



Ontario College
of Pharmacists
Putting patients first since 1871

PHARMACY CONNECTION

SPRING 2018 • VOLUME 25 NUMBER 2
PHARMACYCONNECTION.CA

THE OFFICIAL PUBLICATION OF
THE ONTARIO COLLEGE OF PHARMACISTS



NAVIGATING CHANGE

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COUNCIL MEMBERS

Elected Council Members are listed below according to District. PM indicates a public member appointed by the Lieutenant-Governor-in-Council. U of T indicates the Dean of the Leslie Dan Faculty of Pharmacy, University of Toronto. U of W indicates the Hallman Director, School of Pharmacy, University of Waterloo.

H Régis Vaillancourt
 (President)
 H Nadia Facca
 K Esmail Merani
 K Tracey Phillips
 L Billy Cheung
 L James Morrison
 L Sony Poulou
 M Mike Hannalah
 M Kyro Maseh
 M Laura Weyland
 (Vice President)
 N Gerry Cook
 N Karen Riley
 N Leigh Smith
 P Rachelle Rocha
 P Douglas Stewart
 T Ruth-Ann Plaxton
 TH Goran Petrovic

PM Kathy Al-Zand
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 PM Christine Henderson
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 PM Javid Khan
 PM James MacLaggan
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 PM Shahid Rashdi
 PM Joy Sommerfreund
 PM Dan Stapleton
 PM Ravil Veli
 PM Wes Vickers
 U of T Heather Boon
 U of W David Edwards

Statutory Committees

- Accreditation
- Discipline
- Executive
- Fitness to Practise
- Inquiries Complaints & Reports
- Patient Relations
- Quality Assurance
- Registration

Standing Committees

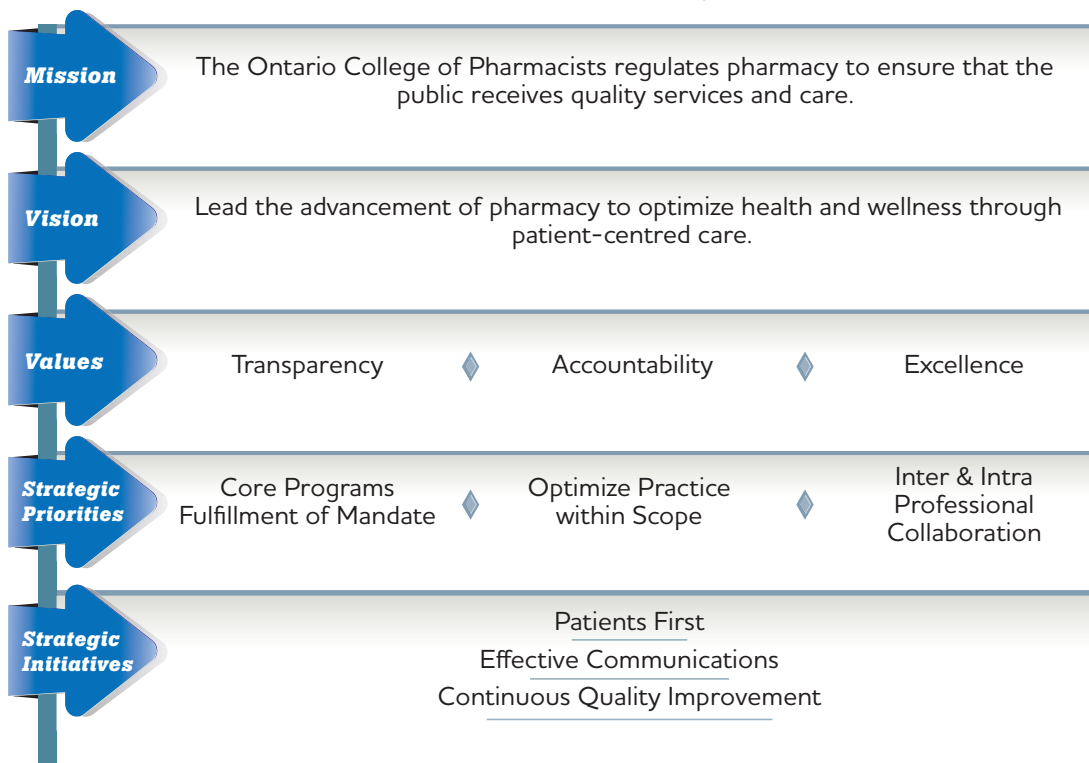
- Drug Preparation Premises
- Elections
- Finance & Audit
- Professional Practice



