SPRING 2018

INFORMED

NEWSLETTER OF THE COLLEGE OF NATUROPATHS OF ONTARIO

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REGISTRATION RENEWAL

Only 4 weeks until the deadline!

It's registration renewal time

Only 4 weeks until the deadline!

Renewing your registration takes about an hour and consists of two parts:
1. Paying the annual fee, and
2. Completing the online Information Return.

Both are due by **March 31, 2018 at 11:59 pm EST.** Visit our website to access the renewal portal and to view the full renewal schedule of important dates and deadlines.

2018 registration fees

Class	Fee	HST	Total
General	$1551	$201.63	$1,752.63
Inactive	$778	$101.14	$879.14

Members will be able to pay their 2018 registration fees online after submitting their Information Return, or at any time by clicking on the cart on their account page. Note that the College must receive both the renewal fee payment and the Information Return form in order for your registration to be successfully renewed.

Members who are not paying online must ensure their cheque, money order or bank draft is received by the College by 5 p.m. on March 29.

NEW: Fee Payment Plan Program

The College is piloting an optional Payment Plan Program this year for Members who want to pay their registration fee in installments rather than in one lump sum payment. Click here for program details and enrolment forms.

IMPORTANT NOTE: If you want to enrol in the Payment Plan Program, you must do so by **no later than March 23, 2018** and must not pay any renewal fees through the College's online portal.

The Information Return

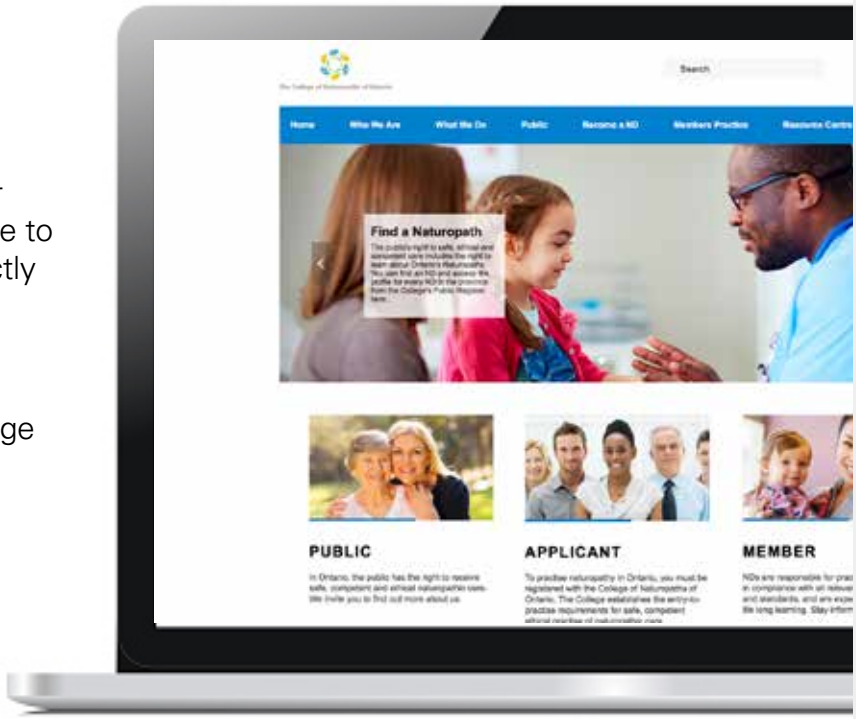
The College also collects certain information from its Members as required under the *Registration Regulation* and to meet the reporting requirements of HealthForceOntario. Details such as a Members' practice hours are asked annually. Certain other previously collected information may be used to pre-populate the online Return each year.

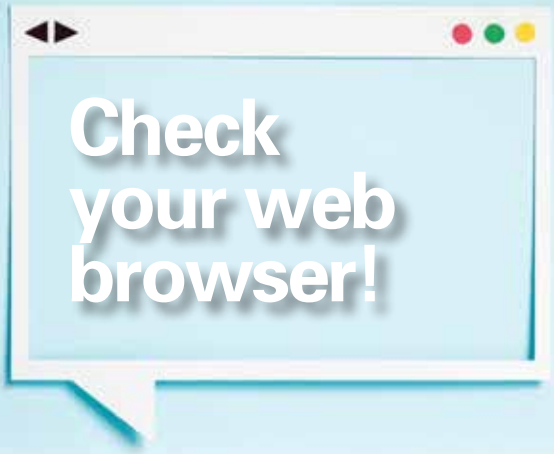
collegeofnaturopaths.on.ca

Help is a click away

Visit our website for

- Information about late fees and other amounts that may apply if you are late to renew or submit information incorrectly
- *Information Return Guides* – General Class and Inactive Class
- Return Guide videos with page-by-page instructions
- Registration Renewal FAQs
- Payment Plan Program Handbook, enrolment forms and webinar





The online renewal portal and the Information Return form are not fully supported by all web browsers, and in particular are not compatible with Internet Explorer. The College recommends using Google Chrome or Firefox to access the form and the website. If you have ongoing difficulties, please contact us at (416) 583-5996 or members@collegeofnaturopaths.on.ca.

UPDATE: New written entry-to-practise examination

Based on a recent meeting between the College, the North American Board of Naturopathic Examiners (NABNE) and the Naturopathic Physicians Licensing Examination Inc. (NPLEX Inc.), this column provides an update about the College's ongoing development of a new entry-to-practise exam for introduction in 2019. Note that naturopaths who are already practising in Ontario will not need to take the new exam because they are already registered with the College.

At its meeting on January 24, 2018, the Council of the College of Naturopaths of Ontario (the College) considered information provided by NABNE and NPLEX Inc. regarding their collective ability to meet the College's needs for a written entry-to-practise examination. After careful consideration, the Council determined that it will continue with its current plans to develop its own written entry-to-practise examination and replace the use of NPLEX in Ontario in 2019.

Over the past several months, a great deal has been said by many different organizations about the College's previous decision to move away from using the Naturopathic Physicians Licensing Examination (NPLEX) as its written examination. As the President of the Council and the Registrar & CEO of the College, we would like to take this opportunity to clear the air about this decision and its overall impact.

