MDA BYLAW 27-09

PHARMACOLOGICAL BEHAVIOUR MANAGEMENT

Approved for distribution by Board – May 28, 2009
BYLAW FOR PHARMACOLOGIC BEHAVIOUR MANAGEMENT

PREAMBLE
Pharmacologic behaviour management – Anxiolysis, sedation, general anesthesia - is a continuum. It is not always possible to predict how an individual patient will respond to a drug. Members planning to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended. For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

Members may make a written request to the Registrar for modification of the document or continuing competence requirements based on their individual practice circumstances. Upon review, the Registrar may allow modifications to the document or continuing competence requirements if they do not reduce the intent or purpose of those requirements. A member must continue to comply with the document or continuing competence requirements of this bylaw until a modification is approved by the Registrar.

DEFINITIONS
ACLS – Advanced Cardiac Life Support
DRA - Dental Regulatory Authority
HCP - Basic Life Support for Health Care Providers Certification

RAMSEY SEDATION SCALE (RSS) - LEVELS OF SEDATION
RSS LEVEL 1 - Patient is anxious and agitated or restless, or both.
RSS LEVEL 2 - Patient is co-operative, oriented, and tranquil.
RSS LEVEL 3 - Patient responds to voice commands only.
RSS LEVEL 4 - Patient exhibits brisk response to light tap between eyebrows/LOUD auditory stimuli.
RSS LEVEL 5 - Patient exhibits a sluggish response to light tap between eyebrows/LOUD auditory stimuli.
RSS LEVEL 6 - Patient exhibits no response.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) CLASSIFICATION OF PATIENT PHYSICAL STATUS
A.S.A.I - A normal healthy patient.
A.S.A.II - A patient with mild systemic disease.
A.S.A.III - A patient with severe systemic disease.
A.S.A.IV - A patient with severe systemic disease that is a constant threat to life.
A.S.A. V - A moribund patient who is not expected to survive without the operation.

<table>
<thead>
<tr>
<th>ASA</th>
<th>Patient's Health</th>
<th>Status of Underlying Disease</th>
<th>Limitations on Activities</th>
<th>Risk of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>excellent; no systemic disease; excludes persons at extremes of age</td>
<td>none</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>II</td>
<td>disease of one body system</td>
<td>well-controlled</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>III</td>
<td>disease of more than one body system or one major system</td>
<td>controlled</td>
<td>present but not incapacitated</td>
<td>no immediate danger</td>
</tr>
<tr>
<td>IV</td>
<td>poor with at least 1 severe disease</td>
<td>poorly controlled or end stage</td>
<td>incapacitated</td>
<td>possible</td>
</tr>
</tbody>
</table>
| V   | very poor, moribund | incapacitated | imminent | imminen
SECTION I - ANXIOLYSIS – SINGLE ORAL SEDATIVE AGENT

Anxiolysis is the reduction of agitation or nervousness allowing for patient co-operation and calmness while the patient maintains orientation and responsive to oral commands. The MDA encourages members to use communication and other non-pharmacologic behavior management techniques to ease patient anxieties. In situations where non-pharmacologic efforts are unsuccessful and dental services are necessary, all members may use a single sedative agent within the parameters of this section.

The use of oral sedatives will be considered for anxiolytic purposes only if a member limits the use of oral sedatives to ambulatory adult patients (ASA classification I – II) and prescribes no more than the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use. The drug and dosage parameters accepted by the MDA are listed (Appendix I-1). If a member wishes to prescribe drugs not listed or at dosages greater than identified, the member must comply with the requirements for SECTION II – CONSCIOUS SEDATION – SINGLE ORAL SEDATIVE AGENT.

Regardless of the type of drug or dosage, members must discontinue performing dental services if the patient exceeds Ramsey Sedation Scale Level 3. Patients exceeding Ramsey Sedation Scale Level 3 must have their vital signs and sedation level continuously monitored and can only be discharged to the care of their escort when they return to Ramsey Sedation Scale Level 2.

All members using a single sedative agent for anxiolytic purposes must comply with the following requirements:

1. FACILITY REQUIREMENTS
   a. EMERGENCY DRUG KIT
      i. Oxygen (type E cylinder, regulator and flowmeter up to 15 liters per minute
      ii. Epinephrine
      iii. Antihistamine (diphenhydramine or accepted substitute)
      iv. Nitroglycerine
      v. Bronchodilator (salbutamol or accepted substitute)
      vi. Acetylsalicylic acid (ASA)
      vii. Oral glucose source (insta - glucose™ or accepted substitute)
   b. DOCUMENTS (must be available at request of Registrar):
      i. Policy and procedure manual
      ii. If not included in your manual, please provide the following documents/reports:
         ▪ GENERAL:
            i. Fire plan
            ii. HCP training for all applicable personnel
            iii. Accidental exposure plan
            iv. Office/sexual harassment policy
         ▪ INFECTION CONTROL
            i. Infection control protocols
            ii. Service logbook for sterilization with spore test reports
         ▪ DRUGS
            i. Available drug list
            ii. Written inspection protocol for emergency drugs quantity and viability (unexpired) maintenance
            iii. Protocols to secure, store and control in-office drugs to protect against abuse
            iv. Service logbook to monitor use of drugs stored in-office
PATIENT SAFETY PROTOCOLS – PRE AND POST

i. Emergency plan

ii. Medical history and physical assessment
   o Includes blood pressure, height, weight, medications, pre-existing conditions

f. ARMATARIUM – EQUIPMENT
   i. Pocket mask (adult)
   ii. Reservoir mask
   iii. 1 – 3 ml syringes with 23 guage, 1.5 inch needle
   iv. Sphygmomanometer
   v. Stethoscope or equivalent
   vi. Ambu bag
   vii. Oropharyngeal suction device

2. CONTINUING COMPETENCE
   ALL MEMBERS
   a. Must record in the patient chart all oral sedative prescriptions and usages during dental services contemporaneous with their performance;
   b. Must maintain a separate contemporaneous log of all oral sedative prescriptions for dental services (for format, see Guidelines appendix I-2). Log must be available at request of Registrar;
   c. Must maintain annual HCP recertification status. Proof must be available at request of Registrar.

