

Standards For The Use Of Sedation In Non-Hospital Dental Practice

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INTRODUCTION

This document is the standard of practice for administration of sedation with respect to dental services in Alberta. The Standards apply to the administration of sedation in a non-hospital dental practice. Contravention of these Standards constitutes **unprofessional conduct**.

Specifically, the Standards for the Use of Sedation in Non-Hospital Dental Practice apply to:

- Dental practices where sedation is administered;
- Dentists who administer sedation;
- Dentists who administer Modalities 1 through 4 in a dental practice that is within or part of a non-hospital dental practice; and
- Clinical personnel who provide surgical or sedation support to dentists administering sedation.

There are four Modalities of Sedation. These Standards are divided into four sections for the four Modalities. The Modality determines the physical equipment and personnel requirements of the dental setting, the training requirements of the dentist administering the sedation and the clinical personnel assisting the dentist.

The requirements for each Modality, when used separately or in combination by a dentist in a non-hospital dental practice, must be met.

Modality 1: Nitrous Oxide and Oxygen Sedation.

Modality 2: Oral Administration of a **Single Dose of a Single Sedative Drug** (Benzodiazepines or Benzodiazepine-like drugs and antihistamines only).
Supplemental use of a single oral sedative drug falls under Modality 3.

Modality 3: Oral Administration of a Single Sedative Drug with Nitrous Oxide and Oxygen or Supplemental use of a Single Sedative Drug.

Modality 4: Parenteral and Parenteral-like Sedation (Administration of Sedative Drugs other than Oral (intravenous, intramuscular, subcutaneous, submucosal or intranasal)).

Where more than one modality of sedation is administered (including pre-sedation) at a single appointment, a dentist may only assess a fee for the highest modality administered at that appointment.

The ADA+C Dental Facilities Accreditation (DFA) Standards and/or College of Physicians and Surgeons Non-Hospital Surgical Facilities (CPSA NHSF) Standards and Guidelines must be met when administering neurolept analgesia/anesthesia. This document does **NOT** apply to the administration of neurolept analgesia/anesthesia.

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SEDATION

The techniques contained herein are to be used only when indicated and only as an adjunct to appropriate, non-pharmacologic means of patient management.

Sedation is a pharmacologically-induced, minimally to moderately depressed level of consciousness that retains the patient's ability to independently and continually maintain an airway and respond to physical stimuli and verbal command. In dentistry, sedation may be indicated to treat patient anxiety associated with dental treatment, to enable treatment for patients who have cognitive impairment or motor dysfunction which prevents adequate dental treatment, to treat patients below the age of reason or for traumatic or extensive dental procedures. In non-hospital dental practice only minimal to moderate sedation is permitted so that the patient independently and continuously maintains an airway and can respond appropriately to physical stimuli and verbal command.

The techniques utilized **MUST** carry a margin of safety wide enough to prevent a patient from entering into deep sedation or general anesthesia.

Deep sedation is a pharmacologically induced state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command. Any technique leading to these conditions in the patient including neurolept analgesia/anesthesia or dissociative anesthesia, regardless of the route of administration, constitutes "Deep Sedation".

General anesthesia is a loss of all reflexes, including loss of consciousness, irregular respiration, irregular protective reflexes, lack of or incoherent verbal communication and inability to maintain an airway.

General anesthetic drugs (including but not limited to Propofol, Ketamine and ultra-fast acting barbiturates) because of their low margin of safety must not be used for sedation except in accredited facilities by medical and dental anesthetists and Oral and Maxillofacial Surgeons.

Chloral Hydrate must not be used for sedation because it can cause hypersensitivity of the myocardium and its low therapeutic index (i.e. its small margin of safety).

Patients with an American Society of Anesthesiologists (ASA) Classification greater than II must be treated in a Dental Surgical Facility (DSF), Non-Hospital Surgical Facility (NHSF) or hospital if they require sedation.

If a patient's response to sedation results in depression beyond the level of sedation intended, OR entry of the patient into levels of deep sedation or general anesthesia OR if the patient's response or an unanticipated event results in the need for transfer of the care of the patient to another provider, a Dental Surgical Facility, an Non-Hospital Surgical Facility or hospital, it is a **Reportable Incident** and must be reported to the Registrar of the Alberta Dental Association and College (ADA+C). (See Appendix V)

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MODALITY 1 NITROUS OXIDE AND OXYGEN SEDATION

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 SEDATIVE DRUG TO ENSURE THAT THE INTENDED LEVEL OF SEDATION IS NOT EXCEEDED. THESE PATIENTS MUST BE MONITORED MORE CAREFULLY THAN AN INDIVIDUAL WHO HAS COME NON-PRE-SEDATED AND THIS NEEDS TO BE TAKEN INTO CONSIDERATION WHEN NITROUS OXIDE AND OXYGEN IS ADMINISTERED.

1A1 SUMMARY OF RESPONSIBILITIES

To administer Modality 1 sedation, the dentist must:

- Maintain competency related to this modality and participate in appropriate educational programs and continuing competency requirements;
- Sedate **only** to the level of sedation that training permits;
- Register annually on their use of sedation;
- Ensure the dental office is properly staffed and equipped for this modality as prescribed in these Standards;
- Ensure sedation and monitoring equipment conforms to current appropriate Canadian Standards Association (CSA) standards for functional safety and maintenance as per the manufacturer's recommendations and keep a log for review by the ADA+C when requested;
- Ensure the Standards for the Use of Sedation in Non-Hospital Dental Practice are followed by all personnel; and
- Report all Reportable Incidents to the ADA+C.

1A2 EDUCATIONAL REQUIREMENTS

1A2.1 The dentist must successfully complete a training program designed to produce competency in Modality 1 sedation. This program must include:

- Indications;
- Contraindications;
- Patient evaluation;
- Patient selection;
- Pharmacology of relevant drugs; and
- Management of potential adverse reactions.

1A2.2 DDS/DMD degree or equivalent provided that the curriculum included specific training in this modality or training has been obtained through an appropriately approved alternative.

1A2.3 Current Health Care Provider CPR (HCP.CPR) certification.

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1A2.4 The dentist must register annually with the ADA+C at the time of practice permit renewal specifying the modality used, their training for this modality, and their current certification in HCP.CPR.

1A2.5 Approved training programs are as follows:

- Alberta Faculty of Medicine and Dentistry undergraduate, graduate and postgraduate programs;
- Other Faculties of Dentistry undergraduate, graduate and postgraduate programs **approved in advance** by the Alberta Dental Association and College (ADA+C);
- Alberta Faculty of Medicine and Dentistry continuing education programs; and
- Other continuing education courses, **approved in advance** by the ADA+C Sedation Standards Committee, which follow the general principle that they shall be organized and taught by dentists or medical doctors qualified to administer sedation or anesthesia and supplemented as necessary by persons experienced in the technique being taught as the techniques apply to dentistry.

1B ADMINISTRATIVE STANDARDS

1B1 INFECTION PREVENTION AND CONTROL

Refer to the ADA+C Infection Prevention and Control Standards and Risk Management for Dentistry found on the members' website at www.abdentists.com. These standards must be complied with in all facilities. (See Appendix VI)

1B2 PATIENT CONSENT

Written informed consent by the patient or responsible adult for the administration of Modality 1 sedation must be obtained in advance of the administration of any consciousness altering agents as per the ADA+C Code of Ethics, Article A5. An explanation of the risks of sedation by the dentist must be included in the consent process.

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1B3 REPORTABLE INCIDENTS

Reportable Incidents are incidents that occur related to sedation that create a substantial health risk to the patient and include:

- When a reversal agent has been used;
- When a patient's response to sedation results in depression beyond the level of sedation intended or entry of the patient into levels of deep sedation or depression beyond sedation or into general anesthesia;
- Incidents that required emergency interventions inside the office, such as, but not limited to cardiovascular collapse where resuscitation occurred on site and the patient was not subsequently transferred to hospital;
- Transfers of the patient or the care of the patient to another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation, regardless of whether or not the patient was admitted;
- Unexpected treatment by another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation procedure;
- Deaths in office or within 10 days of the sedation procedure; and
- Missing or non-locatable drugs are to be reported as a Reportable Incident.

In the event of a Reportable Incident, a telephone report to the ADA+C must be made by phone to the Registrar of the Alberta Dental Association and College immediately or no later than 9:00 a.m. the following morning for incidents occurring after hours and no later than 9:00 a.m. Monday for incidents occurring on a weekend.

A written report is required within two weeks of the telephone reporting. The report must contain the following:

- Name, age, and sex of the person affected;
- Medical history of the person affected including ASA status;
- Name of witness (es) to the incident;
- Date and name of procedure (if applicable);
- Nature of the incident and treatment rendered;
- Analysis of reasons for the incident;
- Outcome; and
- A copy of the full chart as requested by the ADA+C.

An Outline for a Reportable Incident is found in Appendix V. This outline must be completed and forwarded to the ADA+C.

The ADA+C will review the circumstances with the dentist. If necessary, the ADA+C may immediately suspend the sedation practices on suspicion of continued risk.

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1C SEDATION

1C1 DENTISTS AND AUTHORIZED PROVIDERS WHO ADMINISTER NITROUS OXIDE AND OXYGEN SEDATION

1C1.1 Only the following persons are permitted to administer Nitrous Oxide and Oxygen sedation:

- A dentist;
- A provider authorized to do so by the Health Professions Act of Alberta or other Alberta Enactment. These non-dentist providers must follow the standards established by the ADA+C and their College. In this situation, the dentist providing the dental treatment must have the same sedation training as though they were providing the sedation themselves, be registered with the ADA+C in this modality AND be regularly administering this modality of sedation.

1C1.2 Dentists and authorized providers must hold current certification in Health Care Provider CPR (HCP.CPR).

1C1.3 The dentist and authorized providers must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

1D CLINICAL SUPPORT PERSONNEL

1D1 All clinical staff must have the training and ability to perform Health Care Provider CPR (HCP.CPR) and hold current certification.

1D2 The clinical staff must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

1E PATIENT CARE

1E1 PATIENT CARE – PRE-OPERATIVE

1E1.1 Patient Selection

1E1.1.1 A determination of the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (See Appendix II), careful evaluation of any other factors which may affect their suitability for sedation, and risk assessment must be determined. These findings will be used as a guide in determining the appropriate facility and technique used.

1E1.1.2 ASA classification must be determined and recorded in the patient's clinical record prior to the administration of sedation.

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1E1.1.3 Only ASA I and ASA II patients may be sedated in the dental office. If sedation is required for a patient who is ASA III and higher, they must be referred to an accredited Dental Surgical Facility, Non-Hospital Surgical Facility or hospital.

