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Board of Directors of Drugless Therapy NATUROPATHY

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Ms. Barbara Sullivan, Chair
Health Professions Regulatory Advisory Council
55 St. Clair Avenue West, Suite 806
Toronto, ON M4V 2Y7

Sent by Fax to: (416) 326-1549

Dear Ms. Sullivan

The Board of Directors of Drugless Therapy-Naturopathy (the BDDTN) was pleased to have the opportunity to attend and participate in the HPRAC consultation on Friday, August 15, 2008. By way of follow-up, we have prepared the following brief to HPRAC relating to the "Application for Review of the Scope of Practice of Dietitians in Ontario" submitted by the College of Dietitians of Ontario and Dietitians Canada (the Dietitians).

Enteral Nutrition (EN) and Parenteral Nutrition (PN): The Dietitians' submission proposes making the performance of both EN and PN one or more controlled acts under the RHPA. We understand that Enteral Nutrition involves the administration of substances into the gut via a tube that bypasses the oral cavity. The definition of PN, however, is unclear, both from the Dietitians' submission and from the discussion at the HPRAC consultation.

The BDDTN is assuming that Parenteral Nutrition is synonymous with *Total Parenteral Nutrition* (or TPN). In our interpretation, TPN is the determination of substances to be injected into the body in order to meet the total nutritional needs of an individual. This contrasts with nutritional supplementation that may be provided parenterally, involving the use of specific substances for therapeutic purposes, but not total food replacement.

Naturopathic doctors regularly prescribe nutritional, botanical and homeopathic substances for patients who must receive their nutrients enterally. NDs are educated and trained to prescribe and administer substances enterally to address such concerns as essential fatty acid, magnesium and other nutritional deficiencies, digestive enzyme insufficiency and to treat infections. If EN becomes a controlled act, NDs would need to have access to it in order to continue to meet the needs of their patients.

Currently, approximately 120 Naturopathic Doctors are registered to perform Parenteral Therapy (PT) to address such conditions as elevated levels of toxic substances, atherosclerosis, immune support and for the purpose of providing nutrients, particularly in conditions with poor gut integrity. The Board acknowledges that Parenteral Therapy poses significant risk of harm for patients if performed by inadequately trained or

otherwise incompetent practitioners. The Board has implemented a Parenteral Therapy Policy (copy attached) that, among other things, defines the requirements for post graduate Parenteral Therapy Certification, the standards for the practice of PT and the substances that NDs are permitted to inject.

The BDDTN is not convinced that the public interest case for prescribing and managing of TPN being a controlled act has been conclusively made. The discussion at the HPRAC consultation relating to risk of harm and examples of misadventures relating to EN or TPN failed to illustrate how a controlled act would have changed the course of events or the outcome.


If the prescribing and managing of "PN" is to become a controlled act, it is essential from the Board's perspective that the wording of the controlled act clearly apply to Total Parenteral Nutrition as "PN" is an ambiguous term. PN has at times been seen as equivalent to TPN, but has also been interpreted to mean the application of any nutritional substance parenterally. Clarity on this point would be critical in any legislation. If the actual wording of the act is restricted to TPN, the BDDTN does not see the need for NDs to be authorized to perform it. Because of the importance of the wording, however, the Board would like to continue to be involved in the discussions and reserves its position pending finalization of the wording.

Therapeutic Diets: The Dietitians' submission proposes making the formulation of a therapeutic diet a controlled act. Once again, there was a considerable lack of clarity with respect to the definition of a "therapeutic diet" and where the line is drawn between clinical nutrition, which NDs utilize extensively in practice, and a therapeutic diet. Clinical nutrition forms a cornerstone of naturopathic practice and involves the recommendation of specific diets and nutritional substances for the prevention and treatment of disease, the correction of dietary inadequacies and the promotion of wellness. NDs in Ontario perform this function safely and effectively. Patients of NDs have every right to expect to continue to receive clinical nutritional advice and treatment from their ND.

If prescribing and managing a therapeutic diet is defined in the proposed controlled act in such a way as to encompass or overlap with clinical nutrition, then NDs should be authorized to perform this act.

We are grateful for the opportunity to provide HPRAC with our comments on the submission from the College of Dietitians of Ontario and Dietitians Canada.

Sincerely

A handwritten signature in black ink, appearing to read "Angela M. Moore", enclosed within a large, hand-drawn oval.