3. REPORTING OBLIGATIONS
   ALL MEMBERS
   a. Must report any adverse reactions or incidents - during or after use of an oral sedative - requiring use of emergency kit; use of basic or advanced life support techniques; contact of emergency services; and/or referral to hospital to the Registrar within 15 days of the incident. (Form – see Appendix G-1).
SECTION II - CONSCIOUS SEDATION - SINGLE ORAL SEDATIVE AGENT

Conscious sedation is the alteration of behaviour, mood, cognition or perception allowing for patient comfort, co-operation and/or calmness without the loss of protective reflexes. The MDA encourages members to use communication and other non-pharmacologic behaviour management techniques to improve patient comfort and ease anxieties.

The use of oral sedatives will be considered for conscious sedation purposes only if a member limits the use of oral sedatives to ambulatory patients (ASA classification I - II). Please note the requirement distinctions between adults and children.

Regardless of the drug or dosage, members must discontinue performing dental services if the patient exceeds Ramsey Sedation Scale Level 4. Patients exceeding Ramsey Sedation Scale Level 4 must have their vital signs and sedation level continuously monitored and can only be discharged to the care of their escort when they return to Ramsey Sedation Scale Level 2.

All members using a single sedative agent for conscious sedation purposes must comply with the following requirements:

1. FACILITY REQUIREMENTS
   a. EMERGENCY DRUG KIT
      i. Oxygen (type E cylinder, regulator and flowmeter up to 15 liters per minute
      ii. Epinephrine
      iii. Antihistamine (diphenhydramine or accepted substitute)
      iv. Nitroglycerine
      v. Bronchodilator (salbutamol or accepted substitute)
      vi. Acetylsalicylic acid (ASA)
      vii. Oral glucose source (insta-glucose™ or accepted substitute)
   b. PERSONNEL
      i. Registered dental assistant with proof of current HCP certification status
   c. DOCUMENTS (must be available at request of Registrar):
      i. Policy and procedure manual
      ii. If not included in your manual, please provide the following documents/reports:
         • GENERAL
            i. Fire plan
            ii. HCP training for all applicable personnel
            iii. Accidental exposure plan
            iv. Office/sexual harassment policy
         • INFECTION CONTROL
            i. Infection control protocols
            ii. Service logbook for sterilization with spore test reports
         • DRUGS
            i. Available drug list
            ii. Written inspection protocol for emergency drugs quantity and viability (unexpired) maintenance
            iii. Protocols to secure, store and control in-office drugs to protect against abuse
            iv. Service logbook to monitor use of drugs stored in-office
PATIENT SAFETY PROTOCOLS – PRE AND POST

i. Emergency plan
ii. Medical history and physical assessment
   o Includes blood pressure, height, weight, medications, pre-existing conditions

d. OFFICE ASSESSMENT
   i. Member must allow facility visit by Registrar or Registrar’s designate on reasonable notice.

e. ARMATARIUM – EQUIPMENT
   i. Pocket masks (age appropriate sizes)
   ii. Reservoir mask
   iii. 1 – 3 ml syringes with 23 guage, 1.5 inch needle
   iv. Sphygmomanometer
   v. Stethoscope or equivalent
   vi. Ambu bag
   vii. Oropharyngeal suction device

2. INITIAL QUALIFICATIONS/TRAINING
   NEW REGISTRANTS
   a. Ambulatory adults (ASA classification I - II) - a member may apply for a certificate to provide dental services under oral sedation. The applicant must provide proof:
      i. Completed a course of study with a minimum of 6 hours of didactic instruction specific to oral sedation in the last five years.
   b. For children under 10 years (ASA classification I - II) - a member may apply for a certificate to perform dental services under oral sedation. In addition to meeting the requirements for ambulatory adults, the applicant must provide proof:
      i. Completed a course of study with a minimum of 6 hours of didactic instruction specific to oral sedation techniques for children in the last five years.
      ii. Performed 5 supervised cases of oral sedation for children between 5-10 years of age in a programme or course recognized by a DRA;
   c. Provide proof of current HCP certification status.

CURRENT MEMBERS
   a. Members may continue to perform oral sedation services they currently provide for patients. The MDA will accept a current member’s ability based on the self report filed by each member in 2009.
   b. Present proof of current HCP certification status.

3. CONTINUING COMPETENCE
   ALL MEMBERS
   a. Must record in the patient chart all oral sedation prescriptions and usages during dental services contemporaneous with their performance.
   b. Must maintain a separate contemporaneous log of all oral sedation prescriptions and usages during dental services (for format, see Guidelines appendix I-2 and II-1). Log must be available at request of Registrar.
   c. For ambulatory adults (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services under oral sedation. The applicant must provide proof:
      i. Completed a DRA recognized course of study with a minimum of 6 hours of didactic instruction specific to oral sedation.
      ii. Performed 5 cases of oral sedation in practice per year.
d. For children under 10 years (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services under oral sedation. The applicant must provide proof:
   i. Completed a DRA recognized course of study with a minimum of 6 hours of didactic instruction specific to oral sedation techniques for children in the last five years.
   ii. Performed 5 cases of oral sedation for children 5-10 years of age in practice per year.

e. Must maintain annual HCP recertification status. Proof must be available at request of Registrar.