Ontario College of Pharmacists
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Strategic Framework

2015-2018



The objectives of *Pharmacy Connection* are to communicate information about College activities and policies as well as provincial and federal initiatives affecting the profession; to encourage dialogue and discuss issues of interest to pharmacists, pharmacy technicians and applicants; to promote interprofessional collaboration of members with other allied health care professionals; and to communicate our role to members and stakeholders as regulator of the profession in the public interest.

We publish four times a year, in the Fall, Winter, Spring and Summer.

We also invite you to share your comments, suggestions or criticisms by letter to the Editor. Letters considered for reprinting must include the author's name, address and telephone number. The opinions expressed in this publication do not necessarily represent the views or official position of the Ontario College of Pharmacists.

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communications@ocpinfo.com



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Régis Vaillancourt,
O.M.M., C.D., B. Pharm.,
Pharm. D., R. Ph.

President

In late March, Council gathered for three days of dialogue and planning to prepare the College's next three year strategic plan. While we look forward to revealing the final framework in the coming weeks and months, I wanted to share with you how Council approached this process.

Our regulatory environment is constantly evolving and as a College we needed to be able to take a thorough look at what we are doing and how it is contributing to our fundamental role to put patients and the public interest first. The work on our new strategic plan was informed by input from the public, government, pharmacy professionals and other health system and regulatory partners and reflects the growing momentum among regulators and the broader healthcare system towards adopting collaborative and holistic approaches that don't just look at professions, providers or issues in silos, but that reflect broad-based societal concerns.

The new strategic plan reaffirms our collective commitment to putting patients – and their necessary trust in both pharmacy and the College – first. It also acknowledges the increased focus on patient

protection, as demonstrated by the recent implementation of additional regulations to the *Protecting Patients Act* (see page 14). The College strongly supported this Act and its intention to protect patients from harm and promote greater transparency for the public.

New issues and areas of focus in the healthcare and regulatory sectors are emerging every day. These can present both challenges for the College, pharmacy professionals and patients, but they also represent exciting opportunities. As pharmacy professionals, we have the opportunity every day of our practice to raise the bar for our patients. It's not enough for us to just follow the rules; we need to actively seek out opportunities to make things better for our patients.

One fundamental way we do that is to build continuous quality improvement into the services and care we provide. As we move towards commencing full implementation of our medication safety program later this year (see page 17), we expect pharmacies, pharmacists and pharmacy technicians to embrace this chance to support learnings and improvements across the province by starting to educate themselves and their colleagues about the program and its goals. It's not just about reporting incidents, and it is definitely not about blame; it is about opportunities to enhance the whole system and improve the care that patients receive.

Whether it is about asking yourself if you have sufficient knowledge and skills to appropriately treat veterinary patients (page 46), delving into an ethical dilemma to explore how you might make decisions in practice (page 36), or re-examining whether you are conducting the necessary patient

assessments for refills (page 32), there are always opportunities to self-assess, educate and improve.

As a profession and a College, we also need to effectively respond to issues that are beyond just the scope of the healthcare system. With cannabis set to become much more accessible very soon, we have a collective responsibility to address how we may need to care for and communicate with patients in new ways. Like our work on the Opioid Strategy, a Cannabis Task Force has been established to develop a cannabis strategy for pharmacy which will be discussed at our next Council meeting. It's another example of how we're working together to be a responsive regulator on issues that matter.

Over the summer we will be electing five new members of Council and appointing a number of new non-council committee members. I invite all of you to consider whether you have the skills, knowledge and experience to help protect the public and contribute to quality and safe pharmacy practice in Ontario. Council does not exist to represent members – it exists to ensure that the public interest is protected. Being a part of Council, or College committees, after all is a privilege.