1E1.2 Sedation Equipment and Drugs

1E1.2.1 It is the dentist's responsibility to ensure that the dental office in which sedation is being performed is equipped with the following:

- Stethoscopes;
- Sphygmomanometer or an automatic blood pressure monitoring machine with cuffs of appropriate sizes;
- Portable apparatus for intermittent positive pressure resuscitation (e.g., Ambubag); and
- Sufficient quantities of medical supplies such as syringes and needles.

1E1.2.2 It is the dentist's responsibility to ensure the dental office contains a sufficient quantity of non-expired drugs for the management of emergencies, including **but not limited to**:

- Oxygen;
- Epinephrine;
- Nitroglycerin;
- Parenteral antihistamine (e.g., Diphenhydramine);
- Bronchodilator (e.g., Salbutamol);
- Acetylsalicylic acid (ASA); and
- Agents for management of hypoglycemia (e.g., glucagon/glucose tablets).

1E1.3 Patient Assessment and Care

1E1.3.1 An accurate and clearly recorded current medical history including age, weight, height, BMI, present and past illnesses, hospital admissions, current medications and/or non-prescription drugs and/or herbal supplements along with dosages, 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.

1E1.3.2 The medical history must form a permanent part of each patient's record consistent in content with Appendix III and must be updated at each appointment.

1E2 PATIENT CARE – INTRA-OPERATIVE

1E2.1 Patients undergoing sedation must be supervised by a dentist and must never be left unattended while sedated.

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- 1E2.2 The patient must be monitored by direct and continuous clinical observation for level of consciousness and assessment of vital signs until there is certainty that the patient has reached a safe level of consciousness to warrant discontinuation of continuous monitoring.
- 1E2.3 During the treatment of all sedated patients, a minimum of two clinical personnel must be in attendance at all times.
- 1E2.4 A staff member of the same sex must accompany a sedated patient to the washroom and be outside the unlocked door and in constant verbal communication with the patient.
- 1E2.5 If the administration of any drug produces depression beyond the level of sedation intended, the dental procedures must be halted. Appropriate support procedures must be administered until the level of depression is no longer beyond that of sedation or until additional emergency assistance is effected. This is a Reportable Incident and must be reported to the Registrar of the Alberta Dental Association and College. (See Appendix V)

1E3 PATIENT CARE – POST-OPERATIVE

- 1E3.1 Recovery status post-operatively must be specifically assessed and recorded by the dentist who must remain in the facility until the patient is discharged.
- 1E3.2 The patient must be discharged to the care of a responsible adult. The only time a dentist may exercise discretion as to whether a patient may be discharged unaccompanied is when Nitrous Oxide and Oxygen alone is the technique used unless the patient is under 18 years of age.
- 1E3.3 Patients under 18 years of age must be discharged to the care of a responsible adult.
- 1E3.4 A person qualified for this sedation modality, and who is responsible for the patient, must not leave the facility until the patient is discharged.
- 1E3.5 **Instructions for Post-Operative Medication.**
Prescribed analgesics or the patient’s own current medications when combined with sedation might delay or interfere with consciousness after discharge. For example, Benzodiazepines and Benzodiazepine-like drugs and their metabolic products are pharmacologically active after discharge and are secreted in the bile after a meal. This can result in “re-sedation” of patients after a meal especially if the patient is concomitantly taking other medications which are also consciousness depressing in their action.

The dentist providing sedation must be well informed of a patient’s medications and be cautious in prescribing post-operative medications.

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1F SPECIFIC REQUIREMENTS FOR NITROUS OXIDE AND OXYGEN

1F1 Gas delivery systems used for the administration of nitrous oxide and oxygen:

- Must have a fail-safe mechanism such that it will not deliver an oxygen concentration of less than 30percent in the delivered gas mixture;
- Must have pipeline inlet fittings, or pin-indexing, that do not permit interchange of connections with oxygen and nitrous oxide;
- Must be checked regularly and receive **appropriate care and maintenance according to manufacturer's instructions. A written record of the maintenance/servicing must be kept on file for review by the Alberta Dental Association and College when requested;**
- Installed systems must be equipped with a common gas outlet compatible with 15mm male and 22mm female conical connectors;
- Must be equipped with connectors, tubing and reservoir bag which allow use of a full-face mask for resuscitative ventilation with 100 percent oxygen;
- Must have a readily available separate reserve supply of oxygen ready for immediate use;
- Must be equipped with a scavenging system installed per manufacturer's specifications; and
- Must have alarm settings and an audio component on monitoring equipment which must be used at all times.
 - A nitrous oxide monitor to measure ambient waste nitrous oxide in the operatory is recommended; or
 - The use of nitrous oxide dosimeters used bi-annually, or where there is a concern about ambient waste nitrous oxide by other dentists or staff in the office is recommended.

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MODALITY 2 ORAL ADMINISTRATION OF A SINGLE DOSE OF A SINGLE SEDATIVE DRUG (Benzodiazepines or Benzodiazepine-like drugs and antihistamines only)

Modality 2 sedation is a single dose of a single oral sedative drug administered in the dental office taking into account the time required for drug absorption.

Supplemental use of a single sedative drug falls under Modality 3 Oral Administration of a Single Sedative Drug with Nitrous Oxide and Oxygen or Supplemental use of a Single Sedative Drug.

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. THESE PATIENTS MUST BE MONITORED MORE CAREFULLY THAN AN INDIVIDUAL WHO HAS COME NON-PRE-SEDATED AND THIS NEEDS TO BE TAKEN INTO CONSIDERATION WHEN ANY ORAL DRUGS ARE ADMINISTERED.

2A1 SUMMARY OF RESPONSIBILITIES

To administer Modality 2 sedation, the dentist must:

- Maintain competency related to this modality and participate in appropriate educational programs and continuing competency requirements;
- Sedate **only** to the level of sedation that training permits;
- Register annually on their use of sedation;
- Ensure the dental office is properly staffed and equipped for this modality as prescribed in these Standards;
- Ensure sedation, anesthesia and monitoring equipment conforms to current appropriate Canadian Standards Association (CSA) standards for functional safety and maintenance as per the manufacturer's recommendations and keep a log for review by the ADA+C when requested;
- Ensure the Standards for the Use of Sedation in Non-Hospital Dental Practice are followed by all personnel; and
- Report all Reportable Incidents to the ADA+C.

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2A2 EDUCATIONAL REQUIREMENTS

2A2.1 The dentist must successfully complete a training program designed to produce competency in Modality 2 sedation. This program must include:

- Indications;
- Contraindications;
- Patient evaluation;
- Patient selection;
- Pharmacology of relevant drugs; and
- Management of potential adverse reactions.

2A2.2 DDS/DMD degree or equivalent provided that curriculum included specific training in this modality or training has been obtained through an appropriately approved alternative.

2A2.3 Current Health Care Provider CPR (HCP.CPR) certification.

2A2.4 The dentist must register annually with the ADA+C at the time of practice permit renewal specifying the modality used, their training for this modality, and their current certification in HCP.CPR.

2A2.5 The training program must be obtained from one or more of the following sources:

- Alberta Faculty of Medicine and Dentistry undergraduate, graduate and postgraduate programs;
- Other Faculties of Dentistry undergraduate, graduate and postgraduate programs approved in advance by the Alberta Dental Association and College (ADA+C);
- Alberta Faculty of Medicine and Dentistry continuing education programs; or
- Other continuing education courses **approved in advance** by the ADA+C Sedation Standards Committee which follow the general principle that they shall be organized and taught by dentists or medical doctors qualified to administer sedation or anesthesia and supplemented as necessary by persons experienced in the technique being taught as they apply to dentistry.

2B ADMINISTRATIVE STANDARDS

2B1 INFECTION PREVENTION AND CONTROL

Refer to the ADA+C Infection Prevention and Control standards and Risk Management for Dentistry found on the members' website at www.abdentists.com. These standards must be complied with in all facilities. (See Appendix VI)

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2B2 PATIENT CONSENT

Written informed consent from the patient or responsible adult for the administration of Modality 2 sedation must be obtained in advance of the administration of any consciousness altering agents as per the ADA+C Code of Ethics, Article A5. An explanation of the risks of sedation by the dentists must be included in the consent process.

2B3 REPORTABLE INCIDENTS

Reportable Incidents are incidents that occur related to sedation that create a substantial health risk to the patient and include:

- When a reversal agent has been used;
- When a patient's response to sedation results in depression beyond the level of sedation intended or entry of the patient into levels of deep sedation or depression beyond sedation or into general anesthesia;
- Incidents that required emergency interventions inside the office, such as, but not limited to cardiovascular collapse where resuscitation occurred on site and the patient was not subsequently transferred to hospital;
- Transfers of the patient or the care of the patient to another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation, regardless of whether or not the patient was admitted;
- Unexpected treatment by another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation procedure;
- Deaths in office or within 10 days of the sedation procedure; and
- Missing or non-locatable drugs are to be reported as a Reportable Incident.

In the event of a Reportable Incident, a telephone report to the ADA+C must be made by phone to the Registrar of the Alberta Dental Association and College immediately or no later than 9:00 a.m. the following morning for incidents occurring after hours and no later than 9:00 a.m. Monday for incidents occurring on a weekend.

A written report is required within two weeks of the telephone reporting. The report must contain the following:

- Name, age, and sex of the person affected;
- Medical history of the person affected including ASA status;
- Name of witness (es) to the incident;
- Date and name of procedure (if applicable);
- Nature of the incident and treatment rendered;

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- Analysis of reasons for the incident;
- Outcome; and
- A copy of the full chart as requested by the ADA+C.

An Outline for a Reportable Incident is found in Appendix V. This outline must be completed and forwarded to the ADA+C.

The ADA+C will review the circumstances with the dentist. If necessary, the ADA+C may immediately suspend the sedation practices on suspicion of continued risk.

2C SEDATION

2C1 DENTISTS AND AUTHORIZED PROVIDERS WHO ADMINISTER ORAL ADMINISTRATION OF A SINGLE SEDATIVE DRUG (Benzodiazepines or Benzodiazepine-like drugs and antihistamines only).

2C1.1 Only the following persons are permitted to administer Oral Administration of a Single Dose of a Single Sedative Drug (Benzodiazepines or Benzodiazepine-like drugs and antihistamines only).

- A dentist;
- A provider authorized to do so under the Health Professions Act of Alberta or other Alberta Enactment. These non-dentist providers must follow the standards established by the ADA+C and their College. In this situation, the dentist providing the dental treatment must have the same sedation training as though they were providing the sedation themselves, be registered with the ADA+C in this modality AND be regularly administering that modality of sedation.

2C1.2 Dentists and authorized providers must hold current certification in Health Care Provider CPR (HCP.CPR).

2C1.3 The dentist and authorized providers must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

2D CLINICAL SUPPORT PERSONNEL

2D1 All clinical staff must have the training and ability to perform Health Care Provider CPR (HCP.CPR) and hold current certification.

