hours
- **Triazolam** — individual dosing range of 0.125 to 0.25 mg, with 0.25 mg being the maximum individual dose, limited to a single dose, with the total dosage not to exceed 0.25 mg per day, for a maximum duration of 1 day
- **Alprazolam** — individual dosing range of 0.25 to 0.5 mg, with 0.5 mg being the maximum individual dose, limited to a single dose, with the total dosage not to exceed 0.5 mg per day, for a maximum duration of 1 day

References

Anesthesia Organizations

- American Society of Anesthesiologists
- Association of Anaesthetists of Great Britain and Ireland
- Australian Society of Anaesthetists
- Canadian Anaesthesiologists' Society
- European Society for Paediatric Anaesthesiology
- Royal College of Anaesthetists
- Société Française d'Anesthésie et de Réanimation
- Society for Pediatric Anesthesia

Other Organizations

- Royal College of Dental Surgeons of Ontario
- American Dental Association
- American Academy of Pediatrics and the American Academy of Pediatric Dentistry
- Canadian Institute for Health Information
- CSA Group
- College of Physicians and Surgeons of Ontario
- Health Canada
- Public Health Agency of Canada
- Royal College of Physicians and Surgeons of Canada

Patient Safety Organizations

- Anesthesia Patient Safety Foundation:
- Healthcare Excellence Canada
- Institute for Healthcare Improvement

[21] This is the current version as of December 13, 2020. Registrants are responsible for ensuring updates to information.

[22] SCHEDULE 3-DRUGS THAT MAY BE PRESCRIBED (Anti-Anxiety), *Chiropody Act, 1991*, ONTARIO REGULATION 203/94, GENERAL