Finally, I'd like to say that it has been an honour to serve as President for the past two years. I'm proud of all that we have accomplished in our mission to ensure patients are protected.

Sincerely,

A handwritten signature in black ink that reads "Régis Vaillancourt". The signature is written in a cursive, flowing style.

MARCH 2018

COUNCIL MEETING

As recorded following Council's regularly scheduled meeting held on March 25th - 27th, 2018.

COUNCIL SETS STRATEGIC PRIORITIES, FRAMEWORK FOR 2019 – 2021

Shifting public expectations of regulators and the growing opportunities to contribute to improved patient outcomes and a better health system served as an important backdrop as College Council participated in a facilitated planning session aimed at setting a new strategic plan to guide the work of the College, and its public-protection mandate, over the next three years.

While reflecting on the College's accomplishments since 2015, Council members considered the input received from the public, government, professionals and other health system and regulatory partners in establishing updated vision, mission and values statements and setting new strategic priorities for 2019-2021. These priorities are focused on strengthening the College's capacity and ability to respond to emerging regulatory and healthcare system priorities, improving patient outcomes through collaboration and practice optimization, and enhancing communication and public education.

The College will now move forward with preparing an operational plan, with the final vision, mission, values and strategic priority statements,

for approval at the June 2018 Council meeting.

NEW ELECTED MEMBER ON COUNCIL

Council welcomed newly-elected member from District H, Ms. Nadia Facca. Ms. Facca will be serving on the Accreditation, Drug Preparation Premises and Quality Committees of the College.

CANNABIS TASK FORCE

The Cannabis Task Force is currently in the process of drafting a Cannabis Strategy that it plans to present to Council in June. One of the Strategy's goals is to address the need for members to respond to changes in the pharmacy practice environment related to the impact on patients as a result of the impending legalization of recreational cannabis. Agreeing that this is a significant and time-sensitive issue, Council discussed and unanimously supported the recommendation that the College require all Part A pharmacists to complete cannabis education in preparation for these anticipated practice changes.

College staff will work towards establishing a process for implementation of the requirement and collaborate with continuing education providers to assure appropriate courses are accessible to pharmacists to

meet this mandatory education requirement. More information on the requirement, including implementation timeline, will be communicated as details are confirmed over the coming months.

COUNCIL APPROVES AUDITED STATEMENTS FOR 2017 COLLEGE OPERATIONS

Council approved the audited financial statements for the operations of the College for the 2017 fiscal year as prepared by Tinkham LLP, Chartered Professional Accountants. The audit and resulting financial statements were prepared in accordance with Canadian Auditing Standards for not-for-profit organizations. Council was pleased to note that the auditors did not identify any major issues of concern. The summarized financial statements can be found on the [College's website](#).

2017 ANNUAL REPORT


The College's 2017 annual report, entitled "Putting Patients First", is now available for download as a PDF document on the public website and includes the audited financial statements approved by Council. A web-friendly supplementary version of the annual report can be viewed on any computer or mobile device at www.ocpannualreport2017.ca.



COMMUNICATION AND SOCIAL MEDIA

Building on a presentation at the December 2017 Council meeting that focused on 2018 communication priorities, Council members received an update related to media and social media activities at the College. The presentation focused on the latest communication and media trends observed by staff and best practices to help Council and committee members understand the College's role

and their responsibilities when communicating in the public eye. An e-learning module on "[Social Media Awareness for Regulated Health Professionals](#)" is currently available on our website in our e-learning library.

Council meetings are open to the public and, unless otherwise stated, are held at the College: 483 Huron Street, Toronto, ON M5R 2R4. If you plan to attend, or for more information, please contact Ms. Ushma Rajdev, Council and Executive Liaison at council@ocpinfo.com. 

