MANITOBA DENTAL ASSOCIATION

# THE BYLAW FOR USE OF BOTULINUM TOXIN

**MANITOBA DENTAL ASSOCIATION**
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**Board Approval for Bylaw Distribution: 02 November 2013**
**Member Ratification of Bylaw:**

# BYLAW FOR THE USE OF BOTULINUM TOXIN

**PREAMBLE**

**In the Province of Manitoba, the scope of practice of dentistry is determined by *The Dental Association Act* (*The Act*). Relevant to the prescription or administration of a substance, drug or vaccine by any method, subsection 2(1) of *The Act* provides for the following:**

***Persons deemed practising dentistry***

***2(1) A person shall be conclusively deemed to be practising dentistry within the meaning of this Act who***

***(a) performs any such operation or gives or renders any such treatment, advice, service or attendance as is usually performed, given or rendered by a dentist; or***

***(b) performs or attempts or professes to perform an operation of any kind on, or treats or attempts or professes to treat a disease, disorder, affection or lesion, of the oral cavity, teeth, maxillary or mandibular bones, related soft tissues and contiguous structures of a human being or corrects or attempts or professes to correct a malposed position thereof or makes any examination or diagnosis thereof with intent to perform any such operation or to treat any such disease, disorder, affection or lesion or to correct any such malposed position; or***

***(f) by sign or circular pamphlet or newspaper or in any way whatsoever advertises or indicates or authorizes or knowingly permits it to be advertised or indicated that he or she does or will personally or by his or her servants, agents or employees practise dentistry within the meaning of this Act; or***

***(g) manages or conducts as proprietor, owner, or otherwise, a place where dentistry is practised.***

**A dentist may use any legally prescribed drugs to diagnose, manage or treat a patient if the use is within the scope of practice of dentistry.**

**Botulinum toxin blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals and inhibiting the release of acetylcholine. Injectable drugs (the toxin) derived from this paralytic agent are listed in Schedule 1 of the Manual for Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities.**

**The toxin in therapeutic doses produces partial chemical denervation of the muscle resulting in reduction in localized muscle activity and potential muscle atrophy. Reinnervation of the muscle may occur over time reversing the effect of the toxin.**

**The toxin may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.**

**The toxin is available under a variety of proprietary and non-proprietary names with each product having its own individual potency which cannot be used interchangeably. The labeled usage of each product may vary.**

**Some of the labeled uses for the toxin include the following disorders or conditions:**

- **Prophylaxis of headaches in adult patients with chronic migraine ≥15 days per month with headache lasting 4 hours a day or longer);**
- **Temporarily reduce the appearance of upper facial rhytides in adult patients ≤65 years of age;**
- **Management of upper limb spasticity in adult patients;**
- **Management of cervical dystonia in adult patients;**
- **Management of strabismus in patients ≥12 years of age;**
- **Management of blepharospasm associated with dystonia in patients ≥12 years of age;**
- **Management of severe axillary hyperhydrosis inadequately managed by topical agents in adult patients; and**
- **Urinary incontinence due to detrusor overactivity associated with a neurologic condition in adult patients.**

**The purpose of this bylaw is to:**

1. **protect the public by authorizing access to services in a regulated manner;**
2. **define the usage of the toxin for members in the Province;**
3. **establish a roster identifying members authorized to use the toxin;**
4. **mandate specific requirements for members using the toxin; and**
5. **establish a process for maintaining the roster.**

**The bylaw contains nine sections. The first two sections define the categories of use. The third establishes a roster and a process for members allowing use of the toxin for the specified purposes. Sections four through eight mandate specific requirements and restrictions on delegation, recordkeeping, documentation and marketing for members using the toxin. The final sections establish a process for annual review and removal from the roster.**

**SECTION I - LABELLED USAGE OF THE TOXIN BY MEMBERS**

**There are no current labeled usages for the toxin in the scope of practice of dentistry.**

**SECTION II - OFF-LABELLED USAGE OF THE TOXIN BY MEMBERS**

**Off label usage of any drug is only considered for experimental or research purposes within the scope of practice of dentistry for members with the requisite knowledge, skill and judgement.**

**Experimental treatments are limited to adult patients.**

**Experimental treatments should be considered for a patient only after conventional treatments have proven unsuccessful.**

**Research purposes are limited to members participating in a university, corporate or government supported research project that has received approval from a recognized ethical research board.**

**Members participating in a research project or experimental treatment must receive and document full informed consent from patients prior to using the toxin.**