4. REPORTING OBLIGATIONS
   ALL MEMBERS
   a. Must report any adverse reactions or incidents - during or after use of an oral sedative - requiring use of emergency kit; use of basic or advanced life support techniques; contact of emergency services; and/or referral to hospital to the Registrar within 15 days of the incident (Form – see Appendix G-1).
SECTION III - CONSCIOUS SEDATION - NITROUS OXIDE INHALATION

Conscious sedation is the alteration of behaviour, mood, cognition or perception allowing for patient comfort, co-operation and/or calmness without the loss of protective reflexes. The MDA encourages members to use communication and other non-pharmacologic behaviour management techniques to improve patient comfort and ease anxieties.

The use of nitrous oxide inhalation will be considered for conscious sedation purposes only if a member limits the use of nitrous oxide inhalation sedation to ambulatory patients (ASA classification I - II). Please note the requirement distinctions for children and adults.

Members must discontinue performing dental services if the patient exceeds Ramsey Sedation Scale Level 4. Patients exceeding Ramsey Sedation Scale Level 4 must have their vital signs and sedation level continuously monitored and can only be discharged to the care of their escort when they return to Ramsey Sedation Scale Level 2.

All members using a nitrous oxide inhalation for conscious sedation purposes must comply with the following requirements:

1. FACILITY REQUIREMENTS
   a. EMERGENCY DRUG KIT
      i. Oxygen (type E cylinder, regulator and flowmeter up to 15 liters per minute
      ii. Epinephrine
      iii. Antihistamine (diphenhydramine or accepted substitute)
      iv. Nitroglycerine
      v. Bronchodilator (salbutamol or accepted substitute)
      vi. Acetylsalicylic acid (ASA)
      vii. Oral glucose source (insta-glucose™ or accepted substitute)
   b. PERSONNEL
      i. Registered dental assistant with proof of current HCP certification status
   c. DOCUMENTS (must be available at request of Registrar):
      i. Policy and procedure manual
      ii. If not included in your manual, please provide the following documents/reports:
         • GENERAL
            i. Fire plan
            ii. HCP training for all applicable personnel
            iii. Accidental exposure plan
            iv. Office/sexual harassment policy
            v. Written outline of duties and responsibilities of director
            vi. Outline of facility administration with organization chart
            vii. Names of directors and owners of facility including corporations
            viii. Job descriptions – including duties and responsibilities for all personnel
            ix. Room ventilation report
            x. Nitrous oxide occupational hazard sheet for staff
            xi. Service logbook for periodic atmospheric testing
         • INFECTION CONTROL
            i. Infection control protocols
            ii. Service logbook for sterilization with spore test reports
**DRUGS**

i. Available drug list  
ii. Written inspection protocol for emergency drugs quantity and viability (unexpired) maintenance  
iii. Protocols to secure, store and control in-office drugs to protect against abuse  
iv. Service logbook to monitor use of drugs stored in-office

**PATIENT SAFETY PROTOCOLS – PRE AND POST**

i. Emergency plan  
ii. Pre-operative checklist  
iii. Medical history and physical assessment  
   o Includes blood pressure, height, weight, medications, pre-existing conditions  

**FACILITY CERTIFICATION**

Facility where nitrous oxide is performed must be audited and certified by the MDA every five years. No member may perform or allow others to perform nitrous oxide sedation in an uncertified facility. The nitrous oxide facility audit process and requirements are set out in Guidelines appendix III-3.

**ARMATARIUM – EQUIPMENT**

i. Pocket masks (age appropriate sizes)  
ii. Reservoir mask  
iii. Syringes (1-3ml in size) with 23 gauge, 1.5 inch needle  
v. Sphygmomanometer  
vi. Stethoscope or equivalent  
ix. Ambu bag  
vii. Oropharyngeal suction device  
viii. An appropriate scavenging  
ix. Appropriate sizes and quantity of masks and airways

2. **INITIAL QUALIFICATIONS/TRAINING**

**NEW REGISTRANTS**

a. Ambulatory adults (ASA classification I - II) - a member may apply for a certificate to provide dental services using nitrous oxide sedation. The applicant must provide proof:  
   i. Completed a course of study with a minimum of 6 hours of didactic instruction specific to nitrous oxide in the last five years.  
   ii. Performed 6 supervised cases of nitrous oxide sedation in a programme or course recognized by a DRA.  

b. For children under 10 years (ASA classification I - II) - a member may apply for a certificate to perform dental services under nitrous oxide sedation. The applicant must provide proof:  
   i. Completed a course of study with a minimum of 6 hours of didactic instruction specific to nitrous oxide sedation techniques for children in the last five years;  
   ii. Performed 6 supervised cases of nitrous oxide sedation for children under 10 years in a programme or course recognized by a DRA.  

c. Provide proof of current HCP certification status.
CURRENT MEMBERS
   a. Members may continue to perform nitrous oxide sedation services they currently provide for patients. The MDA will accept a current member’s ability based on the self report filed by each member in 2009.
   b. Provide proof of current HCP certification status.

