



Maintaining Naturopathic Doctors' Access to Substances

The controlled act of prescribing, dispensing, selling and compounding is required for Naturopathic Doctors to preserve current access to substances and patient care and to regain access to those that have become restricted at the federal level. Loss of substances that are integral to naturopathic medicine will limit the scope of practice of the profession and access to care for patients.

There is a misconception that all natural substances are without restriction and safe for consumer self-selection. This is not the case. Continuing regulatory change and re-classification has addressed potential risks associated with some natural substances by restricting access to knowledgeable practitioners. This process of re-classification will continue to restrict naturopathic practice unless prescribing authority is granted.

The following restrictions to naturopathic practice are likely following transition to regulation under the Naturopathy Act in the absence of the controlled act of prescribing, dispensing, selling and compounding:

- High probability of loss of injectable substances and inability to compound or combine these substances in clinical practice: iron, certain vitamins and minerals, chelating agents, certain botanicals, etc. depending on interpretation of NAPRA schedules, threatening loss of comprehensive naturopathic infusion therapy currently being used to provide advanced care in oncology, cardiology, and many other conditions.
- Continuing loss of access to naturopathic substances that are currently Schedule I: L-carnitine, botanicals such as rauwolfia, yohimbe, red yeast rice and others, bioidentical hormones and tissue glandulars, folic acid above 1mg, resulting in reduced capacity to provide naturopathic treatment for endocrine disorders, cardiovascular disease, women's health issues, etc.
- Likelihood of loss of or limits on additional naturopathic substances as a result of implementation of the Natural Health Products regulation on January 1, 2010, such as current restriction of niacin above 500mg, leading to reduced capacity to provide naturopathic treatment for neurological conditions, high cholesterol, etc.
- Loss of current authority under the Drugless Practitioners Act to compound, dispense and sell any Schedule II naturopathic substances.
- Continuing or increased limits on access to emergency medicines NDs are trained to use to respond to emergency care in office: oxygen, epinephrine, Benadryl, bronchodilators, etc.

A more detailed explanation of these restrictions is provided in the background section.

Given the complexity and dynamic nature of the regulation of substances, secure access to substances and patient care cannot be achieved through a regulatory change. Changes to regulations on an ongoing basis takes months or more likely years to take effect while changes in access to natural substances are happening all the time even now without the introduction of new federal legislation.

Background:

The OAND is generally satisfied with the overview of the risk of loss of substances provided in HPRAC's *Critical Links* report.

Current ND Use of Restricted Substances

Under the Drugless Practitioners Act, NDs do not use pharmaceuticals, but are authorized to use a number of therapeutic natural substances that are listed by NAPRA on Schedule I and II. Specifically, there are certain substances that have been approved by the BDDT-N (the provincially-appointed regulator) for use in Parenteral Therapy by Ontario NDs that are also included in Schedule 1 when used "in injectable form for parenteral nutrition". A list of restricted substances that NDs are currently permitted to use is attached as Appendix I. Key examples are vitamins and minerals in injectable form used for parenteral nutrition, and amino acid solutions for parenteral use. More details on Ontario's concerns are contained in the paper "Key Issues in NAPRA Classification of Substances" attached as Appendix II. Parenteral therapy is currently used with ND patients with the most critical health conditions, including oncology and cardiology. The loss of substances would preclude NDs from providing meaningful and clinically safe health care for these patients. Other substances are restricted in dosage. *Critical Links* provides a listing of the classes of natural substances (called Prescription Therapeutic Products) that are integral to naturopathic medicine.¹

Naturopathic Substances Not Currently Available in Ontario

A number of substances that are integral to naturopathic medicine are already unavailable for use in Ontario due because they have been made prescription-only. Examples include L-Carnitine, L-Tryptophan, toxic botanicals such as rauwolfia, yohimbe, topical progesterone cream, and all glandulars. These substances are available to NDs in most other regulated jurisdictions.

Continuing Loss of Access Resulting from Natural Health Products Regulation

Implementation of the Natural Health Products regulation on January 1, 2010 will likely result in substances not suitable for consumer self-selection moving onto restricted schedules. NHPs are only those substances and dosages suitable for consumer self-selection. For example, under the NHP regulation, Niacin is no longer available above 500mg daily.

Compounding

While the DPA does specifically restrict NDs from prescribing pharmaceuticals, the DPA contains no such limitation on dispensing, selling and compounding substances. Patients seek out NDs for their expertise in the use of therapeutic natural substances. NDs are recognized as being trained and competent to undertake these acts. As a result of having access to these acts, patients have benefited from receiving customized treatments that address specific diseases, conditions or symptoms. Compounding, dispensing and selling is restricted when any natural substances are Schedule I or Schedule II, and as a result NDs require this Controlled Act to maintain this area of their scope of practice.