2D2 The clinical staff must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

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2E PATIENT CARE

2E1 PATIENT CARE – PRE-OPERATIVE

2E1.1 Patient Selection

- 2E1.1.1 A determination of the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (See Appendix II), careful evaluation of any other factors which may affect their suitability for sedation, and risk assessment must be determined. These findings will be used as a guide in determining the appropriate facility and technique used.
- 2E1.1.2 ASA classification must be determined and recorded in each patient's clinical record prior to the administration of sedation.
- 2E1.1.3 Only ASA I and ASA II patients may be sedated in the dental office. If sedation is required for a patient who is ASA III and higher, they must be referred to an accredited Dental Surgical Facility, Non-Hospital Surgical Facility or hospital.
- 2E1.1.4 There are two exceptions to the requirement that an oral sedative be administered only in the dental office:
- The practitioner has determined that the patient requires an oral sedative to facilitate sleep the night prior to the dental procedure; and
 - The patient's anxiety is such that sedation is required to permit arrival to the dental office.
- 2E1.1.5 In addition to the requirements above in 2E1.1.4, the following additional requirements apply in these two situations:
- Each patient must be screened by the dentist at a prior appointment, with an appropriate medical history.
 - Only one sedative drug can be administered at any one time and this must be a Benzodiazepine or Benzodiazepine-like drug or antihistamine. Oral sedation given outside the dental facility is for anxiolysis only.
 - An opioid must not be used for sedation outside of the dental office.
 - In each case, clear written instructions must be given to the patient or guardian explaining how to take the medication, the need for accompaniment and listing the expected effects and possible side effects of this drug.
 - All pre-sedated patients must be escorted to and from the dental facility by a responsible adult.

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2E1.2 Sedation Equipment and Drugs

2E1.2.1 It is the dentist's responsibility to ensure that the dental office in which sedation is being performed is equipped with the following:

- Stethoscopes;
- Sphygmomanometer or an automatic blood pressure monitoring machine with cuffs of appropriate sizes;
- Portable apparatus for intermittent positive pressure resuscitation (e.g., Ambubag); and
- Sufficient quantities of medical supplies such as syringes and needles.

2E1.2.2 It is the dentist's responsibility to ensure the dental office contains a sufficient quantity of non-expired drugs for the management of emergencies, including **but not limited to**:

- Oxygen;
- Epinephrine;
- Nitroglycerin;
- Parenteral antihistamine (e.g., Diphenhydramine);
- Bronchodilator (e.g., Salbutamol);
- Flumazenil (if a Benzodiazepine is administered);
- Acetylsalicylic acid (ASA); and
- Agents for management of hypoglycemia (e.g., glucagon/glucose tablets).

2E1.3 Patient Assessment and Care

2E1.3.1 An accurate and clearly recorded current medical history including age, weight, height, BMI, present and past illnesses, hospital admissions, current medications and/or non-prescription drugs and/or herbal supplements along with dosages, 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.

2E1.3.2 The medical history must form a permanent part of each patient's record consistent in content with Appendix III and must be updated at each appointment.

2E1.3.3 The patient must be accompanied by a responsible adult to the facility if the patient has been pre-sedated.

2E1.3.4 The patient must be accompanied by a responsible adult from the facility.

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2E2 PATIENT CARE – INTRA-OPERATIVE

- 2E2.1 A single dose of a single oral sedative drug used to induce sedation must be administered to the patient in the dental office taking into account the time required for drug absorption.
- 2E2.2 Patients undergoing sedation must be supervised by an appropriately trained dentist and must never be left unattended while sedated.
- 2E2.3 The patient must be monitored by direct and continuous clinical observation for level of consciousness and assessment of vital signs until there is certainty that the patient has reached a safe level of consciousness to warrant discontinuation of continuous monitoring.
- 2E2.4 During the treatment of all sedated patients, a minimum of two clinical personnel must be in attendance at all times.
- 2E2.5 A staff member of the same sex must accompany a sedated patient to the washroom and be outside the unlocked door and in constant verbal communication with the patient.
- 2E2.6 Should the administration of any drug produce depression beyond the level of sedation intended, the dental procedures must be halted. Appropriate support procedures must be administered until the level of depression is no longer beyond that of sedation, or until additional emergency assistance is effected. Furthermore, this is a **Reportable Incident** and must be reported to the Registrar of the Alberta Dental Association and College. (See Appendix V)

2E3 PATIENT CARE – POST-OPERATIVE

- 2E3.1 Recovery status post-operatively must be specifically assessed and recorded by the dentist who must remain in the facility until the patient is discharged.
- 2E3.2 Patients may only be discharged to the care of a responsible adult taking into account the time required for drug absorption.
- 2E3.3 Patients may only be discharged to the care of a responsible adult when they are orientated to time, person and place relative to pre-anesthetic condition, ambulatory with stable vital signs and alert.
- 2E3.4 The patient must be instructed to not drive a vehicle, operate hazardous machinery, make important decisions or consume alcohol for a minimum of 18 hours or longer if drowsiness or disorientation persists.

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2E3.5 Should a reversal agent be required, the patient must remain in the office for at least 75 minutes after the reversal agent has been administered to assess level of consciousness and vital signs up to and including the period of time the effects of each dose of the reversal agent is expected to last. Attention must be given to the half-life of the sedative administered as this may significantly affect the length of time the patient must remain in the office.

REVERSAL AGENTS MUST NOT BE USED TO EXPEDITE PATIENT DISCHARGE.
REVERSAL AGENTS ARE FOR EMERGENCY USE ONLY.
THE USE OF A REVERSAL AGENT IS A REPORTABLE INCIDENT.

2E3.6 Instructions for Post-Operative Medication

Prescribed analgesics or the patient's own current medications when combined with sedation might delay or interfere with consciousness after discharge. For example, Benzodiazepines and Benzodiazepine-like drugs and their metabolic products are pharmacologically active after discharge and are secreted in the bile after a meal. This can result in "re-sedation" of patients after a meal especially if the patient is concomitantly taking other medications which are also consciousness depressing in their action.

The dentist providing sedation must be well informed of a patient's medications and be cautious in prescribing post-operative medications.

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MODALITY 3 ORAL ADMINISTRATION OF A SINGLE SEDATIVE DRUG WITH NITROUS OXIDE AND OXYGEN OR SUPPLEMENTAL USE OF A SINGLE SEDATIVE DRUG

Modality 3 sedation is the administration of a single oral sedative drug or the combination of an oral sedative drug with Nitrous Oxide and Oxygen or supplemental use of a single sedative drug.

This Modality also includes the supplemental use of a single oral sedative drug. Supplemental use means the administration of small incremental doses of a drug until the desired clinical effect is observed. The supplemental use allows the dentist to administer a second dose of a sedative drug after a reasonable time if the initial dose does not achieve the desired level of sedation

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 SEDATIVE DRUG TO ENSURE THAT THE INTENDED LEVEL OF SEDATION IS NOT EXCEEDED. THESE PATIENTS MUST BE MONITORED MORE CAREFULLY THAN AN INDIVIDUAL WHO HAS COME NON-PRE-SEDATED AND THIS NEEDS TO BE TAKEN INTO CONSIDERATION WHEN ANY ORAL DRUGS ARE ADMINISTERED.

3A1 SUMMARY OF RESPONSIBILITIES

To administer Modality 3 sedation, the dentist must:

- Maintain competency related to this modality and to participate in appropriate educational programs and continuing competency requirements;
- Sedate **only** to the level of sedation that training permits;
- Register annually on their use of sedation;
- Ensure the dental office is properly staffed and equipped for this modality as prescribed in these Standards;
- Ensure sedation, anesthesia and monitoring equipment conforms to current appropriate Canadian Standards Association (CSA) standards for functional safety and maintenance as per the manufacturer's recommendations and keep a log for review by the ADA+C when requested;
- Ensure the Standards for the Use of Sedation in Non-Hospital Dental Practice are followed by all personnel; and
- Report all Reportable Incidents to the ADA+C.

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3A2 EDUCATIONAL REQUIREMENTS

3A2.1 The dentist must successfully complete a training program designed to produce competency in Modality 3 sedation. This program must include:

- Indications;
- Contraindications;
- Patient evaluation;
- Patient selection;
- Pharmacology of relevant drugs; and
- Management of potential adverse reactions.

3A2.2 A sedation program approved by the ADA+C.

3A2.3 Current Health Care Provider CPR (HCP.CPR) certification.

3A2.4 Modality 3 sedation must not be used unless the dentist has had the following additional training:

- Dentists with training that has specifically incorporated the teaching of techniques utilizing supplemental use of a sedative drug, and whose competency has been evaluated and attested to by the course instructor and program director who have been approved by the ADA+C; or
- Dentists who qualify for the administration of deep sedation and general anesthesia; or
- Dentists who qualify for the administration of parenteral and parenteral-like sedation as outlined in Modality 4 sedation.

3A2.5 Those dentists whose prior training is not described herein who practice or intend to practice this modality must submit their qualifications in advance to the ADA+C for approval.

3A2.6 The dentist must register annually with the ADA+C at the time of practice permit renewal specifying the modality used, their training for this modality, and their current certification in HCP.CPR. All dentists who administer Modality 3 sedation require a sedation permit from the ADA+C.

3B ADMINISTRATIVE STANDARDS

3B1 INFECTION PREVENTION AND CONTROL

Refer to the ADA+C Infection Prevention and Control standards and Risk Management for Dentistry found on the members' website at www.abdentists.com. These standards must be complied with in any facility. (See Appendix VI)

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3B2 PATIENT CONSENT

Written informed consent from the patient or responsible adult for the administration of Modality 3 sedation must be obtained in advance of the administration of any consciousness altering agents as per the ADA+C Code of Ethics, Article A5. An explanation of the risks of sedation by the dentist must be included in the consent process.

3B3 REPORTABLE INCIDENTS

Reportable Incidents are incidents that occur related to sedation that create a substantial health risk to the patient and include:

- When a reversal agent has been used;
- When a patient's response to sedation results in depression beyond the level of sedation intended or entry of the patient into levels of deep sedation or depression beyond sedation or into general anesthesia;
- Incidents that required emergency interventions inside the office, such as, but not limited to cardiovascular collapse where resuscitation occurred on site and the patient was not subsequently transferred to hospital;
- Transfers of the patient or the care of the patient to another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation, regardless of whether or not the patient was admitted;
- Unexpected treatment by another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation procedure;
- Deaths in office or within 10 days of the sedation procedure; and
- Missing or non-locatable drugs are to be reported as a Reportable Incident.

