

The IVIT Inspection Program Issue



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Registrar's Message

Introducing the IVIT Inspection Program

After many, many years of developing, consulting on, finalizing and submitting a draft, and waiting for approval, the Regulation supporting an IVIT focused inspection program received Royal Assent on December 2, 2016. The regulation, which included a 90-day delay in implementation came into force on March 2, 2017.

Due to the lengthy development process, Members will not have had the program top of mind. As a result, we know that there are many questions, including "When will inspections begin?" and "When will we need to install a laminar air flow hood?" As one of several ways for the College to address these questions, we are devoting most of this edition of iNformeD to this important topic.

Three Important Elements

As Registrar of the College, I would like to present three important elements to this discussion which place it in context.

First and foremost, the intention of the program is to ensure Ontarians who wish to access IVIT procedures from a naturopathic doctor can be assured of receiving safe, competent, ethical care. It accomplishes this by establishing important standards governing the locations where the services are being provided, sterility, infection control, safety and emergency preparedness being chief among them. The program also moves Ontario closer to a model where individuals who perform the same controlled acts, such as compounding, are governed by similar standards and controls.

Secondly, the College has taken the time to reach out to Members of the profession who perform IVIT and whose premises will be governed by this program to find out what their concerns are about the program and what are the key questions that they want answered. By doing our homework, we can ensure that the primary questions and concerns are addressed before the program takes effect.

Third and finally, although the inspection program will only impact those Members who compound for or administer IVIT in their clinics, I want all

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Members of the profession and our stakeholders, including Ontarians, to be aware of and have a general understanding of the program.

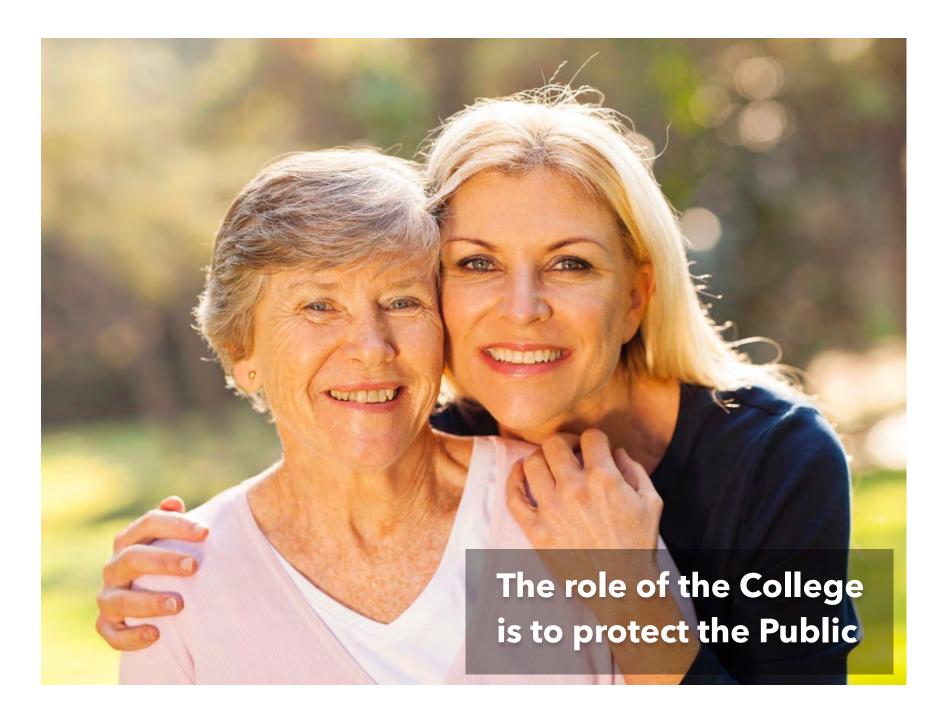
It's important to understand the full regulatory regime

Many Members may decide later to begin offering IVIT and will have to register under this program at that time. For those Members who will never choose to move in this direction, it is always important to have a general understanding of the full regulatory regime.

For our stakeholders, in particular individual Ontarians who receive this newsletter, it is part of our broader education program to ensure that you understand the role of the College and how we accomplish our intended result, protecting the public. It is for these reasons that we have chosen to devote this edition of iNformeD to this topic.

The articles in this edition will provide information, some of which is also available in the Inspection Program Handbook, to help explain the aspects of the program that place new requirements on the profession. We believe the information will be helpful and reduce concerns Members may have and increase the confidence the public has in the profession.

Andrew Parr, CAE Registrar & CEO



The Inspection Program A Brief History

Members often ask why the College developed an inspection program and why it looks the way it does.

The Short Answer has three parts, all with the same underlying theme - public protection.

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1. An inspection process pre-existed under the Board of Directors of Drugless Therapy – Naturo-pathy.

2. The transitional Council of the College of Naturopaths of Ontario identified the controlled act of compounding for, and administering a substance by intravenous injection as presenting a higher degree of risk than other areas of practice, based on a risk assessment of the scope of practice.

3. At about the same time in Ontario, there was an increase in the focus for regulation on the controlled act of compounding due to a number of cancer patients receiving diluted doses of chemotherapy in some hospitals as a result of compounding errors.

The Detail

Background

During the process of transitioning the profession from being regulated under the *Drugless Practitioners Act, 1925* to the *Regulated Health Professions Act, 1991*, the transitional Council of the College of Naturopaths of Ontario debated the need to continue the inspection program conducted by the Board of Directors of Drugless Therapy – Naturopathy.

The transitional Council decided that to continue to have an inspection program would serve the mandate of the regulator to protect the public. The initial draft of the program and the regulation granting the College the authority to conduct the program was very broad and included every Member of the College. After discussions with the Ministry of Health and Long-Term Care the transitional Council conducted a risk assessment of the scope of practice of the profession and decided to narrow the inspection program to the controlled act of administering by intravenous injection; a procedure that, based on the assessment, involved a greater degree of risk.

Also, around this time in Ontario, there was an increase in the focus for regulation on the controlled act of compounding. This was due to a number of cancer patients who had received diluted doses of chemotherapy in some Ontario hospitals as a result of an error in compounding the drugs. The Thiessen Report, which reviewed the oncology under-dosing incident indicated that the IV chemotherapy drugs compounded for administration to patients was done incorrectly and made recommendations to prevent future incidents.

As a result, the College's draft inspection program and regulation included the inspection of premises where compounding for intravenous infusion therapy (IVIT) as well as the administration of IVIT were performed.

> An inspection program preexisted under the Board of Directors of Drugless Therapy - Naturopathy.

The Resulting Program

The requirements to be met by each premises were developed based on the structure of the Out-of-Hospital Premises Inspection Program of the College of Physicians and Surgeons of Ontario as well as the inspection criteria previously used by the BDDT-N.