3. CONTINUING COMPETENCE
   ALL MEMBERS
   a. Must record in the patient chart all nitrous oxide sedation usage during dental services contemporaneous with their performance.
   b. Must maintain a separate contemporaneous log of all nitrous oxide sedation usage during dental services (for format, see Guidelines appendix III-2). Log must be available at request of Registrar.
   c. For ambulatory adults (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services under nitrous oxide sedation. The applicant must provide proof:
      i. Performed 5 cases of nitrous oxide sedation in practice per year.
   d. For children under 10 years (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services under nitrous oxide sedation. The applicant must provide proof:
      i. Performed 5 cases of nitrous oxide sedation for children under 10 years in practice per year.
   e. Must maintain annual HCP recertification status. Proof must be available at request of Registrar.

4. REPORTING OBLIGATIONS
   ALL MEMBERS
   a. Must report any adverse reactions or incidents - during or after use of nitrous oxide - requiring use of emergency kit; use of basic or advanced life support techniques; contact of emergency services; and/or referral to hospital to the Registrar within 15 days of the incident (Form – see Appendix G-1).
SECTION IV - CONSCIOUS SEDATION – PARENTERAL ADMINISTRATION OF A SEDATIVE AGENT

Conscious sedation is the alteration of behaviour, mood, cognition or perception allowing for patient comfort, co-operation and/or calmness without the loss of protective reflexes. The MDA encourages members to use communication and other non-pharmacologic behaviour management techniques to improve patient comfort and ease anxieties.

The intravenous or intramuscular administration of a sedative agent will be considered for conscious sedation purposes only if a member limits the use of intravenous or intramuscular sedation to ambulatory patients (ASA classification I-II). Please note the requirement distinctions for children and adults.

Members must discontinue performing dental services if the patient exceeds Ramsey Sedation Scale Level 4. Patients exceeding Ramsey Sedation Scale Level 4 must have their vital signs and sedation level continuously monitored and can only be discharged to the care of their escort when they return to Ramsey Sedation Scale Level 2.

All members using intravenous or intramuscular administration of a sedative agent for conscious sedation purposes must comply with the following requirements:

1. FACILITY REQUIREMENTS
   a. EMERGENCY DRUG KIT
      i. Oxygen (type E cylinder, regulator and flowmeter up to 15 liters per minute
      ii. Epinephrine
      iii. Antihistamine (diphenhydramine or accepted substitute)
      iv. Nitroglycerine
      v. Bronchodilator (salbutamol or accepted substitute)
      vi. Acetylsalicylic acid (ASA)
      vii. Oral glucose source (insta - glucose™ or accepted substitute)
      viii. Flumazenil (if benzodiazepines used)
      ix. Naloxone (if opiates used)
      x. Parenteral vasopressor (ephedrine or accepted substitute)
      xi. Parenteral corticosteroid (solu-cortef™ or accepted substitute)
      xii. Parenteral atropine
      xiii. Intravenous lidocaine
     xiv. Normal saline solution for perfusion
   b. PERSONNEL
      i. Registered dental assistant with proof of current HCP certification status
   c. DOCUMENTS (must be available at request of Registrar)
      i. Policy and procedure manual
      ii. If not included in your manual, please provide the following documents/reports:
         1. GENERAL
            i. Fire plan
            ii. HCP training for all applicable personnel
            iii. Accidental exposure plan
            iv. Office/sexual harassment policy
            v. Written outline of duties and responsibilities of director
            vi. Outline of facility administration with organization chart
            vii. Names of directors and owners of facility including corporations
            viii. Job descriptions – including duties and responsibilities for all personnel
            ix. Substance abuse awareness and prevention protocols for staff
• INFECTION CONTROL
  i. Infection control protocols
  ii. Service logbook for sterilization with spore test reports

• DRUGS
  i. Available drug list
  ii. Written inspection protocol for emergency drugs quantity and viability (unexpired) maintenance
  iii. Protocols to secure, store and control in-office drugs to protect against abuse
  iv. Service logbook to monitor use of drugs stored in-office

• PATIENT SAFETY PROTOCOLS – PRE AND POST
  i. Emergency plan
  ii. Pre-operative instruction sheet
  iii. Pre-operative checklist
  iv. Pre-operative assessment
  v. Medical history and physical assessment
     o Includes blood pressure, height, weight, medications, pre-existing conditions
  vi. Postoperative instruction sheet
  vii. Discharge criteria
  viii. Hospital transfer agreement for patients requiring emergency care

• EQUIPMENT SERVICE
  i. Service logbook for intravenous or intramuscular conscious sedation equipment
  ii. Service logbook for recovery room monitors
  iii. Service logbook for crash cart inventory and automatic external defibrillator check

• FACILITY CERTIFICATION
  Facility where intravenous or intramuscular conscious sedation is performed must be audited and certified by the MDA every five years. No member may perform or allow others to perform intravenous or intramuscular conscious sedation in an uncertified facility. The intravenous or intramuscular conscious sedation facility audit process and requirements are set out in Guidelines appendix IV-1.