Let us begin by stating very clearly that the initial decision made by Council in 2014, and the review and confirmation of that decision in January 2018, are in no way intended to criticize the value of NPLEX or the organizations that develop and deliver this important examination. The Council of the College has every confidence that the examination is both sound and effective. Unfortunately, there are regulatory requirements in Ontario that cannot be met by the current examination process.

We also have to acknowledge that this is a very complex issue and the myriad of opinions and letters that have been released over the past several months have not done a great deal to help make the issue less complex. The College acknowledges that we too played a role in those exchanges.

As best that we can, we will briefly set out the issues on which the Council has made a decision to continue our examination development process.

AN EXAMINATION IN FRENCH

In our recent discussions with NPLEX Inc., they have offered to prepare a French examination for use by Canadian jurisdictions. This is important as there is a relatively new naturopathic educational program in Quebec which is expected to embark upon the road towards accreditation by the Council on Naturopathic Medical Education (CNME).

The College Council considered this recent offer from NPLEX Inc.; however, the offer was not one that we could act upon as the details were not complete. For example, the plan stated that Ontario (and the other Canadian provinces) would need to subsidize the French exam, but did not outline what that subsidy would specifically be, making it impossible to make an informed financial decision. The plan included the fact that NPLEX Inc. would continue to have full and sole ownership of the French exam, which was troubling, not only from the perspective of the lack of details around the expected financial contribution of CONO but also in terms of a return on the investment. Again, without a specific financial plan, the Council was unable to make an responsible financial decision in the best interest of the College.

The plan also required all Canadian jurisdictions to commit to NPLEX for the next five to 10 years. Again, there was no plan outlined on how these commitments would be secured and what the timeline would be.

Finally, the plan was not clear about how a decision by any of the Canadian jurisdictions to not subsidize the development of the French examination would impact the overall plan.

ACCOMMODATIONS

An accommodation is a process by which a person who is required to sit an examination seeks support from the organization delivering the examination to have a fair and equal opportunity to successfully complete the examination. An accommodation is sought on the basis that the individual has a physical or cognitive disability that prevents them from passing the examination if they sit the examination in the same manner as an individual who does not have the disability.

The reason to accommodate comes from the Ontario Human Rights Code and the duty to accommodate ends only at the point that the organization delivering the examination faces undue hardship, which is strictly defined in law.

NABNE has a process for accommodations, which they shared with the Council. The information seemed to suggest that the process is somewhat comparable to how Ontario handles requests for accommodations. However, the Council was concerned that NABNE continued to be unwilling to provide key pieces of information including, most notably, the name of the Canadian "expert" NABNE uses to evaluate requests for accommodations based on a cognitive disability. The Council required this information

for the reasons of due diligence. At minimum, the College would be required to assure itself that this individual is a registered psychologist with the College of Psychologists of Ontario, that they are in good standing, and that there is no history of discipline or fitness to practice issues.

The College and NABNE had extensive dialogue around who would be accountable for a decision not to grant an accommodation. While NABNE was firmly of the belief that they would be accountable for such decisions, the College had sound legal advice stating that it – and not NABNE - would be responsible for the decisions. Because the College appoints a service provider (NABNE) to administer the examinations, it is obligated to ensure that the provider complies with Ontario legislation. This is in accordance with the *Regulated Health Professions Act, 1991* (RHPA), and the Health Professions Procedural Code included in the RHPA. The College would also be held responsible (either solely or in concert with the service provider) if a provider is alleged to have discriminated against a candidate.

When the College met with NPLEX Inc. and NABNE in November 2017 to discuss the various requirements for the examination and process, NABNE gave the impression that it considers accommodation requests as a means to merely make the examination easier – as opposed to viewing them as legitimate requests by people who suffer from a disability and wish to succeed at the exam with certain accommodations. (NABNE makes decisions on accommodations as it is responsible for administering NPLEX across North America.) This demonstrated a lack of understanding of the environment around the issue of accommodation in Ontario and raised a concern for Council that an accommodation that should be granted would not be, creating a very real financial and legal risk to the College.

IMPLEMENTING OUR REGISTRATION REGULATION

The Council was also very concerned about the inability to properly enforce limitations on the number of times a person may attempt to pass NPLEX. The College's *Registration Regulation* requires that, overall, a person may only make three attempts to pass the examinations. It also requires that after failing a second time, and before sitting a third and final attempt at the examinations, the individual undertakes such education and training as required by the Registration Committee of the College.

In the past, NPLEX Inc. and NABNE have had a limit on the number of attempts (two) a person can make at NPLEX. Those policies were changed based on legal concerns in the United States. The College does not debate the necessity for these changes; however, in Ontario our rules are clear. Under Ontario law, the College simply cannot appoint a provider for examinations that is unable to allow us to enforce the rules set out in our regulation. To do so risks serious legal consequences for the College and therefore the profession.

IMPACT OF THE DECISION

ON MEMBERS

The decision to develop and launch the College's own written entry-to-practice examination in 2019 has no direct impact on Members. A College Member who already has a certificate of registration will never have to write the new examination.

ON THE PROFESSION

Some people have raised concerns about the College's decision causing harm to the profession across Canada and North America. We do not believe that a uniform examination across North America is the defining factor for the naturopathic profession. The profession is not defined by these processes, nor by the organizations that create and administer them, but rather by its seven founding principles, by its holistic and caring approach, and by its approach to look for the underlying root cause of illness and disease rather than focusing on symptoms.

ON THE COLLEGE

Obviously, the decision carries a financial impact for the College as we will be responsible for paying the costs of the development of the new examination. When the Council originally made the decision, it was on the basis that the costs of development would be incorporated into the pricing of the examinations in such a way that they would be recovered over a ten-year period following implementation. This intent has not changed.

ON STUDENTS

We anticipate that students who will graduate in 2019 will be the first to sit the new Ontario written entry-to-practice examination if they wish to practise in Ontario. Those who wish to practise elsewhere may wish to continue to write NPLEX or, for a few, perhaps both examinations depending on the jurisdiction(s) in which they want to practise.

Students who write the Ontario examination and become registered in Ontario will be able to move to any other regulated jurisdiction in Canada. How do we know this? First and foremost, it's the law as embodied in the *Canada Free Trade Agreement*. Second, and of great importance to this Council, we are working closely with the regulators in other Canadian jurisdictions to provide them with the information needed to ensure they are comfortable that this examination also "gets the job done."