In the event of a Reportable Incident, a telephone report to the ADA+C must be made by phone to the Registrar of the Alberta Dental Association and College immediately or no later than 9:00 a.m. the following morning for incidents occurring after hours and no later than 9:00 a.m. Monday for incidents occurring on a weekend.

A written report is required within two weeks of the telephone reporting. The report must contain the following:

- Name, age, and sex of the person affected;
- Medical history of the person affected including ASA status;
- Name of witness (es) to the incident;
- Date and name of procedure (if applicable);
- Nature of the incident and treatment rendered;
- Analysis of reasons for the incident;
- Outcome; and

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- A copy of the full chart as requested by the ADA+C.

An Outline for a Reportable Incident is found in Appendix V. This outline must be used and forwarded to the ADA+C.

The ADA+C will review the circumstances with the dentist. If necessary, the ADA+C may immediately suspend the sedation practices on suspicion of continued risk.

3C SEDATION

3C1 DENTISTS AND AUTHORIZED PROVIDERS WHO ADMINISTER ORAL ADMINISTRATION OF A SINGLE SEDATIVE DRUG WITH NITROUS OXIDE AND OXYGEN OR SUPPLEMENTAL USE OF A SINGLE SEDATIVE DRUG

- 3C1.1 Only the following persons are permitted to administer Oral Administration of a Single Sedative Drug with Nitrous Oxide and Oxygen or Supplemental use of a Single Sedative Drug:
- A dentist,
 - A provider authorized to do so under the Health Professions Act of Alberta or other Alberta Enactment. These non-dentist providers must follow the standards established by the ADA+C and their College. In this situation, the dentist providing the dental treatment must have the same sedation training as though they were providing the sedation themselves, be registered with the ADA+C in this modality AND be regularly administering this modality of sedation.
- 3C1.2 Dentists and authorized providers must hold current certification in Health Care Provider CPR (HCP.CPR).
- 3C1.3 The dentist and authorized providers must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

3D CLINICAL SUPPORT PERSONNEL

- 3D1 All clinical staff must have the training and ability to perform Health Care Provider CPR (HCP.CPR) and hold current certification.
- 3D2 The clinical staff must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

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3E PATIENT CARE

3E1 PATIENT CARE – PRE-OPERATIVE

3E1.1 Patient Selection

- 3E1.1.1 A determination of the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (See Appendix II), careful evaluation of any other factors which may affect their suitability for sedation, and risk assessment must be determined. These findings will be used as a guide in determining the appropriate facility and technique used.
- 3E1.1.2 ASA classification must be determined and recorded in the patient's clinical record prior to the administration of sedation.
- 3E1.1.3 Only ASA I and ASA II patients may be sedated in the dental office. If sedation is required for a patient who is ASA III and higher, they must be referred to an accredited Dental Surgical Facility, Non-Hospital Surgical Facility or hospital.
- 3E1.1.4 Dentists must make themselves aware if the patient is already taking a drug with sedative properties which has not been prescribed by the dentist.
- 3E1.1.5 If an oral sedative has been administered, supplemental use of nitrous oxide and oxygen must be slowly administered to achieve the signs of sedation, with vigilant assessment of the level of consciousness.

3E1.2 Sedation Equipment and Drugs

- 3E1.2.1 It is the dentist's responsibility to ensure that the dental office in which sedation is being performed is equipped with the following:
- Stethoscopes;
 - Reserve source of oxygen;
 - Portable apparatus for intermittent positive pressure resuscitation (e.g., Ambubag);
 - Pulse oximeter;
 - Sphygmomanometer or an automatic blood pressure monitoring machine with cuffs of appropriate sizes;
 - Portable auxiliary battery-operated systems for light, suction and oxygen;
 - Full face masks of appropriate sizes and connectors. All mouthpieces, masks, and other devices in contact with the patient or unfiltered exhaled gases must be single use and disposable OR as per ADA+C IPC Standards, must be reprocessed between patients in accordance with the manufacturer's instructions (See Appendix VI); and
 - Sufficient quantities of medical supplies such as syringes and needles.

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3E1.2.2 It is the dentist's responsibility to ensure the dental office contains a sufficient quantity of non-expired drugs for management of emergencies, including **but not limited to**:

- Oxygen;
- Epinephrine;
- Nitroglycerin;
- Parenteral antihistamine (e.g., Diphenhydramine);
- Bronchodilator (e.g., Salbutamol);
- Flumazenil (if a Benzodiazepine is administered);
- Acetylsalicylic acid (ASA); and
- Agents for management of hypoglycemia (e.g., glucagon/glucose tablets).

3E1.3 Sedation Protocol

The patient must have had nothing to eat or drink for a period consistent with the currently accepted standards for fasting. Possible exceptions to this are usual medications or preoperative medications which may be taken as deemed necessary by the dentist.

3E1.4 Patient Assessment and Care

3E1.4.1 An accurate and clearly recorded current medical history including age, weight, height, BMI, present and past illnesses, hospital admissions, current medications and/or non-prescription drugs and/or herbal supplements along with dosages, 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.

3E1.4.2 The medical history must form a permanent part of each patient's record consistent in content with Appendix III and must be updated at each appointment.

3E2 PATIENT CARE – INTRA-OPERATIVE

3E2.1 Patients undergoing sedation must be supervised by an appropriately trained dentist and must **never** be left unattended while sedated. The patient must be monitored by clinical observation of the level of consciousness.

3E2.2 Clinical observation must be supplemented by the following means of monitoring throughout the period of time the patient is under the effects of the sedation that has been administered:

- Continuous pulse oximeter monitoring of hemoglobin oxygen saturation recorded at intervals of 15 minutes;

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- Blood pressure and pulse taken and recorded preoperatively and throughout the sedation period at intervals of 15 minutes;
- Respiration rate recorded at intervals of 15 minutes; and
- Time and dose of local anesthetic and/or any other drugs administered.

This monitoring and observation must be recorded in the patient's sedation record.

3E2.3 A sedation record must be kept consistent with Appendix IV.

3E2.4 Alarm settings and their audio component on monitoring equipment must be utilized at all times.

3E2.5 During the treatment of all sedated patients, a minimum of two clinical personnel must be in attendance at all times.

3E2.6 A staff member of the same sex must accompany a sedated patient to the washroom and be outside the unlocked door and in constant verbal communication with the patient.

3E2.7 Should the administration of any drug produce depression beyond the level of sedation intended, the dental procedures must be halted. Appropriate support procedures must be administered until the level of depression is no longer beyond that of sedation, or until additional emergency assistance is effected. Furthermore, this is a **Reportable Incident**.

3E3 PATIENT CARE – POST-OPERATIVE

3E3.1 Should a reversal agent be required, the patient must remain in the office for at least 75 minutes after the reversal agent has been administered to assess level of consciousness and vital signs up to and including the period of time the effects of each dose of the reversal agent is expected to last. Attention must be given to the half-life of the sedative administered as this may significantly affect the length of time the patient must remain in the office.

REVERSAL AGENTS MUST NOT BE USED TO EXPEDITE PATIENT DISCHARGE.
REVERSAL AGENTS ARE FOR EMERGENCY USE ONLY.
THE USE OF A REVERSAL AGENT IS A REPORTABLE INCIDENT.

3E3.2 The patient may be discharged only once they are alert and have met the following criteria:

- Conscious and oriented to time, person **AND** place;
- Vital signs are stable; and
- Ambulatory.

3E3.3 The patient must be discharged to the care of a responsible adult.

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3E3.4 **Written** post-sedation instructions must be given to the patient **AND** responsible adult. The patient must be instructed to not drive a vehicle, operate hazardous machinery, make important decisions or consume alcohol for a minimum of 18 hours or longer if drowsiness or disorientation persists.

3E3.5 The patient must be given a 24-hour contact telephone number for the dentist **AND** sedation provider.

3E3.6 Instructions for Post-Operative Medication

Prescribed analgesics or the patient's own current medications when combined with sedation might delay or interfere with consciousness after discharge. For example, Benzodiazepines and Benzodiazepine-like drugs and their metabolic products are pharmacologically active after discharge and are secreted in the bile after a meal. This can result in "re-sedation" of patients after a meal especially if the patient is concomitantly taking other medications which are also consciousness depressing in their action.

The dentist providing sedation must be well informed of a patient's medications and be cautious in prescribing post-operative medications.

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MODALITY 4 PARENTERAL AND PARENTERAL-LIKE SEDATION

Modality 4 sedation is intravenous use of a single Benzodiazepine, Benzodiazepine-like drug or antihistamine. Additional sedative drugs must not be used by any route of administration unless the dentist has had additional training and a permit outlined in section 4A2.10.

Parenteral and parenteral-like sedation may be accomplished utilizing any one of the following routes of administration: intravenous, intramuscular, subcutaneous, submucosal, intranasal, or rectal.

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 SEDATIVE DRUG TO ENSURE THAT THE INTENDED LEVEL OF SEDATION IS NOT EXCEEDED. THESE PATIENTS MUST BE MONITORED MORE CAREFULLY THAN AN INDIVIDUAL WHO HAS COME NON-PRE-SEDATED AND THIS NEEDS TO BE TAKEN INTO CONSIDERATION WHEN IV OR ANY ORAL DRUGS ARE ADMINISTERED.

4A1 SUMMARY OF RESPONSIBILITIES

To administer Modality 4 sedation, the dentist must:

- Maintain competency related to this modality and to participate in appropriate educational programs and continuing competency requirements;
- Sedate **only** to the level of sedation that training permits;
- Register annually on their use of sedation;
- Ensure the dental office is properly staffed and equipped for this modality as prescribed in these Standards;
- Ensure sedation, anesthesia and monitoring equipment conforms to current appropriate Canadian Standards Association (CSA) standards for functional safety and maintenance as per the manufacturer's recommendations and keep a log for review by the ADA+C when requested;
- Ensure the Standards for the Use of Sedation in Non-Hospital Dental Practice are followed by all personnel; and
- Report all Reportable Incidents to the ADA+C.

4A2 EDUCATIONAL REQUIREMENTS

4A2.1 The dentist must successfully complete a training program designed to produce competency in Modality 4 sedation. This program must include:

- Indications;
- Contraindications;
- Patient evaluation;
- Patient selection;

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- Pharmacology of relevant drugs; and
- Management of potential adverse reactions.

4A2.2 Modality 4 sedation using more than one sedative drug must not be administered unless the dentist has had the following additional training:

- Dentists with training that has specifically incorporated the teaching of techniques utilizing more than one sedative agent, and whose competency has been evaluated and attested to by the course instructor and program director who have been approved by the ADA+C; or
- Dentists who qualify for the administration of deep sedation and general anesthesia; or
- Dentists who qualify for the administration of parenteral and parenteral-like sedation.

4A2.3 Those dentists whose prior training is not described herein who practice or intend to practice this modality must submit their qualifications **in advance** to the ADA+C for approval.