Compounding for and administering by IVIT presented a higher degree of risk than other areas of practice.

Risk assessment results Transitional Council of the College of Naturopaths of Ontario

With a focus on risk identification, reduction and monitoring, the program supports continuous quality improvement through the development and maintenance of requirements for the premises where IVIT procedures are performed, given they carry a greater amount of risk. The ultimate objective is to ensure the safety and quality of care for the people of Ontario who choose to access these services.

Public Confidence in NDs

The intention of the program is not to punish Members working in premises that are found to not meet all of the requirements, but through applying conditions to the premises, guide the Members of the College who are performing IVIT procedures in ways to provide safe and competent care. The program also allows the College to act appropriately when it becomes aware of conditions in a premises that potentially are at risk of causing harm to patients.

The inspection program and the outcomes of those inspections that will be posted on the IVIT Premises Register will enable Ontarians to have greater confidence that they will receive safe and competent care from Members of the naturopathic profession who offer IVIT procedures.

An IVIT Premises Register will be publicly available. We believe that posting inspection outcomes will enhance Public confidence in the care and services provided by Ontario's NDs.

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The Inspection Program Costs and Fees

The transitional Council of the College of Naturopaths of Ontario carefully weighed and developed the components of the program to enable the College to effectively carry out its duty of ensuring safe and competent care for patients receiving intravenous

The result was a self-financing program with the costs

paid for by inspection fees charged to the premises being inspected. This route was chosen over that of including the costs of administering the program in the College's overall operating costs, which are paid for through the renewal fees of all Members. Additionally, by charging the fee to the premises where IVIT is

infusion therapy (IVIT). During program development, the cost to both the College and the Members of the profession was carefully considered. Clearly there needed to be a proper balance between building a program rigorous enough to ensure safe care and one that would not cause undo financial hardship to either the Members or the College.

"There needed to be a balance between building a program rigorous enough to ensure safe care and one that would not cause undo financial hardship to either the Members or the College."

The Result - a self-financing program.

performed, in those premises where more than one ND performs IVIT services, there is the opportunity to share the cost of the inspection fee as well as the costs of the additional equipment that is required.

The College's costs to administer the program include the following:

• per diems for inspectors to

prepare for an inspection and draft an inspection report

Payment schedule of the \$2,500 inspection fee: *all fees are plus HST		
Existing Premises	Two \$1,250* payments: First payment due within 30 days of receiving invoice in May 2017. Second payment due within 30 days of receiving invioce in May 2018.	
New Premises	Two \$1,250* payments: First payment due within 30 days of notification of Part I of inspection. First payment due within 30 days of notification of Part II of inspection.	
Additional Inspection Ordered by the College	One \$2,500* payment due within 30 days of notification of inspection.	
Regularly scheduled five (5) year inspection	One \$2,500* payment due within 30 days of notification of inspection.	

Access Inspection Program Resources from next page...

- per diems, travel, meals and accommodations for inspectors to conduct the inspections,
- per diems, travel, meals and accommodations for Inspection Committee members,
- training for committee members and inspectors
- operating costs (eg. printing and postage),
- · legal fees, and
- salaries for staff who administer the program.

Following an extensive budgeting process, the inspection fee that has been determined to meet the above costs and run the inspection program is \$2,500 per premises per inspection.

Schedule of Registering Premises		
Register Existing Premises	Starts March 2, 2017 Ends May 1, 2017	
First Inspection	Anytime after May 2, 2017 All Existing Premises to be inspected by May 2, 2019	
New Premises	May 2, 2017, and forward.	
New Premises Inspections	Part I within 180 days of registering. Part II within six months of Part I	

Inspection Program Resources available on CONO website

Click on any of the links here to access:



Inspection Program Overview

Inspection Program - Handbooks, Tools & Forms (Includes Inspection Program Handbook)

Registering an IVIT Premises

Reporting Type 1 Occurrences

Inspection Program FAQs

General Regulation (includes Inspection Program)

Professional Standards, Policies, Guidelines (includes Laminar Air Flow Hood and AED policies)

The Inspection Program The Designated Member

WHY

The Designated Member of a premises performs a significant role. The intentions behind having a Designated Member are to have one ND responsible for ensuring that the Inspection Program Requirements are met and to streamline communications with the College. Having more than one contact Member at a premises in charge of

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meeting the requirements of the program risks ineffective communication and confusion as to who did what and when.

WHO

The Designated Member must be a Naturopathic Doctor registered with the College who has met the standard of practice for Intravenous Infusion Therapy.

For a premises where there is only one Naturopathic Doctor qualified to compound for and administer IVIT, he/ she must be the Designated Member. In the case of a premises with multiple qualified Naturopathic Doctors, it is up to the NDs at the the Designated Member please see the Inspection Program Handbook.

1. The Designated Member is responsible for completing and submitting the following before an inspection:

i. the "Registering an IVIT Premises Form for an existing premises" between March 2 and May 1, 2017.

ii. the Registering anIVIT Premises Form fora new premises or whena premises moves to anew location after May1, 2017.

iii. the Pre-Inspection
Information and
Member's Declaration of
a Conflict of Interest
Forms when requested
by the College before
the inspection.

iv. the Policies and Procedures Manual when requested by the College before the inspection.

2. The Designated Member is responsible for completing and submitting the following after an inspection:

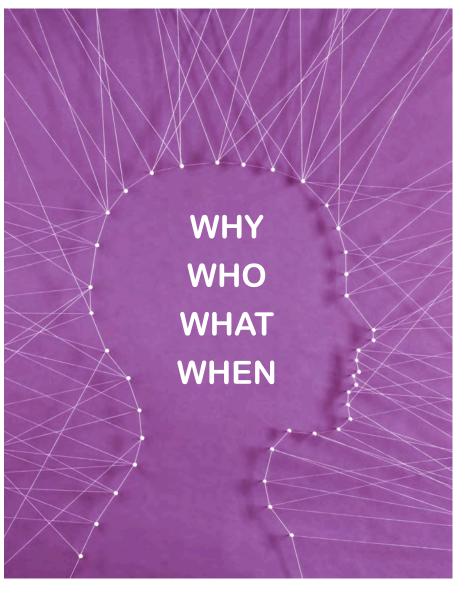
i. the Post-Inspection

Questionnaire. While this is not a mandatory requirement of the program, the College is interested in hearing about the experiences and comments of Members involved in an inspection and they will be taken into consideration when the program is

premises to decide who will take on the role.

WHAT

The responsibilities of the Designated Member are listed below. For more information about the role of



reviewed.

ii. a submission in response to any outcome of a pass with conditions or fail. The submission is to be received by the College within 14 days of the date the outcome is received and should demonstrate any changes that have been made in order to address the conditions. The submission is not mandatory and the Designated Member may work with other Members at the premises to draft the submission.