COUNCIL MEETINGS IN 2018:

- Monday 11 June, 2018
- Monday 17 and Tuesday 18 September, 2018
- Monday 10 December, 2018



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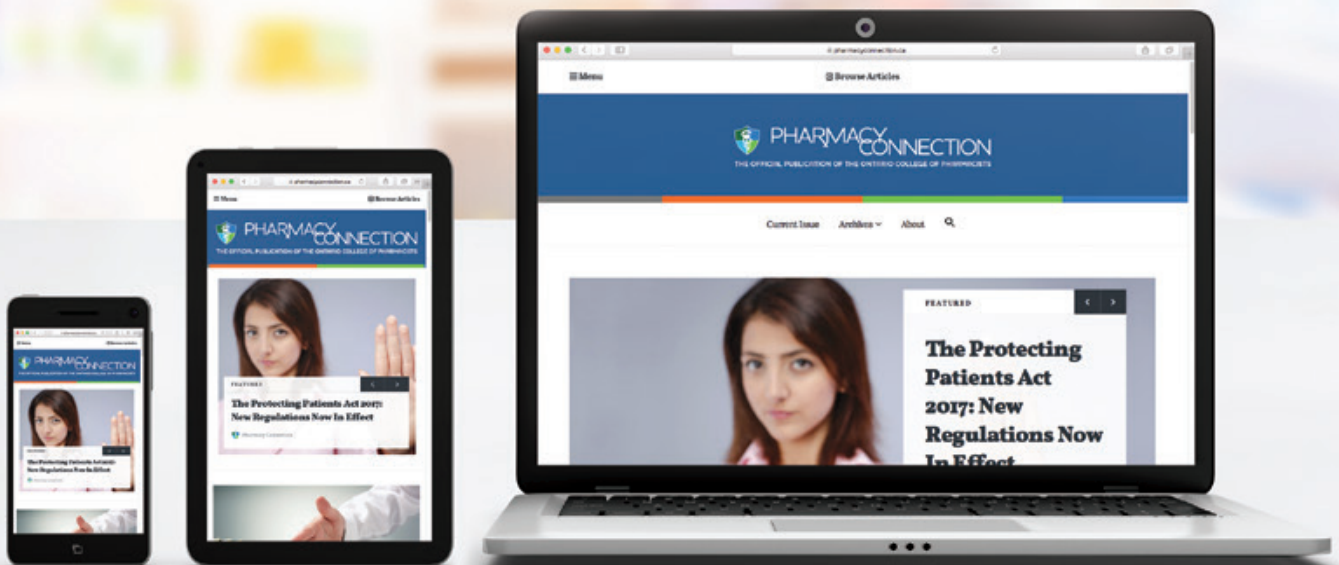


www.youtube.com/ocpinfo

HAVE YOU VISITED THE NEW DIGITAL PHARMACY CONNECTION YET?

In February, the College launched pharmacyconnection.ca, the new digital home of *Pharmacy Connection* magazine. Pharmacyconnection.ca contains all of the same great content as the print magazine.

- ✓ Access it anywhere, anytime and on any device – it's mobile and tablet friendly
- ✓ Easily share articles by email or social media
- ✓ Click to learn more about references and resources mentioned in articles
- ✓ No waiting weeks for your print copy to arrive in the mail
- ✓ Avoid unnecessary environmental waste



Did you know that it takes **2,160,000** pages to print *Pharmacy Connection* four times a year?

Take a moment and check out pharmacyconnection.ca for yourself.
Let us know if you have questions or feedback at communications@ocpinf.com.

Want to help the environment?
You can opt out of receiving a print copy by emailing pconline@ocpinf.com.



This feature in *Pharmacy Connection* is a place to find information about news stories we're following. Here, you'll read summaries of recent stories relating to pharmacy in Ontario and Canada. For the latest updates, stay tuned to [e-Connect](#) and www.ocpinfo.com

EXPANSION OF OHIP+ FOR SENIORS

The government of Ontario has [announced](#) that seniors 65 years of age or older will no longer have to pay a deductible or co-pay for their medications under the Ontario Drug Benefit program. This will be accomplished through the expansion of the OHIP+ program, which already covers free prescription medications for youth aged 24 and under. Ultimately, the program will make over 4,400 medications completely free for everyone 65 and older who is OHIP-insured.