Angela M. Moore, ND
Executive Director

Parenteral Therapy Policy

(November 2002)

BDDT-N REQUIREMENTS FOR THE PRACTICE OF PARENTERAL THERAPY IN ONTARIO

Registrants wishing to practice Parenteral Therapy must comply with the following requirements:

- ❑ Successful completion of an approved course* on IV therapy technique and emergency medicine specifically related to Parenteral Therapy, with written and practical exams (see course outline – prerequisite requirements, Appendix I). The course must be approved by the Board and must have been taken within 12 months prior to writing the Board's Parenteral Therapy examinations.
- ❑ A CPR course (given by St. John Ambulance or equivalent) which must be updated every year, and an emergency medicine course updated every 2 to 3 years. This requirement applies to all registrants and is recommended for any staff working directly with Parenteral Therapy in the clinic.
- ❑ After completing the above requirements, Registrants must within six months make application to the Board to write the Ontario Parenteral Therapy Certification examinations and pay the applicable examination fee (\$400). Practical and written examinations will be held twice each year, usually in February and August.
- ❑ Only Registrants or Candidates who have taken their NPLEX and Ontario Board examinations will be eligible to take the Ontario Parenteral Therapy examinations.
- ❑ Registrants who have passed the Parenteral Therapy examinations must then apply to the Board by completing the Parenteral Therapy Certification application and remitting payment of the initial certification fee, **within six months** following completion of the Parenteral Therapy examinations. The annual fee for this certification is \$400, renewable each year on or before May 1st. Candidates awaiting results of their NPLEX and Ontario Board exams will only be eligible for Parenteral Therapy Certification once they have passed all their regulatory Board examinations and are eligible for registration.
- ❑ Registrants must have malpractice insurance in place that will cover the N.D. and their staff for the practice of Parenteral Therapy. Proof of this insurance coverage must be forwarded to the Board with the Application for Certification.
- ❑ A minimum of five hours of continuing education related to Parenteral Therapy will be required each year for renewal of the certification, over and above any other continuing education requirements for registration.

*Effective January 2004, Registrants may choose Parenteral/IV Therapy training courses that meet the policy criteria and must pass Board certification exams to be certified for the practice of Parenteral Therapy.

NOTE:

Parenteral Therapy must not be performed on individuals under the age of fourteen (14) years.

Many of the courses currently offered in Parenteral Therapy cover topics that are **not** included in the Scope of Practice for Naturopathic Doctors in Ontario. **The Board has not approved the use of ozone therapy, chelation therapy using EDTA, DMSO or DMPS, hydrogen peroxide, ultra violet, or neural therapy for Registrants in Ontario.**

During the first two years of practising Parenteral Therapy, the Registrant's clinic office may be randomly inspected by the BDDT-N at least once a year. After the first two years, further inspections will be conducted at least once every two years.

TREATMENT OF PATIENTS USING PARENTERAL THERAPY

Parenteral Therapy poses significant risk for patients. The following comprise the basic standards of care for all patients. High-risk patients require extra vigilance due to their risk of contracting infection or having their condition exacerbated. High-risk patients include, but are not limited to, people with HIV/AIDS, hepatitis B or C; those undergoing chemotherapy, radiation, radiation over-exposure or receiving immunosuppressive medications; or having had an organ transplant, recent surgery, post-splenectomy or recent burns; or who are malnourished, severely debilitated or weakened, etc. Parenteral Therapy must not be performed on individuals under the age of fourteen (14) years.

- Written consent must be obtained for this procedure
- Change sheets or table examination paper
- Wash hands with disinfectant soap
- Explain procedure; ask for and receive verbal permission before proceeding
- Ask about possible allergic reaction to disinfectant, proposed IV therapy or diagnostic substance
- Swab insertion site with alcohol; betadine may be required first for high-risk patients
- Use only disposable needle or butterfly
- Apply tourniquet only as long as needed and if possible avoid the use of latex tourniquets
- Use only non-latex tape to secure needle and tubing
- Mark IV drip sets with starting time and each time patient is checked. Patients should be checked every 20 – 30 minutes
- Disposable gloves should be worn when inserting and removing needles and when handling needles or tubing during administration. A new pair of gloves must be used for each patient.
- All materials that come in contact with blood or other bodily fluids including swabs, needles, butterflies, etc. should be disposed of in biohazard containers.
- Biohazard containers should be covered when not in immediate use and disposed of according to local regulations.
- Monitor the patient's alertness and physical and mental capacity after each procedure. Do not release the patient until they are safely capable of leaving on their own.
- If the naturopathic doctor designates another person to perform any portion of the procedure, the naturopathic doctor must be present on site during the entire procedure.

CLEAN FIELD:

A clean field is required for the work surface prior to the procedure. The following items should be located within easy reach in the clean field:

- alcohol, cotton swabs
- needles/butterflies, syringes, administration sets
- IV bags/bottles
- vials of substances to be used in the procedure
- tape
- disposable gloves
- marking pen, and other supplies that may be required.