• ARMATARIUM – EQUIPMENT
  i. Pocket masks (age appropriate sizes)
  ii. Reservoir mask
  iii. Syringes (1-3ml in size) with 23 gauge, 1.5 inch needle
  iv. Electronic Sphygmomanometer with fail safe mechanism
  v. Stethoscope or equivalent
  vi. Ambu bag
  vii. Oropharyngeal suction device
  viii. Appropriate sizes and quantity of masks and airways
  ix. Pulse oximeter
  x. Tracheotomy or cricothyroidectomy apparatus
  xi. Endotracheal intubation apparatus or acceptable substitute (combi tube, laryngomask airway)
  xii. Magill forceps
  xiii. Automated external defibrillator

2. INITIAL QUALIFICATIONS/TRAINING NEW REGISTRANTS
   a. Ambulatory adults (ASA classification I - II) - a member may apply for a certificate to provide dental services utilizing intravenous or intramuscular conscious sedation. The applicant must provide proof:
i. Completed a course of study with a minimum of 20 hours of didactic instruction specific to intravenous or intramuscular conscious sedation in the last five years.

ii. Performed 20 supervised cases of intravenous or intramuscular conscious sedation in a programme or course recognized by a DRA.

b. For children under 12 years, a physician anaesthetist, anaesthetist or pediatric anaesthetist must administer the modality.

c. Provide proof of current HCP certification status.

CURRENT MEMBERS

a. Members may continue to perform intravenous or intramuscular conscious sedation services they currently provide for patients. The MDA will accept a current member’s ability based on the self report filed by each member in 2009.

b. Provide proof of current HCP certification status.

3. CONTINUING COMPETENCE

ALL MEMBERS

a. Must record in the patient chart all intravenous or intramuscular conscious sedation drugs used during dental services contemporaneous with their performance.

b. Must maintain a separate contemporaneous log of all intravenous or intramuscular conscious sedation drugs and methods used during dental services (for format, see Guidelines appendix IV-2). Log must be available at request of Registrar.

c. For ambulatory adults (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services under intravenous or intramuscular conscious sedation. The applicant must provide proof:

   i. Performed 5 cases of intravenous or intramuscular conscious sedation in practice per year; and

   ii. Completed a DRA recognized course of study with a minimum of 6 hours of didactic instruction specific to intravenous or intramuscular conscious sedation; and/or

   iii. Participate in a MDA recognized parenteral sedation study group. Members must participate in 3 hours of study club meetings per year to maintain certification as part of this option.

d. Must maintain annual HCP recertification status. Proof must be available at request of Registrar.

4. REPORTING OBLIGATIONS

ALL MEMBERS

a. Must report any adverse reactions or incidences - during or after use of intravenous or intramuscular conscious sedation - requiring use of emergency kit; use of basic or advanced life support techniques; contact of emergency services; and/or referral to hospital - to the Registrar within 15 days of the incident (Appendix G-1).
SECTION V - CONSCIOUS SEDATION – MULTIPLE MODALITIES – COMBINATION OF ORAL SEDATIVES OR NITROUS OXIDE WITH AN ORAL OR PARENTERAL SEDATIVE AGENT

Conscious sedation is the alteration of behaviour, mood, cognition or perception allowing for patient comfort, co-operation and/or calmness without the loss of protective reflexes. The MDA encourages members to use communication and other non-pharmacologic behaviour management techniques to improve patient comfort and ease anxieties.

Regardless of the combination, multiple modality sedation will be considered for conscious sedation purposes only if a member limits the use of sedation to ambulatory patients (ASA classification I - II). Please note the requirement distinctions for children and adults.

Members must discontinue performing dental services if the patient exceeds Ramsey Sedation Scale Level 4. Patients exceeding Ramsey Sedation Scale Level 4 must have their vital signs and sedation level continuously monitored and can only be discharged to the care of their escort when they return to Ramsey Sedation Scale Level 2.

All members using a combination of sedative agents for conscious sedation purposes must comply with the following requirements:

1. FACILITY REQUIREMENTS
   a. EMERGENCY DRUG KIT
      - FOR ALL DUAL MODALITY CONSCIOUS SEDATION TECHNIQUES
         i. Oxygen (type E cylinder, regulator and flowmeter up to 15 liters per minute
         ii. Epinephrine
         iii. Antihistamine (diphenhydramine or accepted substitute)
         iv. Nitroglycerine
         v. Bronchodilator (salbutamol or accepted substitute)
         vi. Acetylsalicylic acid (ASA)
         vii. Oral glucose source (insta - glucose™ or accepted substitute)
      - FOR MULTIPLE MODALITY INVOLVING PARENTERAL TECHNIQUES
         viii. Flumazenil (if benzodiazepines used)
         ix. Naloxone (if opiates used)
         x. Parenteral vasopressor (ephedrine or accepted substitute)
         xi. Parenteral corticosteroid (solu-cortef™ or accepted substitute)
         xii. Parenteral atropine
         xiii. Intravenous lidocaine
         xiv. Normal saline solution for perfusion

   b. PERSONNEL
      i. Registered dental assistant with proof of current HCP certification status

   c. DOCUMENTS (must be available at request of Registrar)
      i. Policy and procedure manual
      ii. If not included in your manual, please provide the following documents/reports:
         - GENERAL
            i. Fire plan
            ii. HCP training for all applicable personnel
            iii. Accidental exposure plan
            iv. Office/sexual harassment policy
            v. Written outline of duties and responsibilities of director
            vi. Outline of facility administration with organization chart
            vii. Names of directors and owners of facility including corporations
            viii. Job descriptions – including duties and responsibilities for all personnel
            ix. Substance abuse awareness and prevention protocols for staff
x. Room ventilation report (if gases other than oxygen or air are used)
xl. Service logbook for periodic atmospheric testing (if gases other than oxygen or air are used)

- INFECTION CONTROL
  i. Infection control protocols
  ii. Service logbook for sterilization with spore test reports