4A2.4 Modality 4 sedation requires the dentist maintain current certification in ACLS.

4A2.5 If a dentist is administering Modality 4 sedation to children between the ages of 18 months and 8 years, they must maintain current certification in PALS.

4A2.6 The dentist must register annually with the ADA+C at the time of practice permit renewal specifying the modality used, their training for this modality, and their current certification in ACLS and PALS. Dentists administering Modality 4 require a sedation permit from the ADA+C.

4A2.7 To administer Intravenous supplemental use of a single sedative, the dentist must have:

- Successful completion of a course of instruction in parenteral sedation that **must be affiliated with an accredited educational institution** and **approved in advance** by the ADA+C and meets the didactic and clinical requirements outlined below;
- A certificate or other evidence of satisfactory completion of the course and a description of the program signed by the course director must be submitted to the ADA+C for consideration. Completion of such a course will be entered onto the dentist's record; and
- Evidence of current certification in a provider course in ACLS and PALS if children between the ages of 18 months and 8 years are treated. ACLS and PALS must be updated every two years with a refresher course or re-certification.

4A2.8 Parenteral Sedation Course of Instruction **Didactic Requirements:**

- The training shall include a minimum of 40 hours of lecture and seminar time presented by dentists formally trained in anesthesia and/or sedation as they apply to dentistry; and
- Dentists in a hospital internship or general practice residency program recognized by the ADA+C **may** be given credit for this didactic requirement, provided that documentation of formal training and competency is obtained from the program director.

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4A2.9 Parenteral Sedation Course of Instruction **Clinical Requirements:**

- The training shall include additional supervised **application** of parenteral sedation **concurrent with dental treatment performed on a minimum of 20 patients in an accredited educational institution**. Observation or assisting of another provider on such cases is **insufficient** to meet this clinical requirement; and
- Intravenous supplemental use of a single Benzodiazepine sedative may be utilized only by those with the training specified above. Only those dentists with additional formal training are permitted to utilize more than a single agent.

4A2.10 Other than a single Benzodiazepine, Benzodiazepine-like drug or antihistamine, additional sedative drugs must not be used by any route of administration unless the dentist has had the following advanced training and has a permit from the ADA+C:

- Dentists who qualify for the administration of deep sedation or general anesthesia as outlined in the Dental Facility Standards; and
- Dentists with formal training that has incorporated the teaching of techniques that specifically utilized parenteral sedation using more than one sedative drug. Such training must be submitted in writing and **approved in advance** by the ADA+C.

4A2.11 Dentists who are authorized to administer deep sedation and general anesthesia as outlined in the DFA Standards are qualified to administer this modality.

4B ADMINISTRATIVE STANDARDS

4B1 INFECTION PREVENTION AND CONTROL

Refer to the ADA+C Infection Prevention and Control Standards and Risk Management for Dentistry found on the members' website at www.abdentists.com. These standards must be complied with in all facilities. (See Appendix VI)

4B2 PATIENT CONSENT

Written informed consent from the patient or responsible adult for the administration of Modality 4 sedation must be obtained in advance of the administration of any consciousness altering agents as per the ADA+C Code of Ethics, Article A5. An explanation of the risks of sedation by the dentist must be included in the consent process.

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4B3 REPORTABLE INCIDENTS

Reportable Incidents are incidents that occur related to sedation that create a substantial health risk to the patient and include:

- When a reversal agent has been used;
- When a patient's response to sedation results in depression beyond the level of sedation intended or entry of the patient into levels of deep sedation or depression beyond sedation or into general anesthesia;
- Incidents that required emergency interventions inside the office, such as, but not limited to cardiovascular collapse where resuscitation occurred on site and the patient was not subsequently transferred to hospital;
- Transfers of the patient or the care of the patient to another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation, regardless of whether or not the patient was admitted;
- Unexpected treatment by another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation procedure;
- Deaths in office or within 10 days of the sedation procedure; and
- Missing or non-locatable drugs are to be reported as a Reportable Incident.

In the event of a Reportable Incident, a telephone report to the ADA+C must be made by phone to the Registrar of the Alberta Dental Association and College immediately or no later than 9:00 a.m. the following morning for incidents occurring after hours and no later than 9:00 a.m. Monday for incidents occurring on a weekend.

A written report is required within two weeks of the telephone reporting. The report must contain the following:

- Name, age, and sex of the person affected;
- Medical history of the person affected including ASA status;
- Name of witness (es) to the incident;
- Date and name of procedure (if applicable);
- Nature of the incident and treatment rendered;
- Analysis of reasons for the incident;
- Outcome; and
- A copy of the full chart as requested by the ADA+C.

An Outline for a Reportable Incident is found in Appendix V. This outline must be used and forwarded to the ADA+C.

In the event of a death within the office, the Medical Examiner must be notified prior to moving the body or removal of any lines or tubes from the body.

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The ADA+C will review the circumstances with the dentist. If necessary, the ADA+C may immediately suspend the sedation practices on suspicion of continued risk.

4C SEDATION

4C1 DENTISTS AND AUTHORIZED PROVIDERS WHO ADMINISTER PARENTERAL AND PARENTERAL-LIKE SEDATION

4C1.1 Only the following persons are permitted to administer parenteral and parenteral-like sedation.

- A dentist,
- A provider authorized to do so under the Health Professions Act of Alberta or other Alberta Enactment. These non-dentist providers must follow the standards established by the ADA+C and their College. In this situation, the dentist providing the dental treatment must have the same sedation training as though they were providing the sedation themselves, be registered with the ADA+C in this modality AND be regularly administering that modality of sedation.

4C1.2 The dentist and authorized providers must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

4D CLINICAL SUPPORT PERSONNEL

4D1 All clinical staff must have the training and ability to perform Health Care Provider CPR (HCP.CPR) and hold current certification.

4D2 The clinical staff must be prepared to recognize and treat adverse responses utilizing appropriate emergency equipment and drugs when necessary.

4E PATIENT CARE

4E1 PATIENT CARE – PRE-OPERATIVE

4E1.1 Patient Selection

4E1.1.1 A determination of the patient's American Society of Anesthesiologists (ASA) Physical Status Classification (see Appendix II), careful evaluation of any other factors which may affect their suitability for sedation, and risk assessment must be determined. These findings will be used as a guide in determining the appropriate facility and technique used.

4E1.1.2 ASA classification must be determined and recorded on the patient's clinical record prior to the administration of sedation.

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4E1.1.3 Only ASA I and ASA II patients may be sedated in the dental office. If sedation is required for a patient who is ASA III and higher, they must be referred to an accredited Dental Surgical Facility, Non-Hospital Surgical Facility or hospital.

4E1.1.4 Patients with a history of sleep apnea, upper airway anomalies or disorders or having a BMI>35 must be excluded from Modality 4 sedation in a dentist's office. These patients must be treated in an accredited Dental Surgical Facility, Non-Hospital Surgical Facility or hospital.

4E1.1.5 Dentists must make themselves aware if the patient is already taking a drug with sedative properties which has not been prescribed by the dentist.

4E1.2 Sedation Equipment and Drugs

4E1.2.1 All anesthetic and monitoring equipment must receive regular documented service and maintenance by qualified personnel according to the manufacturer's specifications, or annually, whichever is more frequent.

4E1.2.2 It is the dentist's responsibility to ensure that the dental office in which sedation is being performed is equipped with the following equipment as required by ACLS/PALS Standards and includes, **but is not limited to:**

- Stethoscopes;
- Reserve source of oxygen sufficient for the number of patients being treated;
- Portable apparatus for intermittent positive pressure resuscitation (e.g., Ambubag);
- Pulse oximeter;
- Sphygmomanometers or an automatic blood pressure monitoring machine with cuffs of appropriate sizes;
- Tonsil suction (Yankauer) adaptable to the suction outlet;
- Full face masks of appropriate sizes and connectors. All mouthpieces, masks and other devices in contact with the patient or unfiltered exhaled gases must be single use and disposable OR as per ADA+C IPC Standards, must be reprocessed between patients in accordance with the manufactures instructions; (See Appendix VI)
- Adequate selection of oral airways;
- Portable auxiliary battery-operated systems for light, suction and oxygen;
- Endotracheal tubes and laryngoscopes (IF TRAINED IN THEIR PROPER USAGE or a Laryngeal Mask Airway (LMA);
- Apparatus for a surgical airway (IF TRAINED IN SECURING A SURGICAL AIRWAY);
- IV set up;
- Minimum Lead 2 Automated External Defibrillator (AED); and
- Sufficient quantities of medical supplies such as syringes and needles.

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4E1.2.3 It is the dentist's responsibility to ensure the dental office contains a sufficient quantity of non-expired drugs for the management of emergencies, including **but not limited to**:

- Oxygen;
- Epinephrine;
- Nitroglycerin;
- Parenteral antihistamine (e.g., Diphenhydramine);
- Bronchodilator (e.g., Salbutamol);
- Parenteral vasopressor;
- Parenteral atropine;
- Parenteral corticosteroid;
- Parenteral lidocaine;
- Reversal agents (e.g., Flumazenil, if benzodiazepines are administered)
(e.g., Naloxone, if opioids are administered);
- Intravenous fluids;
- Acetylsalicylic acid (ASA); and
- Agents for management of hypoglycemia (e.g., glucagon/glucose tablets).

4E1.3 Sedation Team for Parenteral Sedation

4E1.3.1 Parenteral and parenteral-like sedation for ambulatory dental patients must be administered through the combined efforts of the sedation team.

4E1.3.2 The sedation team includes **the dentist, the dental assistant,** and the **sedation/monitoring assistant.**

4E1.3.3 The dentist is directly responsible for the sedation. The dental assistant is responsible for assisting the dentist in dental procedure. The sedation/monitoring assistant's only duty is to continuously observe and monitor the patient's vital signs and verbally report the patient's status to the dentist.

4E1.3.4 It is the **DENTIST'S RESPONSIBILITY** to ensure that the **sedation/monitoring assistant** is adequately trained to perform their duties and has the necessary skills to assist the dentist/sedation provider in performing the following:

- Monitoring of vital signs throughout the procedure and post-procedure until the patient has fully regained consciousness;
- Assessing and maintaining a patent airway;
- Recording appropriate records;
- Venipuncture;
- Administering medications as directed by the dentist; and
- Assisting in emergency procedures.

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4E1.4 Patient Assessment and Care

- 4E1.4.1 An accurate and clearly recorded current medical history including age, weight, height, BMI, present and past illnesses, hospital admissions, current medications and/or non-prescription drugs and/or herbal supplements along with dosages, 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.
- 4E1.4.2 The medical history must form a permanent part of each patient's record consistent in content with Appendix III and must be updated at each appointment.

