Overall Intent of the Prospective
Draft Naturopathic Therapies Regulation

The purpose of this document is to provide information about the draft prospective Naturopathic Therapies Regulation for the purposes of a preliminary consultation. It is intended to offer background information that cannot be conveyed within the draft regulation, further clarifying the intent of the wording of the draft regulation. This document should be read in conjunction with the document entitled Draft Naturopathic Therapies Regulation.

INTENTION – WHY A REGULATION MAY BE WARRANTED

There are several reasons why preliminary consideration is being given to developing a regulation governing therapies involved in naturopathic practice. Contextually, it is important to recognize that the mandate of the College is to serve and protect the public interest. Although the public interest is not defined in legislation, it is commonly understood to be conceptual—an intangible object, it is context-based and requires an unbiased concern for society.

Given that it is the duty of the College of Naturopaths of Ontario (the College) to serve and protect the public interest, it is important to understand that access to competent, safe and ethical practitioners is critical to fulfilling the College's mandate. Safe, in this context, means protecting the public from harm (physical, psychological and financial), dishonesty and disrespect, poor quality care, sexual abuse, breach of laws and ineffective care. Each of these is an important factor in considering any prospective regulation.

In the context of the draft prospective Naturopathic Therapies Regulation, the following are the most important considerations for the College.

1. Clarifying Naturopathic Practice

There is a high degree of uncertainty about what is included within naturopathic practice, the conditions a naturopathic doctor might or can treat and any rules set by the College governing naturopathic practice in Ontario.

Discussions with registrants and system partners relating to the scope of practice are particularly telling when it comes to defining what naturopathic practice includes and excludes. To understand what may be within the scope of practice, we need to consider the Scope of Practice statement within the Act, and the controlled acts authorized to the profession embodied in the Act, as well as the General Regulation which further defines the authorized acts along with the Standards of Practice of the profession.

Developing a Naturopathic Therapies regulation would add an additional and valuable tool in the process of the public's understanding of naturopathic practice. It would provide clarity for the public, the profession and other professions in terms of what NDs in Ontario can do. While one new regulation might not satisfy all the needs of the public and perhaps other professions in gaining a better understanding of what naturopathic practice entails, the draft regulation begins to quantify the practice

to help the public, other professions and even naturopathic doctors in terms of which therapies they might be able to provide.

2. Maximizing Public Protection Benefit

The College, at the request of the Council, is examining opportunities to maximize the public protection benefit to Ontarians through the regulatory framework for the profession. The current regulatory framework consists of:

- The *Regulated Health Professions Act, 1991* (RHPA),
- The Health Professions Procedural Code, Schedule 2 of the RHPA,
- The regulations made under the RHPA
- The *Naturopathy Act, 2007* (the Act)
- The regulations made under the Act, namely the General Regulation, the Registration Regulation, the Quality Assurance Regulation and the Professional Misconduct Regulation.
- The Standards of Practice of the profession as established by the College.

While all these statutes, regulations and standards are of vital importance to the regulatory framework, none of them provide clear guidance to the public or the profession on the activities that can or cannot be undertaken as part of the practice.

The College frequently receives questions about whether a specific therapy can be used in practice. For example, an ND in another jurisdiction planning to relocate to Ontario asked if they could provide neural therapy in Ontario. The regulations, as they currently exist, do not provide clear guidance to either the ND or the public. Neural therapy relies on the injection of anesthetics into scars, peripheral nerves and trigger points among others. Anesthetics are not listed as prescribed substances to be administered by injection, and so the therapy is not permitted.

What we believe we see here is a disconnect between what the public and profession need to know, i.e., “can I provide this service?” and the current regulatory framework which relies on an analysis of the therapy under consideration in the context of what drugs/substances are allowed. It can be done, but it is not easy or straightforward.

The draft naturopathic therapies regulation would work towards the goal of maximizing public protection benefit by clearly stipulating which therapies a naturopathic doctor can and cannot do as a part of their practice.

3. Augmenting Accountability of the Profession

One role performed by every health regulatory College is to hold individual registrants accountable for their conduct through investigations and hearings. Instances of non-compliance are expected, which is one reason why the College exists. However, over the last several years, there have been instances where breaches of the regulatory framework have occurred not due to error or oversight but with intent on the part of the registrants and without any knowledge or understanding on the part of patients.