Patients who are wondering whether their medications are covered by the Ontario Drug Benefit program or OHIP+ can use [Ontario's online search tool](#) to look up the medication.

This change will take effect on August 1, 2019.

INCREASING HARMS OF OPIOIDS

[A recent study](#) by researchers at St. Michael's Hospital found that the rate of opioid-related deaths in Ontario has tripled over the past fifteen years, and was

responsible in 2015 for one out of every six deaths of residents between the ages of 25 and 34.

The provincial government has [reported](#) that there were 1,053 opioid related deaths in Ontario from January to October 2017, an increase of 52 percent over 2016. Partially in response, the Ministry of Health and Long-Term Care has recently begun distributing shipments of posters and brochures to pharmacies to help educate patients about prescription opioid use. Pharmacists are asked to hang the posters in visible areas of their pharmacy and provide the brochures to their patients when they pick up their opioid medication.

To assist pharmacy professionals in providing reliable, take-home information for patients or their caregivers who may have questions and concerns about opioids, the College has created a list of resources specifically for patients on page 22. Pharmacy professionals are reminded that the College has released an [Opioid Strategy for Pharmacy](#). Additionally, resources continue to be added to the [Opioid Practice Tool](#).

UPDATED NALOXONE GUIDANCE

On April 25, 2018 the College revised its naloxone guidance to reflect revisions made by the Ministry of Health and Long Term Care to the Ontario Naloxone Program for Pharmacies (ONPP). All injectable and intra-nasal naloxone spray (INNS) kits provided by pharmacies will require (1) a rescue breathing barrier and (2) an [updated insert with instructions](#) (English and French). This new insert must replace any current instructional insert being used.

Please also note that pharmacists, where possible, must ensure that a quarterly report

relating to outcomes for individuals who were provided a naloxone kit, be completed and returned to the Ontario Ministry of Health and Long-Term Care. Please view [question #16 of the Ministry's naloxone kits FAQ for professionals on page six](#) to learn more. Visit the [Ministry's website](#) for more information and to read the Frequently Asked Questions.

As always, pharmacists who are dispensing naloxone should be familiar with the College's updated [guidance on dispensing or selling naloxone](#).

MIFEGYMISO

In 2017, [more than 4,000 prescriptions](#) for Mifegymiso were dispensed to Canadian women.

Pharmacy professionals are reminded that in November 2017, the College revised its [Mifegymiso guidance document](#) to reflect a [November 7, 2017 Health Product Risk Communication](#) from Health Canada which updates the Product Monograph and Risk Mitigation Plan. These updates extend the gestational age requirement, update the dispensing requirements, and remove the requirement for mandatory prescriber education and pharmacist and prescriber registration with the manufacturer.

Additionally, pharmacy professionals are reminded that the *Safe Access to Abortion Services Act* came into effect on February 1, 2018, allowing pharmacies who provide abortion services to establish safe access zones of up to 150 metres around the pharmacy. Details on how to apply can be found on the government's [Safe Access Zones](#) webpage.

UPDATES FROM HEALTH CANADA

REGULATORY AMENDMENTS FOR PRESCRIBING AND DISPENSING METHADONE

As of May 19, 2018, federal regulatory amendments allow practitioners to prescribe, administer, sell or provide methadone without applying for or obtaining an exemption under subsection 56(1) of the Controlled Drugs and Substances Act. This is for both the treatment of opioid use disorders and for analgesia.

Pharmacists will no longer need to verify if a practitioner holds a valid exemption to prescribe methadone.

Pharmacists are reminded that the College has a [Methadone Maintenance Treatment \(MMT\) and Dispensing Policy](#). All other parts of the policy still apply.

MANDATORY WARNING STICKER AND HANDOUT TO ACCOMPANY ALL DISPENSED OPIOIDS


Health Canada has [also announced that they are making warning stickers and patient handouts mandatory](#) with all prescription opioids dispensed. The sticker will be applied to each container that is given to a patient and warn that the medication can cause dependence, addiction and overdose. The handout will inform patients of the signs of opioid overdose, warn them to keep the medication out of reach of children and not to share it, and advise of other serious warnings and potential side effects.