- DRUGS
  i. Available drug list
  ii. Written inspection protocol for emergency drugs quantity and viability (unexpired) maintenance
  iii. Protocols to secure, store and control in-office drugs to protect against abuse
  iv. Service logbook to monitor use of drugs stored in-office

- PATIENT SAFETY PROTOCOLS – PRE AND POST
  i. Emergency plan
  ii. Hospital transfer agreement for patients requiring emergency care
  iii. Pre-operative instruction sheet
  iv. Pre-operative checklist
  v. Pre-operative assessment
  vi. Medical history and physical assessment
     o Includes blood pressure, height, weight, medications, pre-existing conditions
  vii. Postoperative instruction sheet
  viii. Discharge criteria

- EQUIPMENT SERVICE (as appropriate)
  i. Service logbook for conscious sedation equipment
  ii. Service logbook for recovery room monitors
  iii. Service logbook for crash cart inventory and automatic external defibrillator check

d. FACILITY CERTIFICATION
   Facility where multiple modality conscious sedation is performed must be audited and certified as required for the separate modalities by the MDA every five years. No member may perform or allow others to perform multiple modality conscious sedation in an uncertified facility.
e. ARMATARIUM – EQUIPMENT
   - FOR ALL MULTIPLE MODALITY SEDATION TECHNIQUES
     i. Pocket masks (age appropriate sizes)
     ii. Reservoir mask
     iii. Syringes (1-3ml in size) with 23 gauge, 1.5 inch needle
     iv. Electronic Sphygmomanometer with fail safe mechanism
     v. Stethoscope or equivalent
     vi. Ambu bag
     vii. Oropharyngeal suction device
     viii. An appropriate scavenging system if gases other than oxygen or air are used.
     ix. Appropriate sizes and quantity of masks and airways
     x. Pulse oximeter
     xi. Tracheotomy or cricothyroidectomy apparatus

   - FOR MULTIPLE MODALITY INVOLVING PARENTERAL TECHNIQUES
     xii. Endotracheal intubation apparatus or acceptable substitute (combi tube, laryngomask airway)
     xiii. Magill forceps
     xiv. Automated electronic defibrillator
2. INITIAL QUALIFICATIONS/TRAINING
   NEW REGISTRANTS
   a. Ambulatory adults (ASA classification I - II) - a member may apply for a certificate to provide dental services utilizing multiple modality conscious sedation. In addition to meeting the requirements for the individual modalities, the applicant must provide proof:
      i. Completed a course of study with a minimum of 6 hours of didactic instruction specific to the combining of sedative agents for conscious sedation in the last five years.
      ii. Performed 5 supervised cases combining sedative agents for conscious sedation in a programme or course recognized by a DRA.
   b. For children under 12 years, a physician anaesthetist, anaesthetist or pediatric anaesthetist must administer parenteral sedation modality.
   c. Provide proof of current HCP certification status.

   CURRENT MEMBERS
   a. Members may continue to combine sedative agents for the sedation services they currently provide for patients. The MDA will accept a current member’s ability based on the self report filed by each member in 2009.
   b. Present proof of current HCP certification status.

3. CONTINUING COMPETENCE
   ALL MEMBERS
   a. Must record in the patient chart all combinations of drugs and methods for conscious sedation used during dental services contemporaneous with their performance.
   b. Must maintain a separate contemporaneous log of all combinations of drugs and methods for conscious sedation used during dental services (for format, see Guidelines appendix V-1). Log must be available at request of Registrar.
   c. For ambulatory adults (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services using multiple modality sedation techniques. The applicant must provide proof:
      i. Performed 6 cases of multiple modality conscious sedation in practice per year; and
      ii. Completed a DRA recognized course of study with a minimum of 6 hours of didactic instruction specific to multiple modality conscious sedation; and/or
      iii. Participate in a MDA recognized multiple modality sedation study group. Members must attend at least 3 hours of study club meetings per year to maintain certification.
   d. Must maintain annual HCP recertification status. Proof must be available at request of Registrar.

4. REPORTING OBLIGATIONS
   ALL MEMBERS
   a. Must report any adverse reactions or incidences - during or after use of dual or multiple modality conscious sedation - requiring use of emergency kit; use of basic or advanced life support techniques; contact of emergency services; and/or referral to hospital - to the Registrar within 15 days of the incident (Appendix G-1).
SECTION VI - DEEP SEDATION AND GENERAL ANAESTHESIA

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

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

Regardless of the modality or modalities, members may only perform deep sedation or general anaesthesia on ambulatory patients (ASA classification I - II). Exceptions may be considered in emergency situations. Please note the requirement distinctions for children and adults.

No member can provide dental services under deep sedation/general anaesthesia alone. A separate individual – with training that meets or exceeds the following requirements – must administer the deep sedation/general anaesthesia and monitor patient vital signs, airway patency and ventilation. It is the obligation of the member to verify the deep sedation/anaesthesia provider’s qualifications and experience. Exceptions may be considered for emergency situations. Patients must have their vital signs and sedation level continuously monitored and can only be discharged to the care of their escort when they return to Ramsey Sedation Scale Level 2.