3. The Designated Member is responsible for completing and submitting the following as needed:

- the Type 1 Occurrence Report within 24 hours of learning of an occurrence. (All Members who become aware of a Type 1 occurrence, not just the Designated Member are responsible for submitting a Type 1 Occurrence Report).
- ii. the Type 2 Occurrence Report on an annual basis.
- iii. the Deferral Request form if the Designated Member is unavailable for the inspection when the premises is selected.
- iv. the Cease to Perform IVIT form when a premises closes or ceases to perform compounding for and/or the administration of IVIT.
- v. the Change of Designated Member form, whenever the person filling the role of the Designated Member changes.
- vi. the Change of IVIT Members form whenever the NDs performing IVIT procedures at the premises change. This includes when a ND begins to perform IVIT procedures at the premises and when a ND leaves or stops performing IVIT procedures at the premises.

4. Before an inspection, the Designated Member is responsible for ensuring that:

- i. the inspection fee for the premises is paid to the College in full and on time.
- ii. all College requests for information and/or

documentation are provided in the form and within the timeframe requested,

- iii. the inspection is scheduled at a time and date when IVIT procedures are being performed.
- iv. a list of the patients scheduled to receive
 IVIT on the day of the inspection is made
 available to the inspector.
- v. on the day of the inspection for an existing premises and Part II for a new premises, ten patient records are available for the inspector to review. The records chosen should be representative of patients receiving IVIT at the premises. In the case of a premises with multiple IVIT naturopathic practitioners, the records chosen must include at least one for each of the IVIT NDs.
- vi. on the day of the inspection, all documentation relevant to the performance of procedures is made available to the inspector, including but not limited to policies, appointment books, reports, and patient records as applicable.

5. The Designated Member's general responsibilities are to ensure that:

- all regulated health care professionals, including NDs and non-NDs, have the appropriate qualifications and meet the requirements of their respective regulatory bodies, and only perform the procedures that are within his or her scope of practice and knowledge, skill and judgement.
- ii. all health care professionals are upholding the standards of practice of their profession.
- iii. all non-regulated staff who are involved in IVIT-related patient care have the appropriate qualifications, and the training to perform the procedures safely.
- iv. records for every regulated health care professional and non-regulated staff working at the premises are on file, are kept current, and

- v. all requirements outlined in the Inspection Program Requirements and the Inspection Program Handbook are in place and being followed by the appropriate staff member(s).
- vi. the Policies and Procedures Manual contains all documentation outlined in the Inspection Program Requirements and is kept current.
- vii. all staff has read the Policies and Procedures Manual and has confirmed this with a signature and date. He or she also ensures that all staff

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mation can be found in the Handbook or will be indicated when requested by the College. When the College sends the Designated Member a letter or email with a request for information, the date by which it is to be submitted will be included.

For example:

• the letter notifying the Designated Member of a pending inspection, will state that the Preinspection Information and Member Declaration of a Conflict of Interest forms and the Poli-

> cies and Procedures Manual will need to be submitted to the College within 19 days of the date of the letter.

- a change in the Designated Member is expected to be sent to the College as soon as the new Designated Member assumes the role.
- when IVIT procedures will no longer be offered at a premises, the Cease to Perform IVIT form must be received by the College within 30 days of stopping the procedures.

cordance with Section 19 of the College's bylaws.

ix. patient records are established and maintained, and that they are accurate, legible, complete, and follow a consistent format. He/she also ensures that all patient files meet legislative requirements and adhere to the College's Standard of Practice for Record Keeping.

WHEN

There are timelines attached to some of the information to be provided to the College. The timeline inforAs you can see, the role of the Designated Member is very important in ensuring that the premises succeeds in putting the Inspection Program components and requirements into action as expected and within the established timeframes.



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The Inspection Program Policies and Procedures Manual

For many Members, the idea of developing written policies and procedures may be a daunting one. It can be difficult to know when a policy is needed and how to begin to write it. The College's Inspection Program Requirements documents* outline the type of information necessary in the Policies and Procedures Manual. NDs in IVIT premises are likely already carrying out many of these practices and procedures. It is possible, however, that they've never written them down or compiled them into a policy manual before.

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Handbook provides the framework for the manual and some guidance as to what should be included in the policies and procedures. Different practice environments will determine the specific needs of each premises that are to be reflected in the policies and procedures of the premises. Depending on the practice location, the procedures in place to fulfil the intention of a policy can be quite different. For example, the organizational chart of a premises that is a sole proprietorship with only one ND with one support staff will be very different from a premises with multiple NDs in a multidisciplinary clinic.

This article along with the Inspection Program

* Inspection Program Requirements for Existing

The table in this section summarizes what must be included, at minimum, in each premises' Policies and Procedures Manual. For more information, please refer to the Inspection Program Handbook.

Policies & Procedure Section	Information to include
1. Policies and Procedures Manual Development and Maintenance	 Name(s) of those who will draft the policies and procedures. How often the manual will be reviewed. What is included in the manual.
2. Organizational chart	 The structure of the organization. The relationships between the staff positions/jobs.
3. Scope and limitations of the services provided at the premises	 IVIT procedures that are provided at the premises and any limitations or restrictions that apply.
4. Job Descriptions	 Descriptions for all premises staff who are involved with providing some aspect of IVIT related patient care and compounding. All responsibilities for IVIT supervising staff.
5. Type 1 and Type 2 Occurrences	•How to monitor, report, review and respond to Type 1 and Type 2 occurrences.
	 How all staff are made aware of the possible Type 1 and 2 occurrences that can happen.
	•How and when staff are to ensure occurrences are reported to the College and the Designated Member.
	 How occurrences are to be recorded in the patient file.

Policies & Procedure Section	Information to include
5. Type 1 and Type 2 Occurrences (continued)	 How and when all occurrences that have happened will be reviewed, who will participate in the review, how the review is conducted and the changes in related policies and procedures as a result Establish how Type 1 and 2 occurrences are responded to, including the criteria to determine if emergency services are required
6. Emergency Responses and Safety Precautions	How to manage emergency situations such as: • Patient emergencies • Type 1 and 2 occurrences • Fire • Power failure • Other emergency evacuations • When and how to summon additional staff urgently within the premises • When and how to summon help by 911
7. Urgent Transfer of Patients	 In the event of an emergent situation with a patient, the procedure should include the following: the patient is transferred by an appropriate transportation service; in most cases this would be an ambulance. the ND most responsible for the patient ensures that essential medical information is sent with the patient. a regulated health professional staff member should accompany the patient during the transfer. if the ND most responsible for the patient is not accompanying the patient, he/she must contact the receiving physician/premises immediately, by phone or in person.
8. Storage, handling and disposal of combustible and volatile materials	• The precautions and procedures required for safe storage, handling and disposal of any combustible or volatile materials, such as therapeutic oxygen, on the premises.
9. Delegation	 How the requirements described in Part III of the General Regulation and the Standard of Practice for Delegation are to be met.
10. Maintenance and calibration of equipment	 Which members of staff are responsible for maintaining the IVIT related equipment in accordance with the manufacturer's recommendations and the Inspection Program Requirements. The procedure to record that the maintenance has been done
11. Infection Control	 The Inspection Program Requirements and Standard of Practice for Infection Control. Which staff members are responsible for each of the requirements and for monitoring procedures to ensure expectations are being met.
12. Patient booking system	 Description of the system used. Which members of staff are responsible for booking patients. How to ensure that the requirements set out in the Standard of Practice for Record Keeping are met.