Pharmacy professionals should ensure that patients start receiving the sticker and handout as of October 2018.

NEW GUIDANCE DOCUMENTS REGARDING MANAGEMENT OF POST-CONSUMER RETURNS AND UNSERVICEABLE STOCK

Health Canada has released two new guidance documents meant to clarify the recommended procedures for the collection, handling and destruction of narcotic post-consumer returns and unserviceable stock:

- [Guidance Document for Pharmacists and Dealers Licensed to Destroy Narcotics, Controlled Drugs or Targeted Substances: Handling and Destruction of Post-consumer Returns Containing Narcotics, Controlled Drugs or Targeted Substances](#) and
- [Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances](#).

These guidance documents reflect the [Section 56\(1\) Class Exemption for Pharmacists, Practitioners, Persons in Charge of a Hospital and Licensed Dealers for the Provision and Destruction of Unserviceable Stock and Post-consumer Returns](#). The College's [Destruction of Narcotics, Controlled Drugs and Targeted Substances Factsheet](#) has been updated to reflect these changes. Pharmacy professionals, designated managers and hospital pharmacy managers should review these materials. 

COUNCIL ELECTIONS

Serving and protecting the public interest



Apply your knowledge, skills and experience as a pharmacy professional to help protect the public and contribute to quality and safe pharmacy practice in Ontario as a member of Council of the Ontario College of Pharmacists. This year, elections will be held in Districts H and N.

JOIN COUNCIL IN 2018

There are a total of five Council seats open to pharmacists in districts H and N.

DISTRICT H

Two seats available for a three year term for pharmacists practicing in a hospital in Ontario

DISTRICT N

Three seats available for a three year term for pharmacists in electoral District N

- H** Hospital
- T** Pharmacy Technician
- TH** Hospital Pharmacy Technician



PROTECTING THE INTERESTS, HEALTH AND WELLBEING OF THE PUBLIC

Regulating pharmacy in the public interest is a privilege. The College exists to regulate pharmacy so that the public can be confident in the quality and safety of the pharmacy care and services they receive and trust in the College's

ability to make decisions and act in accordance with its public-protection mandate. Council members do not "represent" those who elected them, and those who elected them are not "constituents". Rather, Council has a fiduciary duty to put their service to the public above all other interests.

COUNCIL COMPOSITION

Members of Council include 15 elected pharmacists (two from hospital), two elected pharmacy technicians (one from hospital), two deans from the faculties of pharmacy at University of Toronto and University of Waterloo and nine to 16 members of the public who are publicly appointed.

Council is the policy-making group and acts as the board of directors for the College. The College's administrative staff are responsible for carrying out these policies and administering the *Regulated Health Professions Act*, the *Pharmacy Act* and the *Drug and Pharmacies Regulation Act* and associated regulations.

Council meetings are held once per quarter and council members may also be appointed to sit on one or more committees. More information about Council can be found on the [College's website](#).

THE ROLE OF A COUNCIL MEMBER

As a Council member, you are expected to observe the highest standards of impartiality, integrity and objectivity. Your major responsibilities include:

- Maintaining a working knowledge of the legislation under which the College operates and making decisions about regulating the profession in the public interest;
- Participating in establishing policy, strategic direction, and goals of the College to successfully meet its mission and purpose;
- Anticipating and responding to changing expectations and emerging trends and addressing emerging risks and opportunities;

- Anticipating and embracing opportunities for regulatory and governance innovation;
- Reviewing all preparation material in advance of Council and committee meetings and contributing and engaging constructively in discussions undertaken at these meetings

NOMINATION PROCESS

To stand for election, you must be nominated by three members of the College who are eligible to vote in the electoral district for which you are nominated.