The College has met with students and will continue to do so as we move towards implementation.

LEGAL AND FINANCIAL CONSIDERATIONS

The Council is always mindful of potential legal and financial consequences that could significantly impact public confidence in the integrity of the College or result in possible registration fee increases. In the case of our entry-to-practise exams, legal repercussions could, for instance, include loss of credibility and reputation if we are deemed to be a discriminatory organization. Financial impacts could include having to pay penalties to claimants if we are found to be discriminatory. Ensuring the financial stability and long-term sustainability of the College is a responsibility that falls not only to the Council and College staff, but to the overall profession as well.

IN CONCLUSION

It was the desire of the Council that it could continue using NPLEX and working with both NPLEX Inc. and NABNE going forward. Unfortunately, the Council did not have the confidence it needed that all of the College's regulatory requirements could be met if we did so.

As a result, in order to meet our obligations to the people of Ontario, as embodied in the *Naturopathy Act, 2007* and the regulations made under that Act, the Council has made its decision to continue developing its own entry-to-practice exam.

Dr. Tara Gignac, ND
President

Andrew Parr, CAE
Registrar & CEO

GET THE FACTS:
New entry-to-practise exams

The following articles and fact sheets explain why and how the exams are being created, who they apply to, the regulatory requirements they are intended to address, and more. Visit our website to access the following (under New Entry-to-Practise Exams for 2019):

- 8 facts about the new entry-to-practise exams
- Student-specific FAQs
- Fall 2017 *iNformeD* newsletter articles

Inspection program progress report

The authority for the College of Naturopaths of Ontario to conduct an inspection of all premises where Intravenous Infusion Therapy (IVIT) procedures are performed came into effect March 2, 2017.

As we approach the one year mark, this article reviews the steps in the inspection process and the progress made to date.

NOTE: All statistical figures presented in this article are as of February 15, 2018.

REGISTERING A PREMISES

Between March 2 and May 1, 2017, all premises that were performing IVIT or compounding for IVIT were required to register with the College as an existing premises.

One hundred and forty-two existing premises registered by the May 1 deadline. Subsequently, nine of these withdrew for the following reasons:

- Moved and are now registered as a new premises – 4 premises
- Chose to stop offering IVIT procedures – 5 premises

After May 1, 2017, any premises that intends to provide IVIT services must register as a new premises. For these new premises, the inspection is conducted in two parts.

- Part I occurs prior to any IVIT procedures being performed and includes the program requirements that must be in place in order to be fully prepared to provide safe and competent IVIT procedures.
- Part II involves the requirements that can only be inspected once procedures have been performed. This includes the observation of the IVIT procedures performed at the premises (compounding for and/or administering IVIT) and a review of IVIT patient records.

INSPECTION FEES

All existing premises were invoiced for the first instalment of the inspection fee on May 31, 2017, with payment being due June 30, 2017. New premises are invoiced for half of the fee when notified that an inspector has been assigned for Part I of the inspection, and similarly for Part II.

To date, all designated members for both existing and new premises have paid the applicable inspection fees on or before the deadline.

SELECTION OF PREMISES AND NOTIFICATION

Existing premises are randomly selected for an inspection. When the premises is selected, the designated member receives notification of a pending inspection by email and mail. This notification includes a request for current information about the premises, the submission of the *Policies and Procedures Manual* and an opportunity to declare a conflict of interest with any of the inspectors. The 10 inspectors also have the opportunity to make a conflict of interest declaration regarding the inspection of upcoming premises.

Once the documents are submitted, the designated member receives an email with the name of the assigned inspector. The inspector then contacts the designated member to schedule the date and time of the inspection within 30 days.

The *General Regulation* requires the College to have inspected all existing premises (that were registered by the May 2017 deadline) by March 1, 2019. It also requires the inspection of a new premises to occur within 180 days of the date it is registered. For the inspection of a new premises, the College makes every effort to notify the premises of a pending inspection as soon as is reasonably possible taking into consideration the availability of an inspector.

55

AVERAGE NUMBER OF DAYS FROM NOTIFICATION OF A PENDING NEW PREMISES INSPECTION TO THE OUTCOME BEING DELIVERED

Once an existing premises has been inspected and a new premises has had both Parts I and II completed, the next inspection will occur within the regularly scheduled five-year inspection cycle.

EXISTING AND NEW PREMISES INSPECTIONS*

49

NUMBER OF EXISTING PREMISES NOTIFIED OF A PENDING INSPECTION

31

NUMBER OF EXISTING PREMISES INSPECTED AND THE OUTCOME DELIVERED

6

NUMBER OF DEFERRAL REQUESTS MADE

5

DEFERRALS GRANTED

1

DEFERRALS DENIED

9

NUMBER OF REGISTERED NEW PREMISES

7

PART I COMPLETED

0

PART II COMPLETED

** As of February 15, 2018*

DETERMINATION OF THE OUTCOME

Once the inspection is completed, the inspector drafts a report based on their observations as to whether the program requirements have been fully met, partially met or not met.

A number of designated members have provided information to the College shortly after the inspection outlining the changes made to address the requirements that were partially or not met as indicated by the inspector.

The inspector submits their report to the College within two weeks of the inspection and the Inspection Committee meets approximately every six to eight weeks. At its meetings, the Committee considers the inspector's report, checklists used during the inspection and any other relevant documents such as the additional information provided by the designated member when determining the outcome of the inspection.

Possible outcomes are a pass, a pass with conditions, or a fail.

17 NUMBER OF EXISTING AND NEW PREMISES RECEIVING AN OUTCOME OF A PASS

13 NUMBER OF EXISTING AND NEW PREMISES RECEIVING AN OUTCOME OF A PASS WITH CONDITIONS

1 NUMBER OF EXISTING AND NEW PREMISES RECEIVING AN OUTCOME OF A FAIL

Deficiencies having led to a pass with conditions include:

- drugs missing from the crash cart,
- lack of or inadequate documentation of informed consent being obtained,
- stocking expired drugs, and
- missing significant portions of the Policies and Procedures Manual.