Policies & Procedure Section	Information to include
13. Informed Consent	 The requirements as set out in the Inspection Program Requirements and Standard of Practice for Consent. The Informed Consent Guideline. Who is responsible for obtaining consent. How consent is documented.
14. Handling and inventory of drugs and substances related to compounding and IVIT	 How the requirements as set out in the Inspection Program Requirements will be met and which staff members are responsible. Which staff members are responsible for ordering and stocking IVIT drugs and substances. The process for ordering and stocking. Proper storage and safe disposal.
15. Patient preparation for procedures	 Which staff members are responsible to ensure the Inspection Program Requirements related to patient preparation are being followed.
16. Latex Allergies	 How an allergic reaction by a staff member or patient is to be handled and by whom. If products with latex are not to be used in the premises, it should be made clear that all steps are taken to avoid their use. This does not mean a policy is not needed, as there may be an instance where latex products are unintentionally brought on site and used.
17. Waste and garbage disposal	 How all waste is to be disposed of properly and safely and in compliance with the Standard of Practice for Infection Control.
18. Monitoring Quality of Care	 The process to be used to regularly monitor the quality of care provided to patients, including but not limited to: Review of regulated and non-regulated staff performance. Review of individual ND performance (procedure/treatment recommendations, patient outcomes, Type 1 and 2 occurrences, etc.). Random selection and review of 5-10 patient records to assess completeness and accuracy of entries, and to ensure records adhere to the Standard of Practice for Record Keeping. Review of compliance with all policies and procedures in the Policies and Procedures Manual. Review of any Type 1 and 2 occurrences that occurred at the premises, including potential remedial actions that may be taken to prevent future occurrences and mitigate harm to patients.
19. Miscellaneous policies and documents	 Standard forms used at the premises (intake form, consent form, etc.). List/inventory of equipment to be maintained. Additional policies, as deemed necessary by each premises.

The Inspection Program Laminar Air Flow Hood and AED Policies

Both Policies come into effect on March 2, 2017

The requirement to install a laminar air flow hood for sterile compounding has perhaps been the one aspect of the Inspection Program that is uppermost on the minds of Members who are qualified to compound for and administer intravenous infusion therapy.

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The College currently has a Guideline for Sterile Compounding in place that recommends the use of a laminar air flow hood. With the Inspection Program coming into effect on of March 2, 2017, it will be a requirement for all premises where sterile compounding for IVIT is performed to use a laminar air flow hood for this procedure.

The practice of using a laminar air flow hood brings the profession up to the same expectations as other professions that have the authority to perform sterile compounding.

The Laminar Air Flow Hood Policy outlines the requirement to install and maintain the hood as well as to ensure that those who are compounding for the purpose of the administration of IVIT are trained on how to properly use the hood.

The policy does not dictate the specifics of the laminar air flow hood that is to be purchased and installed. It is the responsibility of the IVIT qualified Members at each premises to determine the style and specifications of the hood that are most appropriate for their practice.

The Ontario Association of Naturopathic Doctors is offering support to the profession by sourcing laminar air flow hood suppliers as well as providing educational opportunities for proper use of the hood.

The Automated External Defibrillator (AED) Policy which also comes into effect on March 2, 2017, requires all IVIT premises to have an AED on site. This policy outlines the need for the premises to have signage in place, training for staff on its usage, regular maintenance of the equipment and a reporting process when it is used.

The proper installation and use of the laminar air flow hood and the AED increases the ability of each IVIT premises to provide safe and competent care as well as the ability to respond to emergency situations for all patients who choose to access IVIT procedures from a Naturopathic Doctor in Ontario.

Click Here for *Professional Standards, Policies & Guidelines*

The Inspection Program coming into effect on March 2, 2017, requires all IVIT premises to use a laminar air flow hood.

This will bring the profession up to the same expectations as other professions that have the authority to perform sterile compounding.

The Inspection Program The Inspection

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The College acknowledges that having an inspector come into a practice in order to inspect it can be a very stressful experience. In order to reduce that stress somewhat, it likely helps to know what to expect on the day of the inspection. We are therefore providing information here and other opportunities to learn about the process so you're well informed ahead of time. Also the College has undertaken to ensure that all inspectors will be Members of the College who are IVIT qualified, will have been trained to conduct a fair and objective inspection and will have undergone an inspection of his/her own premises.

be requested to complete and submit the Member Declaration of a Conflict of Interest and Pre-Inspection Information forms along with the Policies and Procedures Manual. The Designated Member for the premises will have approximately two weeks to submit these documents to the College.

The Declaration of a Conflict of Interest Form allows the Designated Member to provide information if they feel that there is a conflict of interest between a potential inspector and a member of the staff. The Preinspection Information Form will ask for current information regarding the staff, hours of operation and the record keeping system used.

Assigned Inspector

Prior to assigning an inspector to a premises, each inspector will also complete a Declaration of a Conflict of Interest form for each premises selected at that time. Once the College is confident that no conflict of interest exists, an inspector will be assigned to the premises. The Designated Member will be notified by email of the name of the inspector and to expect him/her to contact them in order to arrange the date and time of the inspection within 30 days.

Premises Selection

During the period between May 2, 2017 and March 2, 2019, all existing premises will be randomly selected to undergo an inspection. The College has the option, in the interest of cost savings and the most effective use of the inspector's time, to schedule inspections in communities that have only two or three premises on consecutive days.

Notification

Once a premises is selected for an inspection, the Designated Member will receive a notification of the pending inspection, by email as well as by letter mail. At this time he/she will



Preparation - Patient Files

In preparation for the inspection the Designated Member will need to select 8-10 patient files for the inspector to review for record keeping practices as outlined in the Inspection Program Requirements. In a premises where there is more than one IVIT qualified ND, there should be at least one file selected for each ND. Files for NDs in the clinic who do not perform IVIT procedures are not to be selected.

The Designated Member as well as all IVIT qualified NDs at the premises should review the Inspection Program Requirements to ensure that all the expectations are fully met to the best of their ability.