**SECTION III - THE TOXIN ROSTER**

**Members authorized to administer the toxin will be recorded on a roster available to the public on the MDA registry.**

**The use of the toxin without first being recorded on the roster shall constitute a deviation from the acceptable standards of practice required of a member and professional misconduct. The matter shall be referred to the Complaints Committee for investigation.**

1. **INFORMATION CONTAINED ON ROSTER**
    a. **member name;**
    b. **purpose for authorization as:**
        i. **experimental treatment; and/or**
        ii. **research purposes.**
    c. **restrictions, conditions or limitations on member use.**

2. **APPLICATION FOR THE TOXIN ROSTER**

    **A member may apply for inclusion on the roster to the Registrar.**

    a. **For experimental treatment, a member shall provide:**
        i. **prescribed application form which at a minimum shall include:**
            1. **intended usage;**
            2. **relevant literature supporting proposed experimental use;**
            3. **specific training; and**
            4. **current transferable knowledge and skills.**
        ii. **supporting documents demonstrating training;**
        iii. **prescribed initial application and roster fees (SCHEDULE A - FEES);**
        iv. **written informed consent document examples for experimental treatments; and**
        v. **prescribed declaration form committing the member to provide the MDA and Health Canada with an incident report of adverse events.**

b. For research purposes, a member shall provide:
    i. prescribed application form which at a minimum shall include:
        1. intended usage;
        2. specific training; and
        3. current transferable knowledge and skills.
    ii. supporting documents demonstrating training;
    iii. prescribed initial application and roster fees (SCHEDULE A - FEES);
    iv. the written proposal from the researching body to the member for participation in a university, corporate or governmental supported research project that has received approval from a recognized ethical research board. The research project should:
        1. identify a clear purpose relevant to the practice of dentistry;
        2. provide appropriate standardized training for dentists in the evaluation, use, documentation and follow-up to calibrate dentists and ensure patient safety;
        3. written informed consent documents for research subjects;
        4. appropriate fee reduction/compensation for research subjects; and
        5. indicate intention to publish results.
    v. original copy of the agreement between the member and the research body;
    vi. copy of the letter from the ethical research board; and
    vii. prescribed declaration form committing the member to provide the MDA and Health Canada with an incident report of adverse events.

3. APPEAL OF APPLICATION DECISION
    a. The applicant may appeal an unfavourable decision by the Registrar to the Extensions and Exemptions Subcommittee (the Subcommittee) of the MDA Continuing Competency Committee.
    b. An applicant has thirty days from written notification of the decision to send an appeal submission to the Chairperson of the Continuing Competency Committee (Chairperson) along with a non-refundable appeal fee (SCHEDULE A - FEES).
    c. The Chairperson shall refer the matter to the Subcommittee within thirty days of receiving the appeal submission.
    d. No member or employee of the MDA involved in the initial review of the application shall participate in the appeal of the Registrar's decision.
    e. The Subcommittee shall schedule the appeal review within sixty days of referral by the Chairperson. The Subcommittee shall provide the applicant written notice of the date, time and place of the review.
    f. In reviewing the decision appeal, the Subcommittee shall consider only the following:
        i. original application and supporting documentation;
        ii. Registrar's written decision and reasons for decision;
        iii. applicant written appeal submission and supporting documents; and
        iv. Registrar's written response to appeal submission.
    g. The Subcommittee may make the following determinations:
        i. confirm the Registrar's decision;
        ii. vary the Registrar's decision with a decision the Subcommittee determines appropriate; or
        iii. refer the matter back to the Registrar for further consideration with direction.
    h. The Subcommittee shall provide the Chairperson a written decision and reason for decision within thirty days of making the decision.
    i. On behalf of the Subcommittee, the Chairperson shall notify the applicant and Registrar within seven days. The written decision and reasons for decision shall be mailed to the applicant and Registrar within thirty days of the Subcommittee decision.
    j. The Registrar shall implement any decision of the Board within a reasonable time period dependent on the nature of the decision.