If a premises receives a pass with conditions or a fail, the designated member has 14 days to make a submission in response to the outcome. Following receipt of a submission, the Inspection Committee may or may not elect to re-inspect the premises. However, no more than 60 days after receiving the submission, the Inspection Committee must do one or more of the following:

- confirm its finding that the premises failed the inspection or passed with conditions,
- make a report and find that the premises passed with conditions, and/or
- make a report and find that the premises passed the inspection.

NUMBER OF SUBMISSIONS MADE IN RESPONSE TO A PASS WITH CONDITIONS AND CONSIDERED BY THE INSPECTION COMMITTEE

8

NUMBER OF FINAL OUTCOMES OF A PASS

The Inspection Committee has determined that there are instances where the deficiencies identified by the inspector do not warrant a condition but do warrant a recommendation being made to the premises in order to bring the issue to the attention of the designated member.

25

NUMBER OF PREMISES RECEIVING ONE OR MORE RECOMMENDATIONS

157

TOTAL NUMBER OF RECOMMENDATIONS MADE

The most common deficiencies having led to a recommendation include:

- emergency procedures not properly displayed,
- emergency lighting not available in all patient areas,
- incomplete risk analysis,
- infection control signage not properly posted,
- incomplete written protocols and procedures for cleaning the premises,
- incomplete drug/substance inventory record, and
- incomplete labelling of an IV bag.

The Inspection Committee Report is posted on the IVIT Premises Register once it is delivered by email to the designated member.

FEEDBACK FROM DESIGNATED MEMBERS

At the end of the inspection the designated member is asked to complete a Post-inspection Questionnaire. The questionnaire asks for feedback about the inspection itself, the inspector, and the College's support for the Member. The response overall has been very positive.

Here is what some of Members have said about the inspection:

- Helpful critiques, professional, great inspection;
- Seemed to go as described in preparation materials provided in advance (few surprises);
- Would have been helpful to have the handbook and requirements as attached in the email communications;
- I feel up until the day of the inspection it felt really stressful. I wish there had been more insights and guidance into the process (i.e., a free course on setting up your clinic, help with clinic materials etc). Inspection process itself was great and a chance to learn; and
- Inspector was kind, professional and helpful at answering questions, made the inspection a great experience.

TYPE 1 AND 2 OCCURRENCE REPORTS

Type 1 and 2 occurrence reports provide information to the College about specific events that take place in premises where IVIT is performed and allow the College to determine whether further action is required, such as an inspection of the premises.

Type 1 Occurrences are:

- death of a patient at the premises after a procedure was performed;
- death of a patient within five days of a procedure being performed on the patient;
- any referral of a patient to emergency services within five days after a procedure was performed;
- any procedure performed on the wrong patient;
- administration of an emergency drug to a patient immediately following a procedure;
- the diagnosis of a patient with shock or convulsions occurring within five days of a procedure being performed; and
- the diagnosis of a patient as being infected with a disease or any disease-causing agent following a procedure, if the Member forms the opinion that the patient is or may have been infected as a result of the procedure.

Type 2 Occurrences are:

- any infection occurring in a patient in the premises after a procedure was performed,
- an unscheduled treatment of a patient by a Member occurring within five days of a procedure being performed, and
- any adverse drug reactions occurring after the performance of a procedure.

All Members who become aware of a Type 1 occurrence are required to inform the College by submitting a Type 1 Occurrence Report Form within 24 hours of learning of the occurrence. This reporting requirement came into effect on March 2, 2017 as part of the Inspection Program.

To date, four Type 1 Occurrence Reports have been received. Three reports were due to the referral of a patient to emergency services within five days of the performance of a procedure at the premises and one due to the death of a patient occurring within five days after a procedure was performed at the premises.

The Inspection Committee reviewed all four reports received and determined that there were no concerns regarding the care provided by the Members. As such, no further action was required.

Type 2 Occurrences are to be reported to the College on an annual basis. The reporting date is May 1 and all designated members will be notified as to how they can provide this information to the College.

INSPECTION PROGRAM PROGRESS REPORT

The Type 2 Occurrence Tracking form to use during the year and keep on record at the premises can be found on the College's website here.

The information received by the College through the inspections themselves, the occurrence reports, and the feedback forms helps us to understand:

- how and where the Inspection Program is working,
- what aspects of the Inspection Program need improving,
- what areas of IVIT practice Members are excelling in, and
- what areas of IVIT practice Members need support in.

The Inspection Program is still in its early stages, however inspection results, outcomes, and feedback from our Members all indicate that the program is working to ensure that patients in Ontario who choose to access IVIT services are receiving safe, competent and ethical care.

IVIT-associated death – recommendations from the Office of the Chief Coroner

The Office of the Chief Coroner issued a report from the Patient Safety Death Review Committee in July 2017 regarding a death associated with an IV Compounding Error and Management of Care in a Naturopathic Centre that occurred in 2014.

The ISMP Canada Safety Bulletin reprinted on the following pages and the Committee report serve as good reminders for anyone who incorporates compounding or IVIT into their practice about the importance of considering the potential risks associated with the compounding process and of establishing emergency protocols to mitigate patient harm.

The College has reviewed the recommendations made by the Office of the Chief Coroner and is committed to working with Ontario's naturopaths and its partners to ensure compliance. We are also reviewing the recommendations to see if programs need to be strengthened.

The College currently has a thorough and detailed program in place to protect the public who receive Intravenous Infusion Therapy (IVIT). Naturopaths who offer IVIT must take mandatory College-approved courses and pass exams for IVIT and Prescribing. We also launched a new program last spring to start inspecting all Ontario facilities where naturopaths offer IVIT procedures.

We also encourage Ontarians to visit our online Public Register. This is where they can search for information about a naturopath, including making sure they are legally registered to practise and that the naturopath has the qualifications to offer extended services like IVIT.

Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

Volume 18 • Issue 1 • January 4, 2018

Death Associated with an IV Compounding Error and Management of Care in a Naturopathic Centre

Patients with a diagnosis of cancer may choose to use complementary and alternative medicine, such as naturopathy, to support conventional medical therapies (e.g., surgery, chemotherapy).[1] The complementary and alternative medicine treatment plan is usually prescribed by a naturopathic doctor and carried out in a complementary care centre (CCC). As part of an ongoing collaboration with a provincial death investigation service, ISMP Canada received a report about the death of an individual who had received, by intravenous (IV) administration at a CCC, a tissue- and wound-healing formulation containing selenium at a much higher concentration than intended. This bulletin highlights some contributing factors identified in the incident analysis, and provides recommendations to prevent similar incidents in the future.