The Day of the Inspection

On the scheduled day, the inspector meets with the Designated Member at the premises to conduct the inspection. The Designated Member should schedule approximately 30 minutes at the beginning of the inspection so that the inspector can be introduced to the staff and respond to any questions. The inspector will conduct the majority of the inspection without the need of a staff member at his/her side. For the observation of the administration of the IVIT, the inspector will speak with the patient in order to obtain his/her consent to observe the treatment. Approximately 45 minutes will be needed at the end of the inspection for the inspector to review his/her observations with the Designated Member, ask any questions they may have and provide the Designated Member with a Post-Inspection Questionnaire. The Questionnaire is not required to be completed, however it will provide valuable feedback to the College.

Inspection Outcome

The inspector is required to submit his/her report to the College within 14 days of the inspection which will be put on the agenda of the next meeting of the Inspection Committee. If he/she chooses to, the Designated Member of the premises can also provide a submission to the Committee.

The Committee, composed of IVIT qualified NDs and public Council member(s), will determine the outcome of the inspection which will then be provided to the Designated Member.

In the case of an outcome of a pass with conditions or a fail, the Designated Member has 14 days from the date the outcome was received to make a submission to the Inspection Committee. The submission allows for the Member to demonstrate the changes that have been made in an effort to rectify any deficiencies that resulted in the outcome.

The Inspection Committee will review the submission and make a determination according to one of the following options:

- Confirm the initial outcome will remain unchanged;
- Change an outcome of a pass with conditions to a pass;
- Change an outcome of a fail to a pass or a pass with conditions that would permit the premises to resume IVIT procedures; or
- Require a second inspection within 60 days of receiving the submission (the cost of which is to be paid by the premises), after which the Committee may confirm the outcome or issue a pass with conditions or a pass.

IVIT Premises Register

In the interest of transparency and public protection, the College will post all inspection outcomes on the IVIT Premises Register.

The Inspection Program Determining Inspection Outcomes

The inspector has conducted the inspection and submitted a report to the College. The next step in the process is determining the outcome of the inspection.

WHO

It is the Inspection Committee's role to determine the outcome of an inspection. The Inspection Committee is made up of IVIT qualified Members of the College, one of whom is also a member of Council, plus public Council member(s).

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HOW

The Committee will consider the information provided in the inspector's report along with any additional information received, such as an accompanying submission from the Designated Member, when determining the outcome.

The inspector's report will contain the observations made with respect to how the premises has met the Inspection Program Requirements. It is possible that a premises could fully or partially meet each requirement, or not meet the requirement at all.

After considering all of the information available, the Committee will make use of a decision tree when determining the outcome of an inspection. The decision process will require the Committee to consider if deficiencies as portrayed in the inspector's report:

- indicate a likely or possible risk of harm to patients,
- are widespread or limited, and
- can they be addressed through placing a condition on the outcome?

WHAT

The potential outcomes for an inspection are either a "pass", a "pass with conditions," or a "fail".

A premises will receive an outcome of a pass, if all

the Inspection Program Requirements are fully met and either no deficiencies have been identified or the deficiencies are not significant enough to warrant a condition.

The College recognizes that different premises may differ in their approach and execution of how they will meet the program requirements, and each still effectively be in compliance. As there is more than one way to meet a program requirement, similarly there is more than one way to achieve an outcome of a pass, a pass with conditions or a fail.

An outcome of a pass with conditions may occur if there are significant deficiencies and the Committee determines that conditions must be placed on the premises, in order to protect the public and for the premises to be in compliance with the Inspection Program Requirements. In such a case, the Committee may determine that certain services can safely be performed, so long as the identified deficiencies are expeditiously remedied. The conditions are intended to bring the identified deficiencies to the attention of the Designated Member in order to make the changes and to be in compliance.

Another example would be a premises that has demonstrated inappropriate use of the laminar air flow hood that could lead to contamination of the contents of the IV bag yet does not receive a fail. The result may be a pass with conditions that IVIT qualified NDs in the premises cannot compound for IVIT until they can demonstrate to the satisfaction of the Inspection Committee that they now are following the proper procedures and use of the laminar air flow hood. While the premises is remedying the deficiencies, they can choose to have their IV bags compounded elsewhere and may continue to administer by IVIT. A premises that shows it has fully met the require-

ise can provide a submission within 14 days of receiving the pass with conditions outcome showing that the conditions have been met, and possibly demonstrate to the committee that a change in the outcome from a pass with conditions to a pass is warranted.

In a premises where one or more deficiencies are identified by the inspector that present a risk of harm to a patient that cannot be addressed through conditions, the Committee may determine that an outcome of a fail is necessary in order to protect the public from harm.

For example, incorrect calculation of os-

molarity along with serious concerns of poor infection control during compounding and administering by IVIT may be

cause for a fail. These types of multiple deficiencies indicate that there is a high risk of harm to a patient and a lack of skill in procedures that are vital to insuring safe IVIT practices.

The Committee will always consider,

- the number of deficiencies identified,
- to what degree the requirement has not been met,

- do any identified deficiencies have a high risk of harm to patients, and
- can the deficiencies be adequately addressed through a condition.

Whenever the Committee is confident that a condition will serve to ensure that patients will receive safe, competent and ethical care, then that will be applied, rather than making a decision of a fail.

WHERE

All inspection outcomes will be posted on the IVIT Premises Register. The Register allows for important information to be available for the public, Members of the College and other health care providers about a premises and how it has or has not met the Inspection Program Requirements set by the College for protection of the public.

WHEN

The General Regulation requires the report containing the outcome to be delivered to the Designated Member of the premises "within a reasonable time after the inspection is completed." Determining and delivering the outcome in a timely manner facilitates a premises in addressing

any identified deficiencies expeditiously and is in the best interest of public protection.

More information about the outcomes and the process following can be found in the Inspection Program Handbook. To access the Program Handbook click *Handbooks, Tools & Forms.*

The Inspection Program Type 1 and Type 2 Occurrences

The categories of Type 1 and Type 2 occurrences, along with the requirement to report them to the College, are new to the profession.

iNformeD

The General Regulation, Part IV, outlines the reporting requirement and what constitutes a Type 1 and a Type 2 occurrence.

Type 1 occurrences are incidences that may or did result in serious harm to a patient. It is important for the College to be made aware of these events in order for it to take appropriate action to protect the public from unsafe care, should any be required.

Type 2 occurrences are related to events that are of lower risk of harm to a patient. However the College must be informed of them, as the information relates to the safe delivery of IVIT procedures. The College will use this information for statistical purposes and for revising the Inspection Program as appropriate or where indicated.