4E1.5 Sedation Protocol

- 4E1.5.1 The medical history must be reviewed for any changes at each sedation appointment. Such review must be documented in the permanent record.
- 4E1.5.2 The patient must not have had solid food for a minimum of six hours prior to the appointment. Clear fluids may be taken up to two hours prior to the appointment. There may be usual medications or preoperative medications which may be taken as deemed necessary by the dentist and/or sedation provider, if the dentist is NOT the sedation provider such as in a Dental Surgical Facility.

4E2 PATIENT CARE – INTRA-OPERATIVE

- 4E2.1 Patients undergoing sedation must be supervised by an appropriately trained dentist and must **never** be left unattended while sedated. The patient must be monitored by clinical observation of the level of consciousness.
- 4E2.2 During the treatment of all sedated patients, a minimum of two clinical personnel must be in attendance at all times.
- 4E2.3 The patient must be **constantly** attended by the dentist and/or appropriately trained staff from the time of administration of the sedative until the patient is discharged.
- 4E2.4 A person qualified for this sedation technique and who is responsible for the patient must not leave the facility until the patient is discharged.
- 4E2.5 Clinical observation must be supplemented by the following means of monitoring throughout the period of time that the patient is under the effects of the sedation that has been administered:
- Continuous pulse oximeter monitoring of hemoglobin oxygen saturation recorded at intervals of 15 minutes;

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- Blood pressure and pulse must be taken and recorded preoperatively and throughout the sedation period at intervals of 15 minutes;
- Respiration rate recorded at intervals 15 minutes; and
- Time and dose of local anesthetic administered.

This monitoring and observation must be recorded in the patient's sedation record.

4E2.6 A sedation record must be kept consistent with Appendix IV.

4E2.7 When intravenous sedation is used, an indwelling IV catheter must be *in situ* and patent at all times during the procedure. Use of an intravenous needle requires a continuous fluid administration to maintain vein patency.

4E2.8 Alarm settings and their audio component on monitoring equipment must be utilized at all times.

4E2.9 A staff member of the same sex must accompany a sedated patient to the washroom and be outside the unlocked door and in constant verbal communication with the patient.

4E2.10 If the administration of any drug produces depression beyond the level of sedation intended, the dental procedures must be halted. Appropriate support procedures must be administered until the level of depression is no longer beyond that of sedation, or until additional emergency assistance is affected. Furthermore, this is a **Reportable Incident**.

4E2.11 Should a reversal agent be required, the patient must remain in the office for at least 75 minutes after the reversal agent has been administered to assess level of consciousness and vital signs up to and including the period of time the effects of each dose of the reversal agent is expected to last. Attention must be given to the half-life of the sedative administered as this may significantly affect the length of time the patient must remain in the office.

REVERSAL AGENTS MUST NOT BE USED TO EXPEDITE PATIENT DISCHARGE.
REVERSAL AGENTS ARE FOR EMERGENCY USE ONLY.
THE USE OF A REVERSAL AGENT IS A REPORTABLE INCIDENT.

4E3 PATIENT CARE – POST-OPERATIVE

4E3.1 Recovery status post-operatively must be specifically assessed and recorded by the dentist who must remain in the facility until the patient is discharged.

4E3.2 A person qualified for each sedation modality, and who is responsible for the patient, must not leave the facility until the patient is discharged.

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4E3.3 **Instructions for Post-Operative Medication**

Prescribed analgesics or the patient's own current medications when combined with sedation might delay or interfere with consciousness after discharge. For example, Benzodiazepines and Benzodiazepine-like drugs and their metabolic products are pharmacologically active after discharge and are secreted in the bile after a meal. This can result in "re-sedation" of patients after a meal especially if the patient is concomitantly taking other medications which are also consciousness depressing in their action.

The dentist providing sedation must be well informed of a patient's medications and be cautious in prescribing post-operative medications.

4E4 RECOVERY PROTOCOL

4E4.1 The recovery supervisor, under the dentist's supervision, is responsible for supervising and monitoring patients in the recovery area. The recovery supervisor can be any of the sedation team provided another case is not being done.

4E4.2 The patient may only be discharged once the **dentist** or **sedation provider** decides that the patient meets the criteria for discharge as outlined elsewhere in the document.

4E4.3 Where there is a separate dentist providing the sedation, then a sedation assistant or recovery supervisor is not required if the sedation provider is not providing other sedations. In this case, the dentist or second dentist/physician assumes the roles of the sedation assistant and the recovery supervisor.

4E4.4 As described below, recovery accommodation and supervision is mandatory for Modality 4 sedation and throughout the period of time the patient is under the effects of the sedation:

- The recovery area or room must be available to accommodate the post-sedation patient from the completion of the procedure until the patient meets the criteria for discharge. Oxygen and appropriate suction and lighting must be readily available. The operatory can act as a recovery room;
- A sufficient number of recovery areas must be available to provide adequate recovery time for each case. Caseload must be governed accordingly; and
- Supervision and appropriately recorded monitoring by the recovery supervisor must occur throughout the recovery period until the patient meets the criteria for discharge.

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4E5 DISCHARGE PROTOCOL

4E5.1 The patient may be discharged once they are alert and have met the following criteria:

- Conscious and oriented to time, person **AND** place;
- Vital signs are stable; and
- Ambulatory.

4E5.2 The patient must be discharged to the care of a responsible adult.

4E5.3 **Written** post-sedation instructions must be given and explained to **both** the patient and accompanying adult. The patient must be instructed to not drive a vehicle, operate hazardous machinery or consume alcohol for a minimum of 18 hours or longer if drowsiness or disorientation persists.

4E5.4 **The patient must be given a 24-hour telephone contact number for the dentist and the sedation provider.**

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ACLS: Advanced Cardiac Life Support

AED: Automated External Defibrillator

ASA: American Society of Anesthesiologists

Analgesia: the diminution or elimination of pain.

Anxiolysis: the diminution or elimination of anxiety without change to protective reflexes.

BMI: a formula to assess whether a person is within normal weight limits, underweight, overweight, or at risk of becoming overweight or underweight.

Child: a person between eighteen months and eight years of age, or up to 80 pounds (36 kg).

Combination Inhalation and Enteral Sedation (combined sedation) – sedation using inhalation and enteral agents.

Continual: repeated regularly and frequently in a steady succession.

Continuous: prolonged without any interruption at any time.

Dentist: a registered member of the Alberta Dental Association and College (ADA+C).

DSF: Dental Surgical Facility

A facility where Dental Surgical Services are provided and is accredited by the Alberta Dental Association and College (ADA+C).

General Anesthesia: is a loss of all reflexes, including loss of consciousness, irregular respiration, irregular protective reflexes, lack of or incoherent verbal communication, and inability to maintain an airway.

Health Care Provider CPR (HCP.CPR)

Immediately Available: on site in the facility and available for immediate use.

Local Anesthesia: the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

May: indicates freedom or liberty to follow a reasonable alternative.

Must/Should: indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

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Nitrous Oxide and Oxygen: a colorless gas used alone or when used in combination with sedative agents may produce anxiety, minimal sedation, deep sedation or general anesthesia.

NHSF: Non-Hospital Surgical Facility

Non-hospital diagnostic and treatment facilities in which medical and Dental Surgical Services performed are deemed as having sufficient risk of potential harm to a patient. Dental Surgical Services may be performed in these facilities. These facilities must register with and maintain accreditation by the College of Physicians and Surgeons of Alberta (CPSA) and the Alberta Dental Association and College (ADA+C) as a Non-Hospital Surgical Facility.

PALS: Pediatric Advanced Life Support

Reportable Incidents: are incidents that occur related to sedation that create a substantial health risk to the patient and include:

- When a reversal agent has been used;
- When a patient's response to sedation results in depression beyond the level of sedation intended or entry of the patient into levels of deep sedation or depression beyond sedation or into general anesthesia;
- Incidents that required emergency interventions inside the office, such as, but not limited to cardiovascular collapse where resuscitation occurred on site and the patient was not subsequently transferred to hospital;
- Transfers of the patient or the care of the patient to another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation, regardless of whether or not the patient was admitted;
- Unexpected treatment by another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation procedure;
- Deaths in office or within 10 days of the sedation procedure; and
- Missing or non-locatable drugs are to be reported as a Reportable Incident.

In the event of a Reportable Incident, a telephone report to the ADA+C followed by a written report within two weeks of the telephone reporting. (See Appendix V) The report must contain the following:

- Name, age, and sex of the person affected;
- Medical history of the person affected including ASA classification;
- Name of witness (es) to the incident;
- Date and name of procedure (if applicable);
- Nature of the incident and treatment rendered;
- Analysis of reasons for the incident;
- Outcome; and
- The full chart as requested by the ADA+C.

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Sedation: a depressed level of consciousness.

In accord with the particular definition, the drugs and/or techniques used must carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would be considered to be in a state of deep sedation.

Minimal Sedation: the patient with minimal sedation is able to maintain their own airway and to clear their airway should foreign material enter the larynx or pharynx.

- respiration is normal;
- the patient responds normally to tactile stimulation and verbal command;
- eye movements are normal;
- protective reflexes are intact; and
- amnesia may or not be present.

Moderate Sedation: with moderate sedation, the patient responds to verbal commands either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patient airway and spontaneous ventilation is adequate. Cardiovascular function is maintained.

Deep Sedation: is a pharmacologically-induced state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command. Any technique leading to these conditions in the patient including neurolept analgesia/anesthesia or dissociative anesthesia, regardless of the route of administration, constitutes "Deep Sedation".

Should: indicates the recommended manner to obtain the standard; highly desirable.

Supervision: control of personnel from **within** the facility.

Supplemental use: the administration of small incremental doses of a drug until the desired clinical effect is observed.

In accordance with this particular definition, supplemental use of oral medications for the purposes of sedation is unpredictable. **Repeated dosing of orally administered sedative drugs may result in an alteration of the state of consciousness beyond the intent of the practitioner. The maximum recommended dose of an oral medication must not be exceeded. For the purpose of this document, "supplemental use" of a single oral sedative falls under Modality 3. Attention must be given to the half-life of the drug(s) administered as this may significantly affect the length of time the patient must remain in the office.**

Time-Oriented Anesthesia Record: documentation at appropriate intervals or drugs, doses and physiologic data obtained during patient monitoring.

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Routes of Administration

Enteral: any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa (i.e., oral, rectal, sublingual).

Inhalation: a technique of administration in which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

Parenteral and Parenteral-like: a technique of administration in which the drug bypasses the gastrointestinal (GI) tract (i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC)).

Transdermal/Transmucosal: a technique of administration in which the drug is administered by patch or iontophoresis.

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ASA I: A normally healthy patient (*ASA = American Society of Anesthesiologists*).

ASA II: A patient with mild systemic disease (e.g., controlled diabetes or pregnancy).