Your nomination paper must be accompanied by your signature which affirms your commitment to the Objects of the College and that you undertake to comply with the College's policies, the [By-Laws](#), [Code of Ethics](#) and [Code of Conduct](#) and procedures for Council and committee members, all of which can be found on the College website. **Ps**

Learn more about the election process: <http://www.ocpinfo.com/about/council/election-process/>

If you have questions, send an email to Ms. Ushma Rajdev, Council and Executive Liaison at: councilelections@ocpinfo.com

KEY DATES FOR 2018 COUNCIL ELECTIONS



Nominations open
Friday, June 1, 2018

Nominations close
Wednesday, June 20, 2018 at 5:00 pm

Last date for candidates to withdraw
Friday, June 29, 2018

Voting to commence on or by
Monday, July 9, 2018

Voting closes
Wednesday, August 1, 2018 at 5:00 pm

Calling for **VOLUNTEERS** to Serve on College Committees



You can make an invaluable contribution to helping the College regulate pharmacy in the public interest and advance the quality and safety of pharmacy practice in the province as a non-Council committee member!

The College's eight statutory committees play an important role in advancing the College's mandate to serve and protect the public interest. These committees require the appointment of pharmacists and pharmacy technicians who are not elected members of Council and whose competencies, skills and experience are aligned with the College's needs and obligations, to serve on various statutory or standing committees, and from time to time, on various special committees, working groups or task forces (see next page). These competencies reflect the ideas set out in the "Eligibility and Competency-Based Committee Appointment Framework" developed by the Advisory Group for Regulatory Excellence (AGRE) - comprised of the six largest health regulatory colleges - which are rooted in evidence and best practice in regulatory governance in Ontario.

Non-Council committee members (NCCMs) are appointed at the beginning of each Council year (September Council). The Chairs of the Committees are elected on the first day of the Council meeting after which the remaining committee members are appointed.

Each NCCM is responsible for upholding the mandate of the

College and acting in accordance with its values and policies. To further understand the role of an NCCM, please review the College Objects (Appendix 4 of the [Governance Manual](#)), [By-laws](#), [Code of Ethics](#) and [Code of Conduct](#) for Council and Committee members.

THE ROLE OF A NON-COUNCIL COMMITTEE MEMBER

As a NCCM, you are an important part of the College's commitment to advancing the interests, health and wellbeing of the public. As such, you also have a fiduciary duty of undivided loyalty and good faith to the mandate of the College. This duty includes:

- Being **Diligent** – being prepared for meetings, reviewing materials, arriving on time and participating in discussion.
- Being **Civil** – respecting the process and fellow committee members, paying attention (e.g., no mobile devices during the meetings), genuine listening and consideration and not making up your mind before arriving to the meeting.
- Being **Ethical** – using College resources appropriately, being accurate on the facts (e.g.,

reading the materials on a particular matter).

- Being aware of and declaring **Conflicts of Interest** (e.g. financial, adjudicative, organizational).
- Ensuring **Confidentiality** is maintained. This applies to all information obtained in the course of duties for OCP, unless an exception applies. This is especially important when discussing complaints since you will often be dealing with unsubstantiated allegations and maintaining confidentiality will prevent tainting of processes, facilitate exploration of all options and avoid misinterpretation.


COMMITTEE OPPORTUNITIES

The table below provides a brief description of the duties of the Committees, the minimum number of NCCM positions required to be filled and the approximate number of days required for meetings.

Staff will solicit the availability of members well in advance of booking meetings, and will confirm meeting times with participants. For most meetings, material will be made available online and prior to the meeting to allow time for review.