Type 1 Occurrences

Type 1 occurrences as set out in the General Regulation are:

- (a) The death of a patient at the premises after a procedure was performed.
- (b) The death of a patient that occurs within five days following the performance of a procedure at the premises.
- (c) Any referral of a patient to emergency services within five days following the performance of a procedure at the premises.
- (d) Any procedure performed on the wrong patient at the premises.
- (e) The administration of an emergency drug to a patient immediately after a procedure was performed at the premises.
- (f) The diagnosis of a patient with shock or convulsions occurring within five days following the performance of a procedure at the premises.
- (g) The diagnosis of a patient as being infected with a

disease or any disease-causing agent after a procedure was performed at the premises, if the Member is of the opinion that the patient is or may have been in fected because of the performance of a procedure.

All Type 1 occurrences are to be reported to the College on the "Type 1 Occurrence Report" form within 24 hours of learning of the event. It is important to be aware that as the General Regulation states, the reporting requirement <u>applies to all NDs</u>, not just those who performed the IVIT procedure. That mean that all NDs who learn of a Type 1 occurrence are required to report it to the College within 24 hours of learning of the event. While this may appear to be repetitive, this is to ensure that the communication does not somehow slip through the cracks

Type 2 Occurrences

Type 2 occurrences as set out in the General Regulation are:

- (a) any infection occurring in a patient in the premises after a procedure was performed at the premises,
- (b) an unscheduled treatment of a patient by a Member occurring within five days after a procedure was performed at the premises, or
- (c) any adverse drug reaction occurring in a patient after a procedure was performed at the premises.

The Designated Member must report any/all Type 2 occurrences to the College on an annual basis. The first reporting date will be May 1, 2018. Reminders will be sent out prior to the reporting date and will explain how they are to be submitted. It is advisable for every premises to record any occurrences at the time they happen in order to readily compile and provide the information to the College each year.

All premises are required to have policies and procedures in place regarding the monitoring, reporting, reviewing and response to Type 1 and 2 occurrences. More information can be found in this edition of iNformeD as well as in the Inspection Program Handbook and Requirements.

iNformeD,

Professional Conduct: ICRC Corner

I he College takes its role of protecting the public interest seriously. One way that the College protects Ontarians is by investigating complaints about Naturopathic Doctors. It is the College's Inquiries, Complaints and Reports Committee (ICRC) role to investigate and consider the complaints received. The ICRC also considers Registrar's Reports about certain conduct or actions of a Member and takes appropriate action on the information that may result from such a report.

In each edition of iNformeD, we will present and analyze an ICRC scenario based on facts from real cases. We hope these scenarios can assist NDs to recognize any areas of potential concern in their own practices, to enhance NDs' knowledge of the professional standards and regulations that apply to their practices and to further an understanding of the College's complaints process.

This ICRC scenario relates to use of unapproved substances and therapies. By statute the complaints process is confidential, with few exceptions. The participants are not identified, therefore, and details of the case are altered slightly to maintain confidentiality.

Summary of the complaint

A complaint filed against a Member of the College raised concerns regarding the Member's compounding practices, the use of unapproved substances and use of therapies that may be outside the scope for NDs in Ontario.

In considering any complaint before it, the ICRC endeavors to obtain all reasonable and available evidence regardless of whether it supports or undermines the complaint. In this matter, the Panel considered the information provided by the Complainant, and submissions from the Member, and appointed a formal investigator in order to conduct interviews with the parties involved, including the Member's patients and colleagues. Additionally, as generally accepted standards of practice within the profession were at issue, the Panel retained a knowledgeable Naturopathic Doctor to provide an expert opinion.

Although the Member specifically denied using unapproved substances and/or therapies in his/her practice, the Expert identified numerous occasions when the Member may have administered homeopathic solutions, heparin, thymus extract, procaine and activated oxygen to his/her patients. None of the above named substances are currently approved for injection by Naturopaths in Ontario. The Expert also concluded that the compounding practices employed by the Member arguably did not constitute usual ND practices and might contravene the standards of practice of the profession.

Outcome

In making its decision, the ICRC considered the available information, the seriousness of the allegations, and the Member's prior history with the College and the Board of Directors of Drugless Therapy-Naturopathy. Although the concerns expressed were very serious, the ICRC determined that referring specified allegations of professional misconduct for discipline proceedings was not warranted. The ICRC required, however,

This ICRC scenario relates to compounding, and the use of unapproved substances and therapies. that the Member, at his/her own expense:

- successfully complete the Intravenous Infusion Therapy (IVIT) course approved by the College and successfully complete the IVIT Examination,
- attend meetings with a College-approved practice supervisor,
- appear before a panel of the Committee for an Oral Caution.

The ICRC believed that the remediation provided for in their decision would be best able to provide the necessary knowledge, skill and judgment to the Member and reiterate the requirements for compliance with the rules and regulations of the regulatory body in order to prevent future occurrences or complaints of a similar nature.

Analysis

Compounding

The Member asserted to the Committee that his/her compounding practices are consistent with the current standards. The Member also confirmed that s/he was taking all steps to prevent contamination and ensure sterility. Despite the Member's statement, and based on the Expert opinion, the ICRC identified serious concerns regarding the Member's compounding practices. During the Oral Caution, the Committee strongly recommended that the Member review the General Regulation made under the *Naturopathy Act, 2007* and familiarize him/herself with the requirements set out in the regulation.

Under the *Naturopathy Act*, 2007, Naturopaths may only compound a drug that is listed in table 5 of the General Regulation and must do so in accordance with any limitations outlined in the table.

In accordance with the Standard of Practice for Compounding, members are required to:

- have the knowledge, skill and judgment to compound drugs or substances safely, ethically and competently;
- minimize the risks to the patient, self and others that are associated with the compounding of drugs and substances, before, during and after the procedure;
- ensure good compounding practices are in place; and

• ensure that all required information is included with all drugs or substances that are compounded.

Use of unapproved substances

Under the *Naturopathy Act, 2007*, Naturopaths are only authorized to administer by injection the prescribed substances listed in table 2 of the General Regulation, in accordance with the specifications about the route of administration, and any limitations outlined in the table. Contravening, by act or omission, a provision of the Act or the regulations under the Act, is professional misconduct, as defined in the Professional Misconduct Regulation.

Based on the evidence before it, the ICRC seriously considered referring the allegation of administering and/or recommending unapproved substances by the Member to a discipline hearing. The fact that the Member knowingly administered injections of unauthorized substances not only put the Member's patients at risk, but also raised concerns about the Member's governability.

However, in light of a few mitigating factors, such as the fact that the Member had voluntarily taken steps to improve his/her knowledge, skill and judgment in order to comply with the new regulatory framework, the ICRC decided that the concern would be better addressed by ordering the Member to refresh his/her knowledge of the IVIT Standard of Practice through taking the IVIT course and exam, and working with a College-approved IVIT supervisor.

Use of therapies outside the scope

The scope of practice for Naturopaths in Ontario starts with knowledge of regulations and standards governing the profession.