For example, there have been two significant disciplinary cases where the registrants have knowingly engaged in the provision of intravenous infusion therapy (IVIT) without having met the Standards of Practice to do so. In these cases, the public might not be fully aware that there are limits on an ND's ability to provide IVIT as a part of their practice. The prospective regulation will clarify to registrants and patients alike that there are limits and inquiring about these from their ND is not only appropriate but important to do.

Two additional significant disciplinary cases have been encountered where the registrants engaged in providing therapies that are not permitted. How does the College know these therapies were not permitted? Simply because, as outlined in the example above, the substances to be administered as part of the therapy are not included on the table to the General Regulation which is required in order for the therapy to be allowed. Presently, the College Council, and the transitional Council before proclamation, restricted the use of certain therapies by not authorizing the use of certain drugs and substances as part of the practice in the General Regulation.

What we are learning is that this approach may not be sufficiently clear for practitioners, and would therefore be absolutely unclear for the public. This is simply because the downside of relying on the current approach is that the public might not fully appreciate that they are receiving a therapy that was not intended to be authorized to the profession because the practitioner does not identify to the patient that use of the drug or substance is not permitted.

One example of this is chelation therapy. Chelation therapy is the administration of a chelating agent such as ethylenediaminetetraacetic acid (EDTA), dimercaptosuccinic acid (DMSA), 2,3-dimercaptopropanesulfonic acid (DMPA) and alpha lipoic acid (ALA) by IVIT, injection or orally. These substances are not listed in the tables to the General Regulation which sets out which substances and drugs that are allowed to be used by these routes of administration. A patient may consent to chelation therapy not knowing that it is prohibited by the exclusion of the chelating agents for use by NDs.

The prospective Naturopathic Therapies Regulation would move the bar forward because a patient could look to see what therapies are prohibited directly from that regulation or from related information on the College's website. A patient who is offered chelation therapy, and other prohibited therapies by a registrant can also alert the College, enabling better accountability of the profession.

4. Enhancing Patient Safety

Closely aligned with accountability is patient safety. Many of the therapies that rely on drugs or substances that are presently not authorized for use by Ontario NDs represent a serious risk of harm to patients. There are risks to nearly every therapy that is provided in a health care setting; however, some therapies carry greater risk or have a greater potential for harm. As the regulatory authority, it is the College's role to ensure that high risk therapies, where the risk of harm outweighs the potential benefit to patients, are not permitted in practice.

Furthermore, some therapies have little or no evidence of efficacy. Their use in practice results in potential harm to patients who are paying for services they believe will help them when the evidence

would suggest that they will not. Restricting therapies that have no evidence of efficacy protects the public by ensuring that the money they are spending will be on therapies that have a reasonable prospect of success in terms of their treatment.

ABOUT THE DRAFT POTENTIAL REGULATION – THE APPROACH AND MEANING

Approach

While the draft prospective regulation does set out which therapies are proposed to be authorized and unauthorized for use, it is essentially impossible to list every single therapy available today and in the future. Therefore, the regulation needs to provide registrants with a means to evaluate therapies authorized in the regulation and new therapies that may be developed in the future.

Standard of practice re therapies

Section 1 of the draft prospective regulation is designed to provide the profession with that evaluation tool in the form of a standard of practice. Where a therapy is not specifically authorized in the draft regulation but is also not specifically prohibited, this section would be used by an ND to determine whether the therapy can be used with a patient and the registrant's evaluation as such would be part of any future investigation in the event of a complaint.

The provisions within this section require a registrant to only use therapies that meet the following conditions:

Provision	Explanation
Have been demonstrated to be effective and for which they have the knowledge, skill and judgement to use,	The therapy to be used must have "evidence" of being effective in the treatment of the condition being presented by the patient. Furthermore, the registrant must have the competency necessary to use the therapy, i.e. how it is used, its contraindications, the risks, benefits and alternative approaches to explain to the patient.
May be used to treat symptoms, complaints or conditions that are within the scope of practice,	As is the case with most treatments within the profession, the condition being presented by the patient must be within the scope of practice of the profession. A condition is within the scope of practice if the profession has the tools to diagnose the condition, provide one or more treatments, and can effectively monitor the treatment outcomes.
Are supported by sound clinical judgment,	Sound clinical judgment means that other NDs in the same or similar circumstances, would also use this therapy to treat a patient based on their own clinical judgment.
Are informed by evidence and scientific reasoning to a degree that is proportionate to the risks to the patient associated with the therapy	Evidence and scientific reasoning, i.e. that the therapy has been studied and these studies support the efficacy of the therapy,. This provision requires that a registrant knows the risks of harm to the patient from the therapy and where the risk of harm is greater, the greater the evidence and scientific reasoning should be available that supports the use of the therapy.
The potential benefits outweigh the risks taking into consideration, i. The health status of the patient	This provision is similar to the provisions in the General Regulation in regard to using a controlled act on a patient in practice. A risk/benefit analysis is required to ensure that the

ii. The evidence and reasoning regarding the efficacy of the treatment for the patient's symptoms, complaints or condition, iii. The potential for harm to the patient due to factors including the nature of the therapy, the potential interaction with other therapies and treatments the patient may be undergoing, other therapies available from members of the profession and members of other regulated health professions and whether other therapies will be provided concurrently,	benefits of providing the therapy outweigh the risk of harm in considering: • The patient's health status. How good is their overall health? Will this treatment impact other treatments they are also undergoing at the time. • The evidence and reasoning available for using the therapy for this patient's particular condition, complaints or symptoms. Not all therapies are right for each individual patient. • What is the potential for harm to the patient considering their full health status and might other therapies from other health care providers provide similar outcomes with fewer risks?
The patient has given informed consent to its use.	Informed consent, as defined in the Health Care Consent Act, is required for the provision of all naturopathic services. Its addition here is a reminder of that fact to all registrants.

<u>Therapies authorized for use by NDs</u>

This provision sets out the therapies that would be authorized to the profession. The wording "without limiting the generality of the foregoing" is intended to identify that the list of authorized therapies is not intended to limit the application of the standard. In other words, the list is not intended to be all inclusive.

It is important to note that the use of these therapies is conditional on section 1, that is, the application of the standard of practice re: therapies in the use of authorized therapies. The authorized therapies are also conditional on the next section which sets out conditions on their use.

The therapies included on this list are based on the following factors:

- It is part of the education and training of NDs in Ontario and is it currently a part of the practice of the profession,
- The therapy involves a controlled act that is authorized to the profession with some restrictions,
- The therapy is in the public domain (not a controlled act) and carries minimal risk of harm to patients.

The intent of this section is to create a list of the most commonly used therapies that NDs will offer and that patients will encounter. It is acknowledged that there will be other therapies not on the list but that would still meet the standard of practice in section 1 when considered by the treating ND.

<u>The Use of Prescribed Therapies</u>

This provision sets out conditions and limitations on the use of <u>some</u> of the authorized therapies. This section essentially encompasses many of the provisions within the General Regulation as it applies to the performance of controlled acts. They are included to ensure consistency between the two regulations.

The conditions and limitations include the following:

- The therapy may only be delivered with a device that is authorized for sale in Canada by Health Canada,
- The registrant has met the standard(s) of practice to perform the therapy, and
- The registrant may only use the drugs or substances listed in the table of the General Regulation as it applies to that specific therapy.

Therapies prohibited

This provision sets out the therapies that are proposed to be prohibited from use in naturopathic practice in Ontario. This section is set out "notwithstanding" section 1 of the draft prospective regulation. This means that despite any assessment conducted by a registrant of a prohibited therapy for use on a patient, the therapy is prohibited. There is one caveat – an allowance for the possibility that performing the therapy may be delegated by another regulated health professional to an ND, subject to the delegation provisions of the General Regulation.

The therapies set out in this section are included based on one or more of the following factors:

- The therapy is intended for treating a condition that cannot be properly diagnosed by an ND,
- The therapy carries a significant risk of harm to patients,
- The therapy is a controlled act not authorized to the profession,
- The therapy requires a device and/or substance that is not authorized for use by the profession,
- The therapy is used by NDs in other Canadian jurisdictions but is not intended to be used in Ontario,
- There is little or no evidence of the efficacy of the therapy.