Case Description

A patient was discharged from hospital after surgical excision of a cancerous tumour and was further treated, in a collaborative arrangement, by a conventional medical team and a naturopathic doctor at a CCC. The naturopathic doctor prescribed a complex tissue- and wound-healing formulation, which included selenium, for twice-weekly IV administration. The selenium solution was prepared by a compounding pharmacy and was added to the formulation on site at the CCC.

The patient had received this healing formula on 12 previous occasions, with no reported reactions.

Specialty compounding pharmacies:

- *Ensure that the formula's units of measure align with the units of measure displayed by the equipment to be used during compounding; additional conversion calculations should not be required in the process.*
- *Incorporate technology to support patient safety, such as bar coding and scales that print the weight of each item automatically.*
- *Avoid the use of dangerous abbreviations known to lead to medication errors (e.g., "µg" for "micrograms").*

Complementary care centres:

- *Ensure the availability of detailed protocols to be followed if an emergency situation occurs, such as a reaction to an intravenous (IV) infusion.*
- *Define the limitations of the complementary care centre and its healthcare providers. Clearly describe clinical circumstances in which patients must be transferred to a conventional, higher level of care (e.g., emergency room).*
- *Use "mcg" to represent "micrograms" in all written documentation.*

However, shortly after initiation of the 13th dose infusion, she became nauseous and diaphoretic. The infusion was stopped, and homeopathic remedies were administered, with no clinical improvement. Over the next several hours, the patient's condition

continued to deteriorate. When the patient began to experience hypotension, shortness of breath to the point of cyanosis, and chest pain, she was transferred to the emergency department of a local hospital, where she later died. The timeline of these events is presented in Figure 1. Postmortem investigations showed that the selenium concentration in the infusion was 1000 times greater than intended, which likely contributed to the patient's death.

Background

The mineral selenium is an essential trace element in the body that is usually consumed through intake of food and water. It has antioxidant properties and has been studied for use in treating many medical conditions. However, high doses of selenium are toxic, leading to gastrointestinal and cardiovascular complications.[2] Selenium is commercially available in many forms, including as a solution for IV administration.

Tissue- and wound-healing formulations are used in the field of naturopathic medicine as postsurgical support. Naturopathic doctors prepare these complex IV admixtures on site at the CCC, usually from commercially available products. Products that are not commercially available (or that cannot be supplied because of shortages) may be outsourced to compounding pharmacies. Most pharmacies offer some compounding services; however, the scope of such services and the expertise of staff are highly variable. The National Association of Pharmacy Regulatory Authorities (NAPRA) has developed standards for compounding of hazardous and nonhazardous sterile preparations to assist pharmacists and pharmacy technicians in ensuring that the compounding of sterile preparations meets high standards.[3]

Discussion

This bulletin focuses on 3 key opportunities for improvement (listed in Box 1).

Box 1. Key opportunities for improvement

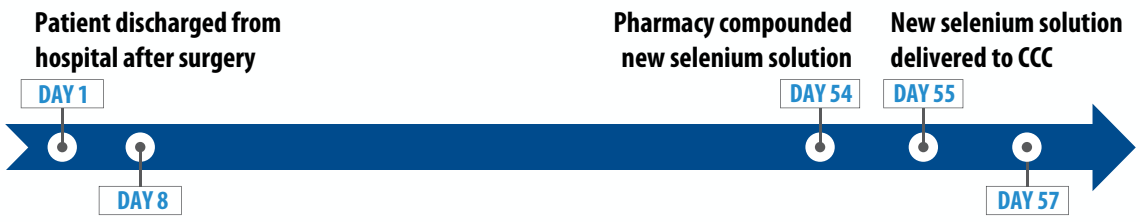
At the pharmacy
- Compounding processes

At the complementary care centre
- Emergency response
- Preparation, storage, and administration of admixtures

Pharmacy: Compounding Processes

The compounding pharmacy had processes in place to verify calculations and weighing of ingredients, as well as a final product check. Nonetheless, the

Figure 1. Timeline of events from the patient's initial hospital discharge until her death



CCC = complementary care centre
IV = intravenous

selenium concentration in the prepared solution was 1000 times what was intended, and this error was not detected at any stage before release of the solution to the CCC. The following factors may have contributed to this undetected error:

- Confirmation bias, which leads individuals to "see" information that confirms their expectations rather than correctly interpreting information that contradicts their expectations, may have played a role.[4] When the amount of selenium powder (in milligrams) required for a 40 mcg/mL solution was weighed and checked, the unit of measure displayed by the scale (grams) may have been incorrectly interpreted as milligrams, with the error in interpretation going unrecognized. Such errors can lead to 1000-fold overdoses.
- The abbreviation "µg" was used for "microgram" in the formula for the selenium solution. This abbreviation is considered dangerous because it is easily confused with "mg" (meaning "milligram"). There have been other medication incident reports where such confusion has led to 1000-fold overdoses.
- Reliance on a visual check of the weighed amount may have contributed to the error. Scales are available that print out the weight of each item to provide a permanent document that can be attached to the compounding record for checking in the final verification step.

Recommendations

- Before compounding a sterile product, refer to the Health Canada Drug Product Database to determine whether the product is commercially available.[5]
- Design formulas and worksheets to present information in a logical sequence, with consistent terminology.
- Ensure that the formula's units of measure align with the units of measure displayed by the equipment to be used during compounding; additional conversion calculations should not be required in the process. For example, if the scale displays weight in grams, the formula should express the amount to be weighed and verified in grams, without necessitating any additional conversion calculations.
- Avoid the use of dangerous abbreviations known to lead to medication errors (e.g., "µg" for "microgram").
- Incorporate technology to support patient safety, such as bar coding and scales that print the weight of each item automatically. Alternatively, have pharmacy staff take photographs of the containers used and the weight readings, and attach the photographs to the compounding record.
- Conduct a review of existing processes, including a cognitive walkthrough (a procedure that involves physically walking through the process or task of interest, examining the mental activities required at each step and the challenges experienced[6]), to ensure that compounding processes comply with professional standards (e.g., NAPRA Model Standards for Compounding of Non-Hazardous Sterile Preparations[7]) and medication safety principles.