Emergency Medications

Critical Links does establish clear criteria for awarding access to emergency substances which in our analysis NDs achieve to the full extent. Specifically, HPRAC recognizes that "any health profession carrying out a procedure in-office should have the knowledge and necessary tools to handle an emergency situation."² HPRAC goes on to conclude that "the benefits of having access to an emergency kit outweigh the risks." NDs therefore require prescribing authority to have access to standard emergency medications to ensure NDs can fully use their training to respond in an emergency situation, subject to terms, conditions and limitations established by the College of Naturopaths of Ontario.

¹ HPRAC, *Critical Links*, pp 266-267.

² *Critical Links*, p. 79

Appendix I: Restricted Substances Currently Authorized to NDs

The attached table lists the substances that are or have been permitted to be used by the BDDT-N which NDs may not be able to access in the absence of prescribing authority. In particular, there is an absence of clarity in cases where the NAPRA National Drug Schedules differ from the federal drug schedules in order to ensure that access to substances is not unduly restricted.

Substance	Schedule and Conditions	Reclassification Date
Vitamins in injectable form	Schedule I for parenteral nutrition. Not in Schedule F.	01/03
Vitamin D3 and D2 (1000 IU or less)	Schedule I (F-II).	12/99
Vitamin K1	Schedule I except for external/oral use (F-II).	10/05
Folic Acid	Schedule I if over 1mg (F-I), otherwise NHP.	12/99
Calcium Chloride	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Calcium Gluconate	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Iron derivatives	Schedule I for parenteral use (repealed in 05/04 on F-II).	9/98
Magnesium Sulfate	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Zinc Chloride	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Zinc Sulfate	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Copper Sulfate	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Cupric Chloride	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Chromium (chromium chloride)	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Manganese	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Selenium	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Potassium Chloride	Schedule I in preparations for injection. Not in Schedule F.	12/99
Potassium Phosphate	?	
Sodium Iodine	Schedule I in injectable form for parenteral nutrition. Not in Schedule F.	1/03
Mixed Amino Acids	Not in Schedule F.	
Amino Acid Solutions	Schedule I for parenteral use. Not in Schedule F.	9/99
Adenosine	Schedule I for parenteral use (F-I).	9/98
Carnitine (levocarnitine)	Schedule I (F-I).	9/98
Serine (cycloserine)	Schedule I (F-I).	9/98
Tryptophan	Schedule I when sold as a single ingredient (F-I).	9/98

Appendix II



Key Issues in NAPRA Classification of Substances

Overview

There is insufficient clarity in NAPRA's National Drug Schedules for substances that are within the scope of practice of Ontario naturopathic doctors (NDs). In Ontario, provincial legislation directly adopts the NAPRA schedules as the provincial drug schedules.

With the approval of Ontario's new *Naturopathy Act* in June 2007, there is additional need for certainty with regard to the classification of the substances that are used by Ontario NDs. Further, the minutes of the National Drug Schedules Advisory Committee (NDSAC) meeting of June 11-12, 2007, available online at www.napra.ca, indicate that the committee will be reviewing the terms of "parenteral nutrition" and "total parenteral nutrition" at its next regularly-scheduled meeting. The minutes indicate that these two terms are used interchangeably in the National Drug Schedules, thereby creating confusion.

There are a number of substances currently being used by Ontario NDs in accordance with the Board of Directors of Drugless Therapy-Naturopathy's (BDDT-N) Parenteral Therapy Policy, which are classified by NAPRA as Schedule I requiring a prescription when being used for parenteral nutrition. Other substances, such as amino acid solutions, are classified as Schedule I for parenteral use. In many cases, these substances are not specifically listed in the federal *Food and Drug Act* schedules.

The OAND had strongly advocated through the legislative process for the *Naturopathy Act*, to be awarded the controlled act of prescribing, which would have provided clearer access to the substances in question, but the provincial government did not grant that request.

In the absence of prescribing, Ontario NDs could have more certainty in the ability to access most of the substances which are integral to naturopathic medicine if NAPRA provided more clarity in the classification of substances particularly related to parenteral nutrition or parenteral use to clarify that this only refers to "total parenteral nutrition". The loss of access to these substances would severely limit the therapies available to Ontario NDs.

Basis for the Ontario Scope of Practice

Ontario NDs will have a new scope of practice under the *Naturopathy Act* based on the standards and regulations that will be developed by the Transition Council. This will come into effect upon full proclamation of the *Naturopathy Act*, expected in 2009. The current scope of practice is established by the *Drugless Practitioners Act* (DPA) based on an exemption in the *Regulated Health Professions Act* (RHPA).