In this matter the Complainant was concerned that the Member may have been using therapies outside the scope of practice of an ND in Ontario, including IV Phototherapy, IV Hydrogen Peroxide, Induced Needle Therapy, HCG diet, and performing intra-articular injections. Having reviewed patient records collected with regard to this complaint, the ICRC did not find references to any of the above-noted therapies in the patient records, except insofar as some of them were listed under the heading "Consider/Provide info brochure". While the therapies were indeed outside the naturopathic scope of practice, the ICRC did not have enough information to support the allegation and decided to take no action with respect to it.

Should the ICRC have found evidence to support the allegation, the matter would potentially have been referred to the Discipline Committee of the College. It is important to remember that the following acts constitute misconduct under the Professional Misconduct Regulation:

- Providing or attempting to provide services or treatment that the member knows or ought to know to be beyond the Member's knowledge, skill or judgment.
- Failing to advise a patient or the patient's authorized representative to consult another member of a health profession within the meaning of the *Regulated Health Professions Act, 1991*, when the Member knows or ought to know that the patient requires a service that the Member does not have the knowledge, skill or judgment to offer or is beyond his or her scope of practice.

Bottom line

Following the change in regulation and requirements due to proclamation of the *Naturopathy Act, 2007*, the College noticed an increase in the number of

complaints/reports related to administering and/or prescribing substances not listed in the General Regulation and providing therapies outside the naturopathic scope of practice. These issues are often raised by patients, other medical professionals in the patients' circle of care, pharmacists or members of the family of the patient. The College is highly concerned about reports it receives of its Members practising outside the scope. The complications that may arise from administering a drug by a person who is not authorized to do so, and may not have the necessary knowledge or skills to assess the patient's response to treatment and deal with any potential side effects, may be very serious.

Part of belonging to a regulatory college means accountability to the public. As regulated health professionals, Naturopaths are expected to recognize their responsibility before the patient, the profession and the regulator, and, hence practise within the limits of the professional scope and competence.



iNformeD

Professional Conduct: Discipline Decision

The Discipline process is one of the ways that the College maintains the high standards of practice of the profession of naturopathy in order to protect Ontarian's rights to safe, competent and ethical naturopathic care. When there are reasonable and probable grounds to believe that a Naturopath may have breached the College's Professional Misconduct Regulation or might be incompetent, the Discipline Committee holds a hearing into the allegations. the interests of transparency and public protection, except for certain special circumstances where for example, there might be safety and security concerns, or where the privacy of a witness must be protected. All Discipline decisions are made in the best interests of the public.

Publishing summaries of the decisions in this newsletter is part of the further transparency of the discipline process, and is also intended to assist Members of the College in understanding what may constitute professional misconduct.

The hearings are open to the public, in

Decision

Member: Dr. Robert Allan Price, ND, Registration #0934

At an uncontested hearing on December 14, 2016, a Panel of the Discipline Committee of the College of Naturopaths of Ontario (the College) made findings of professional misconduct against Dr. Allan Price, ND (the Member) with respect to the following:

- recommending the HCG diet program without the patient having first (i) consulted with a physician, (ii) obtained the necessary blood work, (iii) obtained a prescription for HCG from a physician and/or (iv) received sufficient information from you regarding the relevant potential risks and/or side effects;
- failing to provide an appropriate assessment, care and/or treatment to a patient;
- failing to refer a patient to an appropriate healthcare practitioner when indicated;

- failing to obtain informed consent from a patient with respect to the HCG diet program; and/or
- issuing or allowing to be issued an invoice or invoices that identified naturopathic services, products and/or treatments that had already been billed and/or that were never provided.

A Joint Submission on Order and Costs had been agreed upon prior to the hearing. The parties submitted that the public was protected because Dr. Price, ND had admitted to his wrongdoings and had agreed to an appropriate and significant penalty which included remedial and rehabilitative activities to ensure

Copies of the full discipline decisions are available on the public register on the Members' profiles.

You can also review all decisions in the *Resources* section of the College's website.

his behavior henceforth would be appropriate and that he would comply with all College standards, policies and guidelines.

The Member admitted to the afore-mentioned allegations and signed an Undertaking to the College whereby he would:

- maintain an active certificate of registration throughout the duration of the Undertaking;
- receive an oral reprimand from the Discipline Panel;
- attend at least one and at most two meetings with an Expert in Professional Regulation;
- attend at least two and at most four meetings with an Expert in the practice of Naturopathy; and
- participate in one random inspection of his practice and records.

Additionally, the Discipline Panel imposed an order:

- 1. Directing the Registrar to suspend the Member's certificate of registration for a period of five months during which time he will:
 - not engage in the practise of naturopathy;
 - not use the title "Dr." or "ND" (or any variation or abbreviation);
 - not hold out as an ND or as somebody who is entitled to practice naturopathy;
 - advise his staff that his certificate of registration is under suspension and shall ensure staff are instructed not to do anything that would suggest to patients that he is entitled to engage in the practice of naturopathy during the suspension;
 - ensure that any patient who is informed about his absence from practice related to the suspension, shall be advised that the reason for his absence is due to a suspension by the Discipline Committee of the College; and
 - not supervise any students or graduates of naturopathic medicine.
- 2. Requiring the Member to pay a portion of the College's costs, in the amount of \$7,500.

The Panel concluded that the proposed penalty was reasonable and in the public interest, and that it satis-

fied the principles of specific and general deterrence, rehabilitation and remediation, and public protection.

At the conclusion of the hearing, the Panel delivered its reprimand to the Member.

The Panel was profoundly concerned with the Member's conduct. The Panel noted that the Member brought discredit to the profession and to himself, and that public confidence in the naturopathic profession had been put in jeopardy.

Of special concern to the Panel was the fact that the professional misconduct in which the Member had engaged involved putting a patient at risk and threatening the integrity of the naturopathic profession.

The Panel clarified that though the penalty that it had imposed was fair, a more significant penalty would be imposed in the event that the Member was found to have engaged in professional misconduct again in the future.

The Panel trusted that the lessons of this case would remain with the Member, and that he would learn from this event and from the remediation program he agreed to complete.



KNOW THE RULES!

iNformeD

Website Changes: the Homepage Menu

www.collegeofnaturopaths.on.ca

The College is in the process of finalizing website changes designed to improve users' experience.

The new Homepage menu has six new headings to aid users finding information they want, and to anticipate some of their needs for additional information. The new menu headings are described in the table below.

The other major headings on the Homepage remain somewhat the same.

All changes are to be completed by the end of March. To prepare for this, we are presently moving some information around to ensure maximum benefit of the new menu structure.