Complementary Care Centre: Emergency Response

For any patient receiving IV treatments in a naturopathic setting, vital signs should be monitored and recorded regularly. In this case, there did not seem to be a standardized approach to patient assessment and monitoring.

Naturopathic doctors are required to refer patients to receive conventional medical therapy if their condition requires diagnostic procedures, monitoring, or treatment that is beyond the scope of practice of the naturopathic doctor. In this case, the patient was treated with homeopathic remedies. These remedies did not produce any clinical improvement. Available documentation also indicated that there may have been a lack of appropriate supervision by, and timely help from, the naturopathic doctor on the day of the incident, which may have contributed to the delay in transferring the patient to a higher level of care (e.g., emergency room).

Recommendations

- Ensure the availability of detailed protocols to be followed in emergency situations, such as reaction to an IV infusion. These protocols should meet the standards of a conventional out-of-hospital facility

providing IV infusion therapy, including the following provisions:
  - designated staff trained in Advanced Cardiac Life Support (e.g., nurse, naturopathic doctor) to oversee the emergency care situation;
  - identification of available emergency/rescue medications and devices, their storage locations, and their indications for use; and
  - appropriate patient monitoring and documentation.
- Define the limitations of the CCC and its healthcare providers. Clearly describe the clinical circumstances in which patients must be transferred to a conventional, higher level of care.

Complementary Care Centre: Preparation, Storage, and Administration of Admixtures

The prepared IV tissue- and wound-healing formulation was a complex admixture of 10 ingredients added to sterile water for injection. There is no uniform standard for the preparation of admixtures in a CCC. From the information available in this case, it appears that handwritten changes to the formula may have been made at each session, and that each solution was prepared individually from bulk ingredients. The sources of components of the final product were unknown, except for the selenium solution, which was obtained from a compounding pharmacy.

Recommendations

- Review and adhere to compounding guidelines developed by jurisdictional naturopathic regulatory authorities and NAPRA, to ensure compliance with expected standards of practice.
- Use "mcg" to represent "micrograms" in all written documentation. Avoid the use of the dangerous abbreviation "µg", which is known to have contributed to 1000-fold dosing errors.
- Develop preprinted order sets collaboratively with end-users and ensure that these order sets meet the following criteria:
  - present critical information in a logical sequence with consistent terminology;
  - avoid the use of dangerous abbreviations, symbols, and dose designations that may be misinterpreted (see ISMP Canada's Do Not Use list, available from: https://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf);
  - contain only essential information; and
  - undergo regular review.

Additional Recommendations for Regulatory Agencies

- Consider specific accreditation for facilities that provide specialty compounding services, with criteria to be developed in collaboration with key stakeholders (e.g., NAPRA, Health Canada, and ISMP Canada). The accreditation process should include assessment of compliance with available standards and guidelines.
- Mandate that personnel working in compounding centres have credentials confirming that they have received appropriate training in applicable safe medication preparation and administration practices.

Conclusion

Sterile compounding of pharmaceuticals is a complex process. Without testing, it is difficult to identify errors in the final prepared product. The incident described here involved a complementary health product; however, a similar error could have occurred with any compounded product. Decisions to compound must consider the potential risks associated with the compounding process. Pharmacies and other facilities preparing sterile pharmaceuticals should carefully consider multiple approaches to reduce risk, including use of commercially prepared products when available and implementation of available technologies.

In settings where IV infusions are to be administered, the importance of establishing emergency protocols, as well as ensuring availability of trained personnel, rescue equipment, medication, and supplies, cannot be overstated. Prompt recognition of symptoms necessitating a higher level of care and access to emergency treatment is critical to mitigate harm.

Acknowledgements

ISMP Canada extends appreciation to the family for allowing details of this medication incident to be shared, with the goal of preventing harm to others in similar situations. ISMP Canada gratefully acknowledges expert review of this bulletin by the following individuals (in alphabetical order): Dana Lyons RPhT, Manager – Technical Practice, Pharmacy Services, Foothills Medical Centre, Calgary, AB; Eric Marsden BSc ND, Clinic Director/Naturopathic Oncology Residency Director, Marsden Centre for Excellence in Integrative Medicine, Concord, ON; Joyce Tsang RPh PharmD BScPhm HBSc, University Health Network – Toronto General Hospital, Toronto, ON.

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Stakeholder Consultation on Naming of Biologic Drugs

January 18 to February 9, 2018

On January 18, 2018, the Institute for Safe Medication Practices Canada (ISMP Canada) will post an online questionnaire to seek input from healthcare providers, consumers, and other interested and affected stakeholders on different approaches to the naming of biologic drugs, including biosimilars, in Canada. The questionnaire is being developed collaboratively with Health Canada. Administration of the questionnaire and analysis of responses will be performed by ISMP Canada.

The objective of the consultation is to gain insight into stakeholder views on the practical impacts of different approaches to the naming of biologic drugs and biosimilars throughout the medication-use process, including prescribing, dispensing, and adverse drug reaction reporting.

Results of the consultation will be used to:

- understand the impact of different approaches to biologic drug naming and the perspectives of healthcare providers, consumers, and other interested and affected stakeholders, and
- inform Health Canada's policy decision on a naming convention for biologic drugs.

For more details on this initiative, click here (https://www.ismp-canada.org/biosimilars/Naming-of-Biologic-Drugs-Consultation-NoticeEN.pdf). Additional details will also be available when the questionnaire is launched on January 18, 2018.

We would appreciate your help to distribute this message to your colleagues, members, or stakeholders to inform them of this initiative and the upcoming consultation. If you have any preliminary questions, please contact us via info@ismp-canada.org

Caution: Unlabelled Marking on a Vaccine Syringe Led to Under-dosing of Adult Patients

ISMP Canada received a report that described misinterpretation of an unlabelled marking on the Influvac influenza vaccine syringe resulting in multiple adult patients being administered half the intended dose.

Influvac is provided in a prefilled syringe that contains 0.5 mL of vaccine and a small amount of air; the syringe has a black marking to denote 0.25 mL (but not labelled as 0.25 mL). When administering the vaccine to several adult patients, the practitioner interpreted the black marking as the 'measured dose', and the plunger was pressed until only that amount of the vaccine remained (i.e., along with the air, half the dose was expelled through the needle).