RHPA Regulation 107/96 exempts NDs working within their scope of practice established under the DPA from the RHPA controlled acts.

The DPA establishes the Board of Directors of Drugless Therapy-Naturopathy as the regulator of Ontario's 850 naturopathic doctors, and the standards of practice that they authorize have established the scope and acts that NDs currently use to guide practice. Under the RHPA, NDs must be able to continue to provide the treatments and therapies that are currently available to patients.

The DPA Regulation 278/1990, in the definition of a "drugless therapist" establishes the scope of practice of an ND as "methods taught in education programs that have been certified by the BDDT-N". This education includes prescribing, dispensing and compounding natural substances. However, the DPA contains a prohibition on NDs prescribing or administering drugs. While the DPA does not define "drugs" as a term, it is commonly understood to be substances requiring a prescription. This is established by the *Drug and Pharmacies Regulation Act*, which directly adopts the NAPRA schedules as the basis for provincial drug schedules.

While the DPA does specifically restrict NDs from prescribing drugs, the DPA contains no such limitation on dispensing, selling and compounding substances. NDs are recognized as being trained and competent to undertake these acts. As a result of having access to these acts, patients have benefited from receiving customized treatments that address specific diseases, conditions or symptoms.

In practice NDs do provide patients with recommendations for natural substances that are stored behind the pharmacist's counter, and patients take these recommendations to a pharmacy to be filled. Some compounds that are prescribed in this way do include natural substances that are classified as Schedule II (of the National Drug Schedules) and pharmacists have the authority to dispense these substances to the public.

Classification of Substances by NAPRA

Ontario NDs are seeking more clarity regarding the classification of substances by NAPRA. There are a number of substances listed in Schedule I of the National Drug Schedules which are not specifically listed on the *Food and Drug Act* schedules. More clarity would ensure that access to substances which are integral to naturopathic medicine are not unduly restricted.

Of particular concern is ensuring continued access to substances used in parenteral therapy. The BDDT-N has established the Parenteral Therapy Policy to regulate the practice of parenteral therapy (PT) in Ontario. The policy includes details on the required qualifications for an ND to provide PT (including specialized training, emergency skills, examination, continuing education, and protocols for the treatment of patients).

The BDDT-N policy also lists the substances approved for use in PT. These substances include vitamins, minerals, mixed amino acids, botanicals, immune agents and miscellaneous substances. The PT policy is available on the BDDT-N website: www.boardofnaturopathicmedicine.on.ca/pdf/parenteral_therapy_policy.pdf

As discussed above, NDs in Ontario are exempt from controlled acts, and as a result the PT policy does not anticipate the National Drug Schedules, Schedule I substances. However, many of the substances listed on the PT policy have been reclassified by

NAPRA in recent years, reportedly as a result of an effort by NAPRA to clarify the classification of substances used in solutions intended for total parenteral nutrition. However, NAPRA has listed the substances in question as being Schedule I for “parenteral nutrition” or “parenteral use” rather than using the term “total parenteral nutrition”. This reclassification of some substances on the NAPRA schedule in recent years has created uncertainty about their use by Ontario’s NDs.

It is our understanding that the substances used by NDs for PT are not restricted because they are used for parenteral therapy rather than parenteral nutrition. Parenteral nutrition as we understand in Ontario is seen to be limited to situations where patients are reliant on nutrition being delivered parenterally, up to and including total parenteral nutrition. It is not understood to describe situations where the substances delivered parenterally have a therapeutic effect. It is our view that a definition of the term “parenteral nutrition” would be beneficial to avoid any uncertainty and in particular to ensure that pharmacists can feel confident when providing NDs with the substances used in PT.

Dorlands, for example, defines **parenteral nutrition** as “administration of nutrient intravenously” and **total parenteral nutrition (TPN)** as “intravenous administration, via a central venous catheter, of the total nutrient requirements of a patient with gastrointestinal dysfunction.” The OAND recommends that these definitions be put forward to NAPRA for inclusion in the National Drug Schedules.

The need for this clarification arises from the decision of NDSAC at the September 22-23, 2002 meeting to prepare an exhaustive list of TPN additives. These additives are listed in the National Drug Schedules as scheduled “in injectable form for parenteral nutrition” but there is no definition of the term “parenteral nutrition”.

Other substances, such as amino acid solutions are scheduled “for parenteral use”. The summary of this condition establishes that the restriction is for patients “requiring” amino acid solutions. It would be helpful if the summary provided more clarity that “requiring” refers to situations where patients are not able to fully meet their nutritional needs through other means, rather than requiring these substances to address other healthcare issues identified by a healthcare practitioner.