We hope the changes will enhance users experience with the website, making information more accessible and transparent. We ask for your patience while these changes are underway. If you cannot locate information that you need, please contact the College so that we can assist you at -

Did you know

that there are many users who come to the College's site and for different types of information. For example to name just a few, there are members of the public and patients, NDs, those wishing to become NDs, educators, associations, other regulators and the Ontario government?

info@collegeofnaturopaths.on.ca

New Menu Headings and Descriptions of their Content:

Who We Are	What We Do	Public	Become an ND	Members Practice	Resource Library
Introduces us as a regulatory health college.	Describes the work that we are mandated to	Highlights access to information that	Provides info about the requirements for	Provides info about NDs professional	Contains the documents, publications,
Includes for example, info about the	carry out, and how we carry it out. Includes for	may interest the public, such as, the Public	entering the profession and registering as an	responsibilities and information NDs need to	literature and reference info that serve as
Council, committees and staff, call for	example, QA and Professional Conduct,	Registers of Members and Unauthorized	ND. Includes entry exam- inations and	deliver patient- centred care that is safe,	foundation and support for the regulation of the
submissions and consultations,	Inspections, Registration and	Practitioners, how to submit a	PLAR info.	competent and ethical. For	profession in the public interest,
the Registrar's Office, and Contact Us.	Membership.	complaint, the discipline hearing		example, Regu- latory Guidance, Code of Ethics,	such as legisla- tion and regula- tion, standards,
		schedule.		advisories, info about the controlled acts.	policies, handbooks and forms.

Communications Project Report 2016

hank you to all of the Members who last year participated in the 2016 online "Communications with Members" survey and those who generously offered their thoughts and opinions in interviews.

In November 2016, the information was gathered into a final report and provided to the Registrar of the College. The Registrar had commissioned the report as part of his operational activities based on feedback received over the last half of 2015, following proclamation of the Naturopathy Act, 2007, and into 2016, concerning

Member dissatis-

faction with the communications approach being taken by the College.

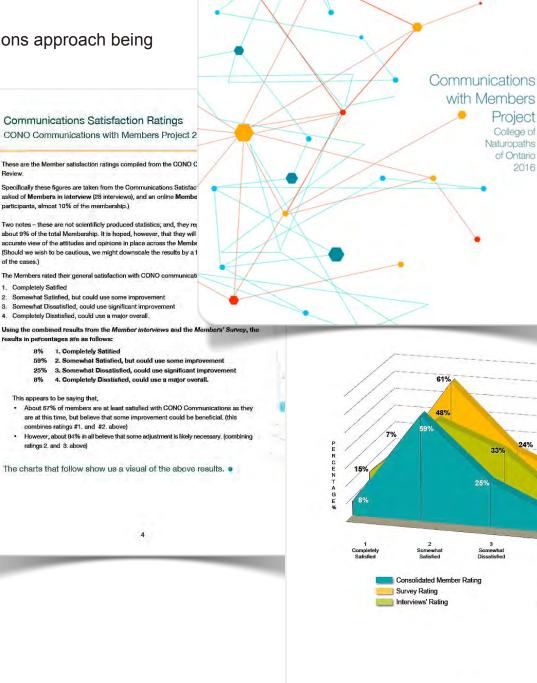
The Members rated their g

Completely Satified

At that time an initiative to gather and evaluate College communications was undertaken.

On January 25, 2017, the Registrar provided the Communications Report to the Council for their information.

For those who may be interested in reading more, the entire report is available on the **CONO** website here.



Did you know

that Members' input into the 2016 Communications Project has assisted the College in communications and operational planning?

> with Members Project College of Naturopaths

> > 2016

In his memorandum introducing the Report to Council, the Registrar noted certain enhancements for future College communications.

"Changes Made and Others Moving Forward

This report is very helpful to the College. When combined with information from other Colleges and other jurisdictions, it dramatically changes our perspective on communications. That said, a relatively positive report is not reason to stop considering our communications activities. The following are some of the changes made and that will be made or implemented in the future:

- Tone the College made a concerted effort in the fall of 2015 to change the tone of its communications. A change was made in terms of who was writing the messages and the format of the messages. It is our belief that this change had a significant and positive impact on the survey results.
- Mobile friendly the College is preparing to implement changes to the menu system and main page of our site to ensure that our website is mobile friendly. This will make it significantly easier for people to access the site from mobile devices and should increase our click through rates.
- Program communications the College has been doing program related communications for some time and this will be reinforced in the upcoming issues of iNformeD.

- Blog and communities the draft operating plan for the next five years includes two initiatives for the first year. A Registrar's blog where Members will hear from and dialogue with the Registrar (and guest bloggers) and communities, which are essentially internally driving social media activities.
- Face to face time with staff and Council - the draft operating plan has a number of initiatives that will address this suggestion. A Registrar's annual tour will be implemented, presentations proposed to the OAND conference and a College booth at the OAND conference where staff and Council will be invited to book time to be there and meet the members of the profession. We also hope to begin broadcasting the Council meetings over the Internet in the next fiscal year allowing all members to be part of the process and meet the Council.
- Public education tools for Members also in our draft operating plan for the next five years is a public education initiative that will see important information made available and promoted to both the profession and the public."

News and Current Events

iNformeD

GET INVOLVED WITH THE COLLEGE

The College is currently seeking volunteers for the Discipline and Fitness to Practise Committees. These are opportunities to participate in developing and maintaining policies and procedures governing the College's Professional Conduct disciplinary and fitness to practice processes.

Volunteer now and/or find more information from the link below,

Sit on the Discipline and Fitness to Practise Committees...

REGISTRATION RENEWAL IN FULL SWING

Reminder - the deadline for paying your fees and completing your information return is March 31, 2017 at 11:59 pm.

Need assistance? Access the Information Return Guides for General and Inactive Classes, Renewal FAQs and all *Renewal Resources Here*

We heard your feedback last year and have made some changes to streamline and make the process more user friendly. We welcome your comments about this year's experience at *info@collegeofnaturopaths.on.ca*.

IIVIT INSPECTIONS PROGRAM

The IVIT Inspections Program Has Begun. Register Existing Premises until May 1, 2017. *Full program info available here*

COUNCIL MEETING

CONO's next regularly scheduled meeting of Council will be held on April 26, 2017 in the Council Chamber at the College. Observers are welcome! If you are interesting in observing this meeting, please contact the College at *info@collegeofnaturopaths.on.ca* to register.

Upcoming Examinations

ONTARIO PRESCRIBING & THERAPEUTICS EXAMINATIONS		
Exam Date June 4, 2017		
Registration Opens	April 24, 2017	
Deadline for Registration	May 15, 2017	

ONTARIO IVT EXAMINATIONS		
Exam Date	May 7, 2017	
Registration Opens	March 27, 2017	
Deadline for Registration	April 14, 2017	

ONTARIO CLINICAL EXAMINATIONS		
Exam Date	July 9, 2017	
Registration Opens	May 15, 2017	
Deadline for Registration	June 5, 2017	





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