| Committee | Frequency of Meetings and Minimum Number of NCCMs Required |
|---|--|
| Accreditation Committee | |
| The Accreditation Committee considers matters relating to the operation of community pharmacies in Ontario and also reviews issues relating to pharmacy assessments conducted by College practice advisors where the pharmacy has failed to comply with the requirements. | Approximately six times a year 2 NCCMs |
| Drug Preparation Premises Committee | |
| The Drug Preparation Premises Committee considers all matters relating to the operation of drug preparation premises (DPPs) in Ontario. | Two to three times a year (coordinated with Accreditation Committee meetings) 2 NCCMs |
| Discipline Committee | |
| Panels of the Discipline Committee hear allegations of professional or proprietary misconduct. | Approximately twenty-five hearings a year, heard by panels*, plus three meetings of the full committee 5 NCCMs |
| Fitness to Practice Committee | |
| The Fitness to Practice Committee considers incapacity matters referred by the Inquiries, Complaints and Reports Committee. | One to two times a year 1 NCCM |
| Inquiries, Complaints and Reports Committee (ICRC) | |
| The Inquiries, Complaints and Reports Committee (ICRC) oversees all investigations into a practitioner's conduct, competence and capacity (this includes pharmacists, pharmacy technicians, students or interns), as well as all complaint investigations, registrar's investigations and health inquiries. | Three panel* meetings a month, plus two meetings of the full committee 7 NCCMs |
| Patient Relations Committee | |
| The Patient Relations Committee advises Council regarding the patient relations program, which enhances relations between practitioners and patients. It also deals with preventing and handling matters relating to sexual abuse of patients by practitioners. | One to three times per year 1 NCCM |
| Quality Assurance Committee | |
| The Quality Assurance Committee develops and maintains the Quality Assurance program. It supports continued competence and encourages continuing professional development of practitioners. | Panel* meetings four to six times a year, plus two to three meetings a year of the full committee. 3 NCCMs |
| Registration Committee | |
| The Registration Committee provides guidance to Council on matters concerning registration, examinations and in-service training required prior to registration. | Monthly panel* meetings, plus two to three meetings a year of full committee 1 NCCM |

*The Discipline, ICRC, Quality Assurance and Registration Committees all operate using panels comprised by interchanging committee members. Note also that for the Discipline Committee, contested hearings may require multiple-day attendance i.e. between 3-5 days at a time

If you are interested in being considered for appointment to a committee, complete the [application form](#) and send by July 31, 2018, to Ms. Ushma Rajdev, Council and Executive Liaison in the Registrar's office at council@ocpinfo.com. You will be contacted after Council's September meeting has taken place if you have been appointed to serve on a committee. 



The Protecting Patients Act 2017: **NEW REGULATIONS NOW IN EFFECT**

On May 1, 2018, new regulations under the Regulated Health Professions Act came into effect. These amendments are part of the Protecting Patients Act, which was passed on May 30, 2017, and which strengthens the prevention of, and response to, incidents of patient sexual abuse, increases supports for victims of sexual abuse by regulated health professionals and improves regulatory oversight and accountability of health regulatory colleges. Visit the Ministry of Health and Long-Term Care website for more information about the [Protecting Patients Act 2017](#).

DEFINING WHO IS A PATIENT, AND WHEN, IN RELATION TO SEXUAL ABUSE ALLEGATIONS

Criteria that specifies under what conditions or circumstances someone will be considered to be a patient, for the purposes of subsection 1 (6) of the *Health Professions Procedural Code*, have now been established. The regulation states that an individual can be considered a patient where there is a direct interaction between the individual and the health professional and any of the following conditions are met:

- The professional has charged or received payment from the individual (or a third party on behalf of the individual) for a health care service provided by the professional;
- The professional has contributed to a health record or file for the individual;
- The individual has consented to the healthcare service recommended by the professional; and

- The professional prescribed a drug for which a prescription is needed to the individual.

In other words, if any of the above interactions takes place between an individual and a pharmacy professional, then that individual would be considered, in the context of sexual abuse allegations, to be a patient.

Pharmacy professionals must use their professional judgment to determine whether a specific interaction with a patient fits within the prescribed definition. Things to consider may be, but are not limited to, whether the patient took any action as a result of the interaction, whether the patient would identify as a patient of the professional, whether the professional is accountable for action taken to provide care to the patient, whether any payment was processed as result of the interaction, and/or what role the professional plays in the pharmacy.

The regulation also establishes a minimum time period of **one year** after the end of a patient-professional relationship during

which a sexual relationship between professionals and former patients are prohibited. This means that any pharmacy professional who engages in a sexual relationship with a patient before waiting a full year since terminating the patient-professional relationship will be subject to mandatory revocation of his/her certificate of registration.

An exception to this definition applies only if **all** of the following conditions are satisfied:

- There is, at the time the professional provides the healthcare services, an existing sexual relationship between the individual and the professional