All members utilizing deep sedation/general anaesthesia must comply with the following requirements:

1. FACILITY REQUIREMENTS
   a. EMERGENCY DRUG KIT
      i. Oxygen (type E cylinder, regulator and flowmeter up to 15 liters per minute
      ii. Epinephrine
      iii. Antihistamine (diphenhydramine or accepted substitute)
      iv. Nitroglycerine
      v. Bronchodilator (salbutamol or accepted substitute)
      vi. Acetylsalicylic acid (ASA)
      vii. Oral glucose source (insta - glucose™ or accepted substitute)
      viii. Flumazenil (if benzodiazepines used)
      ix. Naloxone (if opiates used)
      x. Parenteral vasopressor (ephedrine or accepted substitute)
      xi. Parenteral corticosteroid (solucortef™ or accepted substitute)
      xii. Parenteral atropine
      xiii. Intravenous lidocaine
      xiv. Normal saline solution for perfusion
      xv. Succinylcholine
      xvi. Antihypertensive
   b. PERSONNEL
      i. Registered dental assistant or nurse with proof of current HCP certification status
   c. DOCUMENTS (must be available at request of Registrar)
      iii. Policy and procedure manual
      iv. If not included in your manual, please provide the following documents/reports:
         ▪ GENERAL
            i. Fire plan
            ii. HCP training for all applicable personnel
iii. Accidental exposure plan
iv. Office/sexual harassment policy
v. Written outline of duties and responsibilities of director
vi. Outline of facility administration with organization chart
vii. Names of directors and owners of facility including corporations
viii. Job descriptions – including duties and responsibilities for all personnel
ix. Substance abuse awareness and prevention protocols for staff
x. Room ventilation report (if gases other than oxygen or air are used)
xi. Service logbook for periodic atmospheric testing (if gases other than oxygen or air are used)

**INFECTION CONTROL**

  i. Infection control protocols
  ii. Service logbook for sterilization with spore test reports

**DRUGS**

  i. Available drug list
  ii. Written inspection protocol for emergency drugs quantity and viability (unexpired) maintenance
  iii. Protocols to secure, store and control in-office drugs to protect against abuse
  iv. Service logbook to monitor use of drugs stored in-office

**PATIENT SAFETY PROTOCOLS – PRE AND POST**

  i. Emergency plan
  ii. Hospital transfer agreement for patients requiring emergency care
  iii. Pre-operative instruction sheet
  iv. Pre-operative checklist
  v. Pre-operative assessment
  vi. Medical history and physical assessment
     o Includes blood pressure, height, weight, medications, pre-existing conditions
  vii. Postoperative instruction sheet
  viii. Discharge criteria

**EQUIPMENT SERVICE**

  i. Service logbook for sedation equipment
  ii. Service logbook for general anaesthesia equipment (if applicable)
  iii. Service logbook for recovery room monitors
  iv. Service logbook for crash cart inventory and automatic external defibrillator check

**d. FACILITY CERTIFICATION**

  Facility where deep sedation or general anaesthesia is performed must be audited and certified by the MDA every five years. No member may perform or allow others to perform deep sedation or general anaesthesia in an uncertified facility. The deep sedation/general anaesthesia facility audit process and requirements are set out in Guidelines appendix VI-1.

**e. ARMATURE – EQUIPMENT**

  i. Pocket masks (age appropriate sizes)
  ii. Reservoir mask
  iii. Syringes (1-3ml in size) with 23 gauge, 1.5 inch needle
  iv. Electronic Sphygmomanometer with fail safe mechanism
  v. Ambu bag
  vi. Oropharyngeal suction device
  vii. Appropriate sizes and quantity of masks and airways
  viii. An appropriate scavenging system if gases other than oxygen or air are used.
ix. Pulse oximeter
x. Tracheotomy or cricothyroidectomy apparatus
xi. Endotracheal intubation apparatus or acceptable substitute (combi tube, laryngomask airway)
xii. Magill forceps
xiii. Automated external defibrillator
xiv. Electrocardiograph
xv. Fail - safe low pressure alarm
xvi. Portable battery powered auxiliary systems for suction and light
xvii. Capnometer with fail safe alarm (if providing intubated anaesthetics)
xviii. Thermometer (if providing intubated anaesthetics)
ix. anaesthetic machine (if appropriate)

2. INITIAL QUALIFICATIONS/TRAINING

NEW REGISTRANTS

a. Ambulatory adults (ASA classification I - II) - a member may apply for a certificate to provide dental services utilizing deep sedation or general anaesthesia. The applicant must provide proof:
   i. Completed a minimum 24 month post graduate programme with an evaluated and competency attested deep sedation/general anaesthesia in the last five years.

b. For children under 12 years, a physician anaesthetist, anaesthetist or pediatric anaesthetist must administer the service.

c. Provide proof of current ACLS certification status.

CURRENT MEMBERS

a. Members may continue to deep sedation or general anaesthesia services they currently provide for patients. The MDA will accept a current member’s ability based on the self report filed by each member in 2009.

b. Present proof of current ACLS certification status.

3. CONTINUING COMPETENCE

ALL MEMBERS

a. Must record in the patient chart all deep sedation/general anaesthesia used during dental services contemporaneous with their performance.

b. Must maintain a separate contemporaneous log of all deep sedation/general anaesthesia used during dental services (for format, see Guidelines appendix VI-2). Log must be available at request of Registrar.

c. For ambulatory adults (ASA classification I - II) - a member must recertify with the MDA every five years to continue providing dental services using deep sedation or general anaesthesia techniques. The applicant must provide proof:
   i. Completed a DRA recognized course of study with a minimum of 6 hours of didactic instruction specific to deep sedation or general anaesthesia; and/or
   ii. Participate in a MDA recognized deep sedation or general anaesthesia study group. Members must attend at least 3 study club meetings per year to maintain certification as part of this option.

d. Must maintain annual ACLS recertification status. Proof must be available at request of Registrar.