Biohazard containers should be within easy reach of the clean field, but not in the clean field.

Other necessary procedures include the following:

- The written protocol must be posted near but not on the clean field
- Hands should be washed with a disinfectant soap
- Clean paper is laid out on the work surface
- Procedure equipment is placed within the clean field
- Each vial is disinfected with a separate alcohol-soaked cotton swab
- The precise amount of each substance is drawn into the syringe
- If the syringe contents will be placed in an IV bag or bottle, its port must be disinfected with an alcohol-soaked swab
- Once the clean field is completed, the administration set is assembled in the clean field.

INJECTION SITE:

1. Naturopathic doctors performing injections should wear non-latex gloves during the insertion and removal of the needle and for breakdown of the administration set.
2. The median cubital vein should be used as little as possible in order to prevent scarring that would limit its access for venipuncture. This may not be possible in all patients as each has a different vein pattern.
3. The injection site should be checked for scars, infection, skin abnormalities or conditions, cuts, irritations and vein valves. All of these should be avoided when finding an injection site.
4. Swab the insertion site with alcohol (betadyne may be required first for high-risk patients). A clean cotton swab should be used for each site
5. Injections are performed with the needle bevel up.

6. A needle that will remain in the patient for any length of time (e.g. an IV) must be secured in place with non-latex tape.
7. The injection site should be periodically monitored to ensure that the injection process is operating smoothly and there are no complications.
8. When the administration is complete, the needle should be removed and a clean cotton swab pressed on the site for a minimum of one minute. A longer time may be required for patients on anticoagulant therapy. The site should be covered with a bandage before the patient is allowed to leave.
9. All materials (e.g. needles, administration set, cotton swabs, etc.) that have come in contact with blood or body fluids must be disposed of in a biohazard container. The container must be disposed of according to local regulations.

EMERGENCY PREPAREDNESS AND HANDLING:

- The naturopathic doctor and all staff who will be involved with intravenous therapy or diagnostic procedures should be trained in emergency first aid and CPR (with annual re-certification) through St. John Ambulance or equivalent.
- Oxygen should be available on site in the procedure room and staff should be trained in its use.
- Epi-pens must be available on site in the procedure room and the naturopathic doctor should be trained in their use.
- Any other appropriate antidote for the IV therapy or diagnosis procedures should be in the procedure room and the naturopathic doctor should be trained in its use.
- Hot and cold compresses, stethoscope and sphygmomanometer should be on site in the procedure room.
- A telephone for dialling emergency numbers should be located in the procedure room. Posted next to the telephone should be '911' and other appropriate local emergency numbers.
- An emergency plan should be prepared, reviewed with staff monthly, modified as conditions change (with staff notified of any changes), and posted in the procedure room. The emergency plan will indicate what tasks are to be performed and who will perform each task. It will also describe the best way to exit the building, and include directions for what to tell emergency personnel so they can find the street, building, and procedure room.

The office must also be equipped with the following emergency supplies:

- Bag and mask for CPR
- Benadryl for early symptoms of respiratory distress and skin manifestations
- smelling salts
- ammonia inhalants
- Water soluble gel (xylocaine gel)
- Normal saline bags
- Large gauge catheters
- snacks - e.g. juice and crackers
- Rescue remedy

Note: All patients must have an epi-pen acquired from their pharmacist and must have been taught proper usage techniques by the pharmacist.

STORAGE OF MATERIALS:

- All materials used for IV therapy and diagnosis must be securely stored in order to restrict their access; stored in, or readily accessible to, the procedure room; and stored at the required temperature and away from light.
- Injectable substances should be refrigerated (unless otherwise required) and stored away from light.
- Administration sets, needles/butterflies, syringes, IV bags/bottles and any other supplies should be stored securely and away from light.
- Nearly all IV inventory comes with an expiration date. The expiry date must be respected and all expired inventory should be disposed of in the appropriate manner.

PROCEDURE ROOM:

- The naturopathic doctor may elect to perform IV therapy or diagnosis either in her/his regular office or in a separate procedure room.
- The selected room should be well ventilated, temperature controlled, well lit, contain appropriate chairs or tables for performing IV therapy or diagnosis, and be easily accessible to emergency personnel should their assistance be required.
- A separate refrigerator is required for storage of vials containing injectable substances that require refrigeration. Lockable cabinets should be used to store all other IV inventory.

- Emergency supplies should be in the procedure room or on a moveable cart that can be placed in the office where the procedures will be performed.
- A clean work surface is required, upon which a clean field can be prepared.
- Biohazard containers should be available in the procedure room. When not in use they should be secured to prevent accidental exposure to staff.