Practitioners need to refer back to the original packaging and/or the information leaflet for clarification of any unlabelled markings on the syringe. The manufacturer has been contacted to share these incidents and the labelling concern, as well as the potential for similar errors.

Information about these incidents was also shared through social media for timely notice.

Med Safety Exchange
Webinar Series

Wednesday, January 10, 2018

Wednesday, February 14, 2018

Join your colleagues across Canada for complimentary monthly 60 minute webinars to share, learn and discuss incident reports, trends and emerging issues in medication safety!

For more information, visit www.ismp-canada.org/MedSafetyExchange/

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

HIROC

The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

Stay Informed

To receive ISMP Canada Safety Bulletins and Newsletters visit:

www.ismp-canada.org/stayinformed/

This bulletin shares information about safe medication practices, is noncommercial, and is therefore exempt from Canadian anti-spam legislation.

Contact Us

Email: cmirps@ismp-canada.org
Phone: 1-866-544-7672

The use of restricted titles

Members of the College of Naturopaths of Ontario registered in the General class have the authority to use the restricted title naturopath or naturopathic doctor, as stated in the *Naturopathy Act, 2007*. Members who are in the Inactive class must use the title of naturopath (Inactive) or naturopathic doctor (Inactive).

Restricted titles are an important aspect of regulation and public protection. Every title or designation provides information about the person using the title and creates expectations about the person. When the public sees a particular title used by a regulated health professional they tend to make certain assumptions about that person's skills and knowledge. The purpose of title protection through legislation is to protect the public by ensuring appropriate and authorized use of titles.

The following table contains some of the restricted titles as set out in legislation in Ontario.

Title	Legislation	Regulatory College
"naturopath"	*Naturopathy Act, 2007*	College of Naturopaths of Ontario
"osteopath", "physician" or "surgeon"	*Medicine Act, 1991*	College of Physicians and Surgeons of Ontario
"nurse", "nurse practitioner", "registered nurse" or "registered practical nurse"	*Nursing Act, 1991*	College of Nurses of Ontario
"homeopath"	*Homeopathy Act, 2007*	College of Homeopaths of Ontario
"massage therapist" or "registered massage therapist"	*Massage Therapy Act, 1991*	College of Massage Therapists of Ontario
"chiropractor"	*Chiropractic Act, 1991*	College of Chiropractors of Ontario
"traditional Chinese medicine practitioner" or "acupuncturist"	*Traditional Chinese Medicine Act, 2006*	College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario

Each of the above titles provides information as to what type of practitioner the public will be seeking care from. The use of a restricted title by someone not authorized to do so misleads the public. The only people authorized to use the restricted title are members of that regulatory College.

Legislation restricts not only the use of the title itself but also the use of "a variation or abbreviation or an equivalent in another language". This prevents someone from circumventing the law and misleading the public by using a title that is similar to that which is stated in the legislation. The use of "naturotherapist" or "naturopata" are variations of the title "naturopath" and may not be used.

The College of Naturopaths of Ontario takes the illegal use of titles seriously. Complaints received by the College about the inappropriate use of titles by Members were on the rise in 2017. Advertising by Members using the title "naturopathic physician" or saying they have a "medical practice" is in contravention of the *Medicine Act, 1991* as well as the College's *Standard of Practice for Restricted Titles*.

The College also addresses the use of the title naturopath by those who are not Members of the College. In the interest of public protection the College maintains an Unauthorized Practitioner Register to identify unauthorized individuals who are using the title or a variation thereof. This register, along with the College's Naturopathic Doctor Register, allows the public to find a registered naturopath in Ontario who will provide safe, competent and ethical care.

It is the College's role to hold its Members accountable and ensure the public receives safe, competent and ethical care from naturopathic doctors. It is the professions' role to respect the importance of only using the titles legally authorized to the profession in the jurisdiction where the naturopathic doctor practices. Each member of the profession, and how they choose to present themselves to the public, reflects on the profession as a whole.

For additional guidance, contact our Regulatory Education Specialist Dr. Mary-Ellen McKenna, ND (Inactive) maryellen.mckenna@collegeofnaturopaths.on.ca or 416-583-6020.

Patient confidentiality

In this edition of the newsletter we present and analyze a scenario based on a complaint that illustrates the importance of maintaining patient confidentiality and aims to help Members identify areas of potential concerns within their practice. By law, cases under investigation are confidential. The details of the case below have, therefore, been altered to respect confidentiality.

SUMMARY OF THE COMPLAINT

The College of Naturopaths of Ontario received a complaint about a breach of patient confidentiality by a Member of the College. The Member sent an email to a patient's family member who was not authorized to access medical information for the patient.

The patient was an elderly woman who was accompanied to her appointment by her daughter. Following the patient's initial visit with the Member, the Member received a letter from the patient's son instructing that no further treatment should be provided without his consent. It was in this letter that the Member was made aware that the patient's daughter, who attended the initial visit, was not an authorized decision maker for personal care for the patient.

After receiving this information, the Member emailed the patient's daughter, advising her that the treatment would be discontinued as instructed by the patient's son. The letter received from the patient's son, including a copy of the power of attorney for personal care, was included with the Member's email. The Complainant stated that it was this email that breached patient confidentiality, as the patient's daughter should not have been made aware of the request to terminate treatment with the Member. In addition, this communication appeared to be harmful to family relationships.

In response to the complaint, the Member explained that, during the patient's visit, no indication that the patient required a substitute decision maker was given nor was any information shared regarding power of attorney or family issues. The Member was also not told that communicating with family members moving forward was not allowed.

OUTCOME

Upon completion of its investigation into this matter, the Inquiries, Complaints and Reports Committee (ICRC) found that the complaint did not warrant a referral for a discipline hearing.

The ICRC acknowledged that the Member believed to be acting professionally by communicating with the patient's daughter and that the act of breaching patient confidentiality was not malicious in nature. However, giving information about a patient to a person other than the patient or the patient's authorized representative (except with the consent of the patient or the authorized representative or as required or authorized by law), is considered an act of professional misconduct. Therefore, the ICRC issued a Letter of Advice to the Member to reinforce the importance of maintaining patient confidentiality.