4. REPORTING OBLIGATIONS

ALL MEMBERS

a. Must report any adverse reactions or incidences - during or after use of deep sedation or general anaesthesia - requiring use of emergency kit; use of basic or advanced life
support techniques; contact of emergency services; and/or referral to hospital - to the Registrar within 15 days of the incident (Appendix G-1).
DONE AND PASSED by the Board of Directors of the Manitoba Dental Association at Winnipeg, in Manitoba this 28th day of May 2009.

By-law 27-94 of the Manitoba Dental Association is hereby repealed.

DONE and PASSED by the Board of Directors of the Manitoba Dental Association at Winnipeg, in Manitoba this 29th day of May, 2009.

______________________________
President

______________________________
Secretary

This by-law will become effective on the 15th day of December, 2009, unless 10 members request, in writing, its ratification at a general meeting of the Association (Section 43(2) of The Dental Association Act).
Attached: Appendices “G-1”, “I-1”.
ADVERSE INCIDENT REPORT FORM
MANITOBA DENTAL ASSOCIATION

ADVERSE REACTION REPORT

Manitoba Dental Association Bylaw for pharmacological behaviour management requires that a dentist must file this report for any incident that arises from the administration of nitrous oxide inhalation analgesia, general anesthesia, conscious sedation, local anesthesia, analgesia, or anxiolysis that results in: a serious or unusual outcome that produces a temporary or permanent physiological injury, harm, or other detrimental effect to one or more of a patient's body system(s); or anxiolysis unintentionally becoming conscious sedation or general anesthesia when the member is not listed for administering conscious sedation or general anesthesia. It is NOT necessary to report incidents such as nausea, a single episode of emesis, or mild allergic reaction. This report must be submitted to the MDA Registrar within fifteen business days of the incident by the dentist even when another licensed health care professional who, under contract or employment with the dentist, was the actual person administering the analgesia or pharmacological or nonpharmacological method. A member who fails to comply with reporting of incidents is subject to disciplinary proceedings. You may duplicate this form.

LICENSEE/REGISTRANT INFORMATION

Name (please print): ________________________ License/Registration Number: ________________________
Address: ________________________________
City: __________________ Province: ___________ Zip: ___________

<table>
<thead>
<tr>
<th>I.</th>
<th>REACTION INFORMATION</th>
</tr>
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<tbody>
<tr>
<td><strong>PATIENT ID/INITIALS</strong> (in confidence)</td>
<td><strong>AGE</strong> (yrs)</td>
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<tr>
<td><strong>DESCRIBE REACTION(S)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>RELEVANT TESTS/LABORATORY DATA</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II.</th>
<th>SUSPECT DRUG(S) INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SUSPECT DRUG(S)</strong> (indicate manufacturer and lot #)</td>
<td><strong>DID REACTION ABATE AFTER STOPPING DRUG?</strong></td>
</tr>
<tr>
<td></td>
<td>☐ YES ☐ NO ☐ N/A</td>
</tr>
<tr>
<td><strong>DOSE</strong></td>
<td><strong>ROUTE OF ADMINISTRATION</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INDICATION(S) FOR USE</strong></td>
<td></td>
</tr>
<tr>
<td><strong>DATE OF ADMINISTRATION</strong> (From/To)</td>
<td><strong>DURATION OF ADMINISTRATION</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>III.</th>
<th>CONCOMITANT DRUGS AND HISTORY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONCOMITANT DRUGS AND DATES OF ADMINISTRATION</strong> (Exclude those used to treat reaction)</td>
<td></td>
</tr>
<tr>
<td><strong>OTHER RELEVANT HISTORY</strong> (e.g. diagnosis, allergies, pregnancy with LMP, etc.)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV.</th>
<th>SIGNATURE</th>
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<tbody>
<tr>
<td><strong>SIGNED:</strong></td>
<td><strong>DATE:</strong></td>
</tr>
</tbody>
</table>
## Maximum Recommended Drug and Dosages for Anxiolytic Purposes in Ambulatory Adults

### Nonprescription Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine (Benadryl)</td>
<td>25-50 mg</td>
</tr>
<tr>
<td>Promethazine (Phenergan)</td>
<td>25-50 mg</td>
</tr>
</tbody>
</table>

### Prescription Drugs

#### Benzodiazepines

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triazolam (Halcion)</td>
<td>0.125-0.5mg</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>0.25-2mg</td>
</tr>
<tr>
<td>Diazepam (Valium)</td>
<td>2-10 mg</td>
</tr>
<tr>
<td>Midazolam (Versed)</td>
<td>0.15-0.2 mg/kg</td>
</tr>
</tbody>
</table>

#### Nonbenzodiazepines

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eszopiclone (Lunesta)</td>
<td>1-2 mg</td>
</tr>
<tr>
<td>Ramelteon (Rozerem)</td>
<td>8 mg</td>
</tr>
<tr>
<td>Zolpidem (Ambien)</td>
<td>5-10 mg</td>
</tr>
<tr>
<td>Zaleplon (Sonata)</td>
<td>5-10 mg</td>
</tr>
</tbody>
</table>

#### Barbiturates

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral Hydrate</td>
<td>25-50 mg/kg</td>
</tr>
</tbody>
</table>

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1 The dosage described is the maximum dosage and may not be suitable for all patients. Members must use their clinical judgement in determining the appropriate dosage based on the individual patient’s age, weight and medical history.