ASA III: A patient with severe systemic disease (e.g., uncontrolled thyroid function).

ASA IV: A patient with severe systemic disease that is 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.

E: Emergency operation of any variety (used to modify one of the above classification, e.g., ASA II-E).

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APPENDIX III

Medical History Questionnaire

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MEDICAL HISTORY QUESTIONNAIRE

MEDICAL ALERT:

NAME: MR./MISS./MRS./MS./DR.

DATE OF BIRTH (DAY/MONTH/YEAR): / /

ADDRESS (HOME):

PHONE:

ADDRESS (BUSINESS):

PHONE:

OCCUPATION:

WHO REFERRED YOU TO OUR OFFICE?

IN CASE OF EMERGENCY, WE SHOULD NOTIFY:

NAME:

RELATIONSHIP:

DAY-TIME PHONE:

NAME OF FAMILY DOCTOR:

PHONE OR ADDRESS:

(1) NAME OF MEDICAL SPECIALIST:

AREA OF SPECIALITY:

PHONE OR ADDRESS:

(2) NAME OF MEDICAL SPECIALIST:

AREA OF SPECIALITY:

PHONE OR ADDRESS:

The following information is required to enable us to provide you with the best possible dental care. All information is strictly private, and is protected by doctor-patient confidentiality. The dentist will review the questions and explain any that you do not understand. Please fill in the entire form.

1. Are you being treated for any medical condition at the present or have you been treated within the past year? If so, why?

YES NO NOT SURE/MAYBE

2. When was your last medical checkup?

3. Has there been any change in your general health in the past year? If yes, please explain.

YES NO NOT SURE/MAYBE

4. Are you taking any medications, non-prescription drugs or herbal supplements of any kind? If yes, please list.

YES NO NOT SURE/MAYBE

5. Do you have any allergies? If you answered yes, please list using the categories below:

YES NO NOT SURE/MAYBE

- a) medications
- b) latex/rubber products
- c) other (e.g. hayfever, foods)

6. Have you ever had a peculiar or adverse reaction to any medicines or injections? If yes, please explain.

YES NO NOT SURE/MAYBE

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7. Do you have or have you ever had asthma? YES NO NOT SURE/MAYBE

8. Do you have or have you ever had any heart or blood pressure problems? YES NO NOT SURE/MAYBE

9. Do you have or have you ever had a heart murmur, mitral valve prolapse or rheumatic fever? YES NO NOT SURE/MAYBE

10. Do you have a prosthetic or artificial joint? YES NO NOT SURE/MAYBE

11. Have you ever been advised by your doctor to take antibiotics before dental treatment? YES NO NOT SURE/MAYBE

12. Do you have any conditions or therapies that could affect your Immune system e.g. leukemia, AIDS, HIV infection, radiotherapy, chemotherapy? YES NO NOT SURE/MAYBE

13. Have you ever had hepatitis, jaundice or liver disease? YES NO NOT SURE/MAYBE

14. Do you have a bleeding problem or bleeding disorder? YES NO NOT SURE/MAYBE

15. Have you ever been hospitalized for any illness or operations? If yes, please explain. YES NO NOT SURE/MAYBE

16. Do you have or have you ever had any of the following? Please check.

<input type="checkbox"/> chest pain, angina	<input type="checkbox"/> shortness of breath	<input type="checkbox"/> pacemaker	<input type="checkbox"/> steroid therapy	<input type="checkbox"/> seizures(epilepsy)	<input type="checkbox"/> drug/alcohol dependency
<input type="checkbox"/> heart attack		<input type="checkbox"/> lung disease	<input type="checkbox"/> diabetes	<input type="checkbox"/> kidney disease	
<input type="checkbox"/> stroke	<input type="checkbox"/> prosthetic heart valve	<input type="checkbox"/> tuberculosis	<input type="checkbox"/> stomach ulcers	<input type="checkbox"/> thyroid disease	
		<input type="checkbox"/> cancer	<input type="checkbox"/> arthritis	<input type="checkbox"/> diet pill therapy	

17. Are there any conditions or disease not listed above that you have or have had? If so, what? YES NO NOT SURE/MAYBE

18. Are there any disease or medical problems that run in your family? (e.g. diabetes, cancer or heart disease) YES NO NOT SURE/MAYBE

19. Do you smoke or chew tobacco products? YES NO NOT SURE/MAYBE

20. Are you nervous during dental treatment? YES NO NOT SURE/MAYBE

21. For women only: Are you breast-feeding or pregnant? If pregnant, what is the expected delivery date? YES NO NOT SURE/MAYBE

To the best of my knowledge, the above information is correct:

PATIENT/PARENT/GUARDIAN SIGNATURE: _____ DATE: _____

DENTIST SIGNATURE: _____ DATE: _____

DENTIST'S NOTES

Patient Height: _____

Patient Weight: _____

BMI: _____

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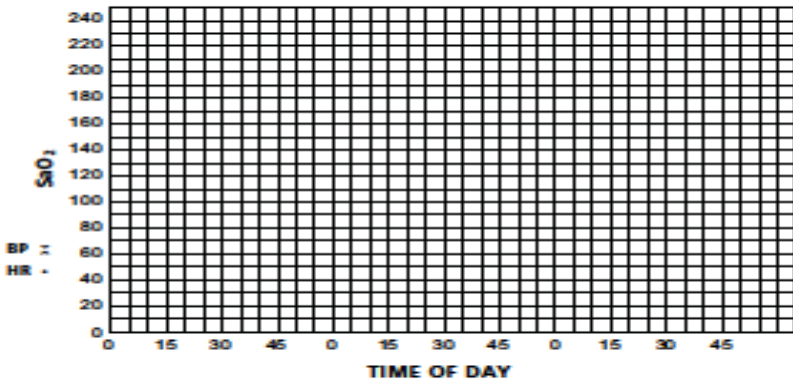
APPENDIX IV

Sedation Record

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A SAMPLE ANESTHETIC RECORD FORM IS SUPPLIED HERE AS AN EXAMPLE ONLY. THE USE OF THIS PARTICULAR FORM IS NOT MANDATORY. EACH PRACTITIONER MAY DETERMINE THE FORMAT OF THEIR OWN RECORD. THE PRACTITIONER SHOULD USE A FORM THAT, AT A MINIMUM, CONTAINS THE INFORMATION LISTED IN APPENDIX III, IN A FORMAT THAT IS CLEAR AND READILY UNDERSTOOD.

PATIENT'S NAME			AGE			DATE						
MEDICAL HISTORY REVIEWED												
ALLERGIES				MEDICATIONS								
NPO				ACCOMPANIED BY RESPONSIBLE ADULT								
Pre-Op BP	Pre-Op HR	Pre-Op O₂ St'n		ASA CLASSIFIC'N	I	II	III	IV	V	E		
PREMEDICATION				TIME								
IV	ANGIO or BF	GAUGE		SITE	R	L	DOH	ACF	FA	OTHER		
FLUIDS		TYPE		VOLUME								
MONITORS		PULSE OXIMETER		BP		ECG		OTHER				
DRUGS				TIME	0	15	30	45	0	15	30	45
O₂ (L/MIN)												
N₂O (L/MIN)												
LOCAL ANAES.				ML OF								
TIME												
START ANAES.												
START PROCEDURE												
END PROCEDURE												
END ANAES.												
TO RECOVERY ROOM												
DISCHARGE CRITERIA												
ORIENTED												
VITAL SIGNS STABLE												
BP		HR										
AMBULATORY												
DISCHARGE TIME												
IN THE COMPANY OF												



NOTES

BMI: _____ ANESTHETIST: _____

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REPORTABLE INCIDENT FORM

A DOCUMENTATION REQUIRED

Within two weeks of the Reportable Incident, please submit the following to the ADA+C via courier or fax (780-433-4864):

1. This form signed by the dentist who performed or was scheduled to perform the sedation and treatment.
2. A copy of the patient's clinical record.
3. A summary by the dentist describing the incident, action taken, possible risk factors and outcome.

The ADA+C will review the circumstances with the dentist and may consult with other practitioners to determine the risk of harm to patients.

B MANDATORY NOTIFICATION – Please print your responses.

1 Identify the Type of Event

- When a reversal agent has been used.
- When a patient's response to sedation results in depression beyond the level of sedation intended or entry of the patient into levels of deep sedation or depression beyond sedation or into general anesthesia.
- Incidents that required emergency interventions inside the office, such as, but not limited to cardiovascular collapse where resuscitation occurred on site and the patient was not transferred to hospital.
- Transfer of the patient or the care of the patient to another care provider, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation, regardless of whether or not the patient was admitted.
- Unexpected treatment by another care giver, a Dental Surgical Facility, Non-Hospital Surgical Facility, medical facility or hospital within 10 days of the sedation procedure.
- Deaths in office or within 10 days of the sedation procedure.
- Missing or non-locatable drugs are to be reported as a reportable Incident.

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APPENDIX V

Reportable Incident Form

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2 Completion of Report

Name of Person Completing this Report _____

Title _____

Telephone _____

Date report completed _____

3 General Information

Name: _____

Office: _____

Dentist: _____

Date of the Incident: Day: _____ Month: _____ Year: _____

Sedation performed by:

Dentist: Dr. _____ (Name)

Modality: _____

4 Patient Information

Patient Identification Number: (if applicable) _____

Patient Name: _____

HT: _____ WT: _____ Gender: Male Female Age: _____

Date of Birth _____

ASA Classification: _____

Treatment Proposed: _____

Treatment Performed: _____

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5 Description of the Event

Describe what happened; brief details of events.

Describe where it happened. Describe the exact location in the office, if possible.

What was the outcome of the transfer including diagnosis, length of stay, sequelae, etc.?

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6 History of the Event

Describe contributing factors to the incident:

a. Patient (co-existing disease conditions, language barriers etc.):

b. Personnel (e.g., number, training, experience, performance):

c. Equipment (list any equipment that may have played a role in the incident):

d. Environment (e.g., noisy, crowded):

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7 Office Response to the Event

If this incident had progressed without corrective action, what might the outcome have been for the patient?

What prevented this incident from becoming more serious?

What steps have been taken to prevent future occurrences such as change to policy or procedures?
Give details.

Dentist Who Provided Treatment and Administered Sedation – I have reviewed the contents of this report:

Signature: _____

Date: _____

Printed Name: _____

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Sedation Standards Annual Registration

All ADA+C members are required to register annually on their Sedation Practice.