VITAMINS, MINERALS AND COFACTORS:

The naturopathic doctor must know the following information and be able to correctly address any patient concerns:

- Indications and contraindications, allergic reactions, adverse reactions and antidotes for all substances and combination of substances used.
- Recommended dose for each substance used.
- Mixing “Dos and Don’ts” for all of the substances in the office.
- Rate of administration for each substance or combination of substances.
- Any other safety issues related to use of these substances.

APPENDIX I

Prerequisite Course Outline for Parenteral Therapy

The prerequisite course in Parenteral Therapies must be a minimum of 32 hours, and must cover the following topics for Registrants to be eligible for certification in Ontario:

1. Clinical rationale for IV therapy
2. Basic Science related to IV therapy
3. Equipment necessary to perform Parenteral Therapy
4. Indications and Contraindications of Parenteral Therapy
 - Subcutaneous
 - Intramuscular
 - Intravenous
 - Intra-dermal
5. Patient Assessment for Parenteral Therapy
 - health history
 - blood work
 - urine analysis
6. Sterile Technique and Waste Disposal for Parenteral Therapy
7. Parenteral Therapy Techniques
8. Parenteral Fluids
 - hypotonic, isotonic, hypertonic fluids
9. Calculation of Osmolarity
10. Rate and Administration of Parenteral Infusions
 - determining factors for infusion rates
 - calculation of flow rates
 - factors affecting flow rates

11. Emergency Procedures for Parenteral Therapy
 - including the use of oxygen, epinephrine, epi-pens
12. Charting and writing orders for Parenteral Therapy
13. Formulas - Vitamins and Minerals, Homeopathics, Botanicals (see Appendix II attached), with appropriate dosages
14. Quality assurance of injectables
15. Each person must start a minimum of 5 intravenous lines and perform a minimum of 5 intravenous push.
16. References -- where to get injectables for Parenteral therapy
17. Separate written and practical examination.

POLICY CURRENTLY UNDER REVISION

APPENDIX II

PARENTERAL THERAPY INJECTABLES

The following substances are approved for use in Parenteral Therapy. (The use of substances not included in this list is **not** permitted.)

VITAMINS

Retinol - Vitamin A - 10,000 IU's or less per dose

Cholecalciferol and Ergocalciferol - Vitamin D3 and D2 - 1000 IU or less per dose

Alpha Tocopherol - Vitamin E (aqueous)

Phytonadione - Vitamin K1

Ascorbic Acid - Vitamin C

Biotin

Methylcobalamin, Cyanocobalamin, Hydroxycobalamin - Vitamin B12

Folic Acid - 1,000 mcg or less per dose

Niacin and Niacinamide - Vitamin B3

Calcium Pantothenate/Dexpanthenol - Vitamin B5

Pyridoxine Hydrochloride - Vitamin B6

Riboflavin-5-Phosphate - Vitamin B2

Thiamine Hydrochloride - Vitamin B1

B-Complex formulas

MINERALS

Calcium Gluconate, Calcium Chloride, Calcium glycerophosphate

Iron - Ferrous Sulphate

Magnesium Sulfate/Chloride

Zinc Chloride, Zinc Sulfate

Copper Sulfate, Cupric Chloride

Chromium

Selenium

Manganese

Molybdenum

Rubidium

Strontium

Boron

Vanadium

Potassium Chloride, Potassium Phosphate

Sodium Bicarbonate

Sodium Iodide

Sterile Water

AMINO ACIDS

Mixed Amino Acids (Amino Acids may only be used in combination; single Amino Acids are not permitted.)

Alanine

Arginine

Aspartic acid

Carnitine

Citrulline

Cystine

Glutamic acid

Glycine

Histidine

Isoleucine

Leucine

Lysine

Methionine

Ornithine

Phenylalanine

Proline

Selenomethionine

Serine

Taurine

Threonine

Tryptophan

Tyrosine

L-Glutamine

Adenosine

BOTANICALS

Echinacea

Aesculus

Viscum

Crataegus

IMMUNE AGENTS

Hydrochloric acid 1:1000, 1:500

Pycnogenol

Glutathione

MISCELLANEOUS

Saline solution

Sterile water

Carbohydrates in water

Carbohydrates in sodium chloride solution

Ringer's solution (sodium, chloride, potassium and calcium)

Plasma volume expanders (dextran, sodium, chloride)

Vitamin and Mineral Mixes

Injectable Homeopathic solutions

INTRAMUSCULAR INJECTABLES

Superficial

Homeopathics

B12

Folic acid

Deep (may be painful)

Magnesium

B - complex

Iron - Z track only

****NEVER IV PUSH POTASSIUM****