**SECTION IV - DELEGATION**

**A member shall not delegate the administration of the toxin.**

**SECTION V - RECORDKEEPING**

1. **At a minimum, a member shall record in the patient chart:**
    a. **medical history including a physical assessment, previous medications, allergies and sensitivities and comprehensive assessment of dental needs updated at appointments where treatment performed;**
    b. **toxin type and concentration used;**
    c. **dosage, number of injections and anatomical site locations;**
    d. **written informed consent;**
    e. **for experimental treatment, a detailed description of conventional treatment performed and results;**
    f. **for research projects, a copy of the patient agreement to participate in the research project;**
    g. **unfavourable or unanticipated outcomes or adverse incidents and member follow up; and**
    h. **copy of adverse incident reports submitted to MDA and Health Canada.**

2. **Records must be available at request of Registrar.**

3. **Records must be submitted to the Registrar within seven days of request.**

**SECTION VI - DOCUMENTATION**

1. **Members on shall maintain a separate contemporaneous log of all usages of the toxin.**

2. **At a minimum, a logbook shall include:**
    a. **patient name;**
    b. **purpose;**
    c. **amount and concentration; and**
    d. **adverse incidents.**

3. **Logbook must be available at request of the Registrar.**

4. **Logbook must be submitted to Registrar within seven days of request.**

**SECTION VII - MARKETING**

1. **A dentist shall not advertise, market, or make any representation by any means whatever for the purpose of promoting directly or indirectly the sale, provision of treatment or services related to the toxin except in compliance with the federal *Food and Drug Act* , *Food and Drug Regulations*, Health Canada Policies and the *MDA Code of Ethics*.**

**SECTION VIII - ANNUAL REVIEW**

1. **On or before the 31st of January, members on the roster shall receive notification to submit documentation for a review of their toxin usage.**

2. **On or before the 28th of February, members shall submit the following documents and fee:**
    a. **toxin usage logbook;**
    b. **file of continuing education activities related to the toxin;**
    c. **the prescribed annual renewal fees (SCHEDULE A - FEES); and**
    d. **any other documents requested by the Registrar in the notification.**

3. **A member who fails to submit the required documents and fee by the 28th of February shall be removed from the roster. The member must file a new application to be considered for inclusion on the roster.**

4. **After initial review, the Registrar may request additional documentation or information from the member.**

5. A member who fails to submit the requested additional document shall be removed from the roster. The member must file a new application to be considered for inclusion on the roster.

6. On completion of the annual review for a member, the Registrar may:
    a. retain the member on the roster;
    b. remove the member from the roster; or
    c. vary the restrictions, conditions or limitations for the member.

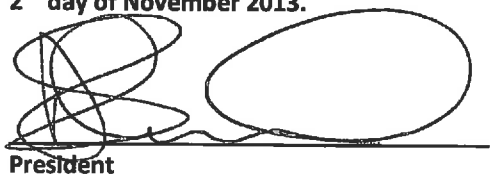
7. A member will receive written notification within thirty days of a decision to remove their name from the roster or to vary the restrictions conditions or limitations for their usage of the toxin.

8. A decision by the Registrar to remove a member from the roster is subject to appeal to the Subcommittee as described in SECTION III clause 3.

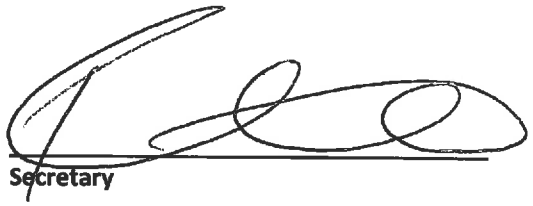
**SECTION IX - REMOVAL FROM ROSTER**

Except as described in SECTION VIII, any violation of this bylaw constitutes professional misconduct and subject the member to removal from the roster. A member removed from the roster for violation of this bylaw shall be ineligible to apply for inclusion on the roster for three years and shall have the matter referred to the Complaints Committee for investigation.

DONE and PASSED by the Board of Directors of the Manitoba Dental Association at Winnipeg, in Manitoba this 2nd day of November 2013.



President



Secretary

This by-law will become effective on the 17th day of December 2013, unless 10 members request on or before the 16th day of December 2013 in writing, its ratification at a general meeting of the Association pursuant to ss. 43(2) of *The Dental Association Act*.

Attached: Schedule A.

## SCHEDULE A - FEES

| | |
|---|---|
| **Botulinum toxin experimental treatment application fee** | **$150.00** |
| **Botulinum toxin research purpose application fee** | **$150.00** |
| **Botulinum toxin experimental treatment annual renewal fee** | **$ 50.00** |
| **Botulinum toxin research purpose annual renewal fee** | **$ 50.00** |
| **Appeal fee** | **$500.00** |

**NOTE: ALL FEES ARE NON-REFUNDABLE.**