Name

XXXXXXXXXX

Practice Permit Number: XXXX **Form Year:** 2011

Do you do any sedation? ***A SINGLE DOSE OF A SINGLE DRUG IS SEDATION (NB MODALITY 2)**

- Yes** (Complete the questions below)
- No** (Scroll to the bottom of the page)

Modality 1: Nitrous Oxide and Oxygen Sedation

Qualifications for administering this Modality: _____
Year of Graduation: _____ Institution: _____ HCP.CPR: _____
(Expiry Date)

**Modality 2: Oral Administration of a Single Dose of a Single Sedative Drug
(Benzodiazepines or Benzodiazepine-like drugs and antihistamines only)**

Qualifications for administering this Modality: _____
List drugs administered for this level of Sedation: _____

Year of Graduation: _____ Institution: _____ HCP.CPR: _____
(Expiry Date)

**Modality 3: Oral Administration of a Single Sedative Drug with Nitrous Oxide and Oxygen or
Supplemental use of a Single Sedative Drug (ADA+C Permit Required)**

Qualifications for administering this Modality: _____
List drugs used for this level of Sedation: _____

Year of Graduation: _____ Institution: _____ HCP.CPR: _____
(Expiry date)

Modality 4: Parenteral and Parenteral-like Sedation (ADA+C Permit Required)

Qualifications for administering this Modality: _____
List drugs used for this level of Sedation: _____

Year of Graduation: _____ Institution: _____
ACLS: _____ (Expiry Date) PALS: _____ (Expiry Date)

Do you have hospital privileges at one or more hospitals? Yes No

By submitting this registration electronically, I acknowledge and agree that the contents are true and complete as if I had signed the document in writing. I declare that the contents of this registration are true and complete and I understand and agree that if I make a false or misleading statement or representation in my registration, I will be deemed to not have satisfied the requirements of registration. I further understand and agree that making a false or misleading statement to the Alberta Dental Association and College is unprofessional conduct.

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Infection Prevention and Control in Dentistry – Safe Use of Sedatives

1. Parenteral Medication Administration:

1.1. Aseptic Technique

- a. Perform hand hygiene prior to accessing supplies, handling vials and IV solutions, and preparing or administering medications.
- b. Use aseptic technique in all aspects of parenteral medication administration, medication vial use, placement of IV lines and injection procedures.
- c. Store and prepare medications and supplies in a clean area on a clean surface.
- d. Never store needles and syringes unwrapped as sterility cannot be assured.
- e. Discard all opened vials, IV solutions and prepared or opened syringes that were involved in an emergency situation.
- f. Medication vials, syringes or supplies should not be carried in uniform or clothing pockets.
- g. Trays used to carry supplies should be cleaned between patients.
- h. Medication vials should be restricted to a centralized medication preparation area separate from the treatment area.

1.2. Single-use or Disposable Devices

- a. Single-use (disposable) devices are designed to be used on one patient and then discarded.
- b. Fluid and infusion sets are single-use, single-patient use items.
 - These are to be used on one patient for one visit. They are not saved for future visits, even in the same day, on that patient.

1.3. Use of Disposable Needles/Cannulas and Syringes

- a. Syringes and needles/cannulas are sterile, single-patient use items.
- b. Remove sterile needle/cannula and/or syringe from package just prior to use.
- c. Never use medication in a syringe for more than one patient even if the needle/cannula is changed between patients. Changing the needle/cannula but not the syringe is unacceptable.
- d. Utilize sharps safety devices whenever possible.
- e. Dispose of used needles/cannulas at the point of use in an approved sharps container.
- f. After direct injection into a vein or entry into (or connection with) a patient's IV infusion, the syringe and needle/cannula should be considered contaminated. Syringes and needle/cannula should be used only for that patient and then directly discarded into a sharps container.
 - Syringes should never be used to draw from a multi-dose vial or inject into another patient after contact with a patient's vein or IV infusion set.

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- g. After direct injection into a vein or entry into (or connection with) a patient's IV infusion, the syringe should not be used to draw from a multi-dose vial, or come into contact with any other patient, even if the needle/cannula is changed.
- h. Syringes should never be used to draw from a multi-dose vial more than once, even if the needle/cannula is changed.
- i. Medications from a syringe must never be injected back into a multi-use vial even if the needle/cannula is changed. Discard unused medication in a syringe appropriately.
- j. Do not prepare medication in one syringe to transfer to another syringe (e.g., drawing up solution into a syringe then transferring the solution to another syringe with plunger removed or injected into the bevel of the syringe to be injected into the patient).
- k. New, unused syringes, needles and related items should be stored in a clean area to avoid contamination by contaminated syringes and equipment.

1.4. Use of Single-Dose Vials

- a. Single-dose or single-use vials should be used instead of multi-dose vials whenever possible.
- b. The ampule, vial or prefilled syringe should be opened at the time of use.
- c. Single-dose vials are single-patient items. This includes all preservative-free ampules, vials and prefilled syringes.
- d. Leftover contents of a single-dose vial should be discarded and never combined for use on another patient.
- e. Always use a new sterile syringe and needle/cannula when entering a vial or ampule. Never enter a vial/ampule with a syringe or needle/cannula that has been used on a patient.
- f. Use filter needles/cannulas to withdraw solution from an ampule.
- g. Always use aseptic technique to draw from a vial.
 - Cleanse the access diaphragm of vials using friction and 70 percent alcohol or other antiseptic. Allow to dry before inserting a device into the vial.
 - Cleanse the neck of glass ampules with an alcohol swab and let dry before opening.
- h. Single-use ampules and vials should be discarded after the contents have been drawn up, and a prefilled syringe should be discarded after use is completed.
- i. Never store or transport vials in clothing or pockets.
- j. Always follow the manufacturer's instructions for storage and use.

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1.5 Use of Multi-Dose Vials

- a. If a multi-dose vial must be used, it should be used for a single patient whenever possible. The risk of transmission posed by inappropriate handling of multi-dose vials has been clearly demonstrated and mandates a practice of one vial per one patient whenever possible. Infection transmission risk is reduced when multi-dose vials are dedicated to a single patient.
- b. Never leave a needle, cannula, or spike device inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.
- c. If multi-dose vial is necessary, aseptic technique should be used each time the vial is entered, including cleaning the diaphragm with 70 percent alcohol and friction, and using a new sterile needle/cannula and syringe into the vial.
- d. Dispose of opened multi-dose medication vials 28 days after opening, unless specified otherwise by the manufacturer, or sooner if sterility is questioned or compromised.
- e. Date all opened multi-dose vials to reflect date opened and date of expiration (e.g., 28 days after opening).
 - A dentist may choose to establish a system wide opened multi-dose discard schedule, (e.g., one date a month established to discard all opened multi-dose vials no matter when the vial was opened during the month).
- f. Inspect vials and discard if sterility has been, or is thought to be compromised.
 - Examine the vial for any particulate matter, discoloration or turbidity. If present, do not use and discard immediately.
 - All vials used during an emergency should be discarded, as sterility cannot be guaranteed.
- g. Keep multi-dose vials away from the immediate patient environment.

1.6 Use of Intravenous (IV) Infusion Sets (bags, fluids, containers, tubing and connections):

- a. All infusions (fluids and containers) and administration sets (IV tubing and connections) are single-patient, single-use. This includes disposable pressure transducers and tubing and other items that contact the vascular system or other sterile body fluids.
 - These items should be discarded after each use on a patient.
 - Do NOT save IV infusion sets for use on that patient at a later time, even on the same day.
- b. Aseptic technique should be used when preparing IV infusion and administration sets, and entry into or breaks in the tubing should be minimized.
- c. Check all containers of parenteral fluids for visible turbidity, leaks, cracks, particulate matter and the manufacturer's expiration date before use. Use single-dose vials for parenteral additives or medications whenever possible.

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- d. Begin/initiate administration of spiked IV solutions (IV bag entered by the tubing spike) within one hour of preparation. If administration is not begun within 1 hour of spiking the bag, the IV and tubing shall be promptly discarded.
- e. Date all spiked IV solutions and tubing.
- f. Never use infusion supplies such as needles, syringes, flush solutions, administration sets or intravenous fluids on more than one patient.
- g. Never use intravenous solution containers (e.g., bags or bottles) to obtain flush solutions, etc. for more than one patient.
- h. Stopcocks, injection ports and other portals of access to sterile fluids should be maintained with sterile technique. Stopcocks should be kept free of blood and covered by a sterile cap or syringe when not in use.
 - Disinfect IV ports using friction and 70 percent alcohol, an iodophor or an approved antiseptic agent. Allow to dry prior to accessing.
- i. For unspiked IV solutions (not accessed by IV tubing spike) follow the pharmacy prepared or manufacturer prepared IV solution expiration date.
- j. Use a clean medication (pharmacy) room to prepare admixtures of IV solutions.

1.7 Flushing of IV Lines

- a. Use single-dose containers for flush solutions whenever possible.
- b. Never use intravenous solution containers (e.g., bags or bottles) to obtain flush solutions, etc. for more than one patient.
- c. If a multi-dose vial must be used, it should be used for only one patient and then discarded. Each entry into the multi-dose vial must be with a new unused sterile needle/cannula and syringe even if the vial is dedicated to a single patient.

1.8 Medication Expiry Timelines

- a. Medications should be drawn up as close as possible to the time of administration.
- b. All medications drawn into a syringe should be discarded within 24 hours or when completely used, whichever comes first, unless otherwise specified by the medication's manufacturer.
- c. An exception to the 24-hour use limit is any medication that is formulated as a lipid emulsion (e.g., Propofol). When used in anesthesia, any unused portion of Propofol in a syringe, reservoir or dedicated administration tubing must be discarded at the end of the procedure or within six hours after the ampule, vial or prefilled syringe is opened, whichever occurs sooner. The IV line should be flushed every six hours and at the end of the anesthetic procedure to remove residual Propofol. A syringe containing Propofol should be labeled with the date and time that the ampule, vial or prefilled syringe was opened.

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2. Non-Parenteral Medications

2.1 Non-Injectable Drugs

- a. Non-injectable drugs such as topical ointments and sprays that are packaged in multiple-dose containers should be administered in such a manner as to avoid cross-contamination.
- b. Any non-injectable drug should be discarded if visible or suspected contamination has occurred.

2.2 Use of Respiratory Equipment for Sedation

- a. Facial masks and reusable respiratory equipment are considered semi-critical medical devices requiring cleaning and, at a minimum, high-level disinfection after each use.
- b. Refer to Alberta Dental Association and College Infection Prevention and Control Standards and Risk Management for Dentistry (September 2010, page 71) for information on reprocessing of semi-critical items.
 - It is important to ensure that items that have been subjected to chemical high-level disinfection are rinsed submerged, at a minimum 3 times, with sterile, or submicron filtered water, to remove all traces of chemical disinfectant. (CSA Standards Z314.8-08. Decontamination of reusable medical devices. Clause 10.8.5.4.1). This is done to ensure patient safety, and to prevent burns, allergic reactions, and other adverse side effects of high-level disinfectant exposure.

Alberta Health Services