ANALYSIS

The Personal Health Information Protection Act

Rules for the collection, use and disclosure of personal health information are outlined in the *Personal Health Information Protection Act, 2004* (PHIPA). Among others, the Act includes the following provisions:

- Consent is required for the collection, use and disclosure of personal health information, with few exceptions;
- Health information custodians are required to treat all personal health information as confidential and maintain its security;
- Individuals have a right to access their personal health information, as well as the right to correct errors; and
- Individuals have the right to instruct health information custodians not to share their personal health information with others.

Upon review of the information collected in relation to this complaint, it was clear that the Member breached patient confidentiality by sharing a letter from the legal representative of a patient with a family member of the patient who was not her power of attorney.

What is Personal Health Information?

Personal Health Information, as defined in section 4 of PHIPA, includes identifying information about an individual in oral or recorded form that:

- relates to the individual's physical or mental health;

- relates to providing health care, including identifying a provider of health care;
- is a plan of service within the meaning of the *Home Care and Community Services Act, 1994*;
- relates to payments or eligibility for health care in respect of the individual;
- relates to the donation of a body part or bodily substance;
- is the individual's health number;
- identifies a substitute decision-maker of that individual.

Based on the above, any correspondence identifying the substitute decision maker for a patient is considered as personal health information. As such, the Member was expected to document the correspondence received from the patient's son in the patient file and keep it confidential.

Health Information disclosure

In PHIPA, disclosure is defined as making information available or releasing it to another custodian or person. The *Professional Misconduct Regulation* made under the *Naturopathy Act, 2007* states that giving information about a patient to a person other than the patient or the patient's authorized representative, except with the consent of the patient or the authorized representative or as required or authorized by law, is an act of *professional misconduct*.

Consent

The patient's consent is required for the collection, use or disclosure of personal health information, unless the collection, use or disclosure is permitted or required by PHIPA. The consent must:

- be knowledgeable;
- relate to the information; and
- not be obtained through deception or coercion.

As per the College's *Standard of Practice for Consent*, to be valid, consent must be informed. The Member has a duty to ensure the patient has sufficient information to make valid decisions about his/her care. Members are required to document in the patient file:

- that a discussion regarding consent took place;
- any modifications to the consent;
- when consent was obtained through the use of an interpreter, alternate means of communication, or a substitute decision maker; the identity of the interpreter or substitute decision maker, the legal entitlement of the substitute decision maker as applicable (documentation on file, copy of Power of Attorney for personal care provided, etc.);
- that the patient withdrew consent, why he/she did so, and what specifically was withdrawn.

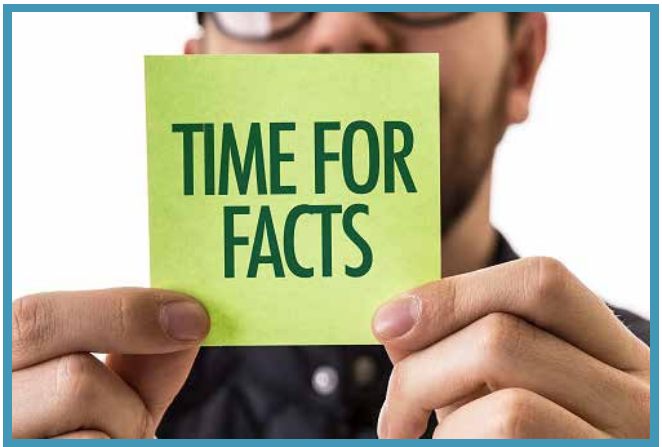
Documentation can take either of the following forms: a note in the patient record or a consent form, that is dated, signed, and witnessed.

The ICRC in this case noted that the consent form in the patient file appeared to be signed by the patient's daughter and not the patient herself. Had the Member taken note of this and inquired further as to why the patient did not sign the consent form herself, this may have led to a conversation regarding power of attorney for personal care, potentially avoiding the situation that resulted in the complaint.

BOTTOM LINE

As regulated healthcare providers, Members of the College must act in accordance with all of their professional and legal obligations.
The ICRC reminds Members that maintaining patient confidentiality is fundamental in patient care and that doing so helps build a successful naturopathic doctor - patient relationship. Members are encouraged to educate their patients about the practitioner's responsibility to keep personal health information confidential as part of the informed consent discussion. Patients who understand that their information will remain confidential are more likely to provide the Member with complete health information, which benefits both the Member and the patient.

Members are reminded that all the discussions and/or communications with the patient or their legal representative must be documented and become part of the patient's medical record (i.e. the patient's health information as defined in PHIPA). Caution must be exercised prior to sharing any of information from a patient's medical record, even when it is not strictly pertaining to the patient's personal health information.



Myth busting: What really happens when you contact the College

Some Members believe that notes are made on an ND's file when they contact us with a question or concern. This is not true. Learn more about how we can help you understand and practise within the regulations and standards of the profession. Read our latest blog post: *To Call or Not to Call*.

Registration renewal deadline

Renewal fees and the online Information Return must both be completed by no later than **March 31, 2018 at 11:59 pm EST.** Renew here.

Upcoming examinations

Ontario Intravenous Infusion Therapy Examination

Spring Session

Exam Date: May 27, 2018
- Registration Opens: April 16 (9:00 am)
- Registration Closes: May 7 (5:00 pm)

Fall Session

Exam Date: December 2, 2018
- Registration Opens: October 22
- Registration Closes: November 12

Ontario Prescribing and Therapeutics Examination

Spring Session

Exam Date: June 10, 2018
- Registration Opens: April 30, 2018
- Registration Closes: May 22, 2018

Fall Session

Exam Date: October 28, 2018
- Registration Opens: September 17, 2018
- Registration Closes: October 9, 2018

Thinking of taking the exam?

Read what NDs have to say about it and their tips to help you prepare.

New video for patients

Check out this new video produced by Ontario Health Regulators to educate the public about how to get reliable information about health care professionals and how Colleges can help them.

Read our latest blog posts!

- *To call or not to call* – what really happens when you contact us with questions or concerns
- *What? Another fee increase?*

Next Council meeting

The next meeting is scheduled for April 25 at the CONO office and is open to Members and the public. Please contact us by phone at 416-583-6010 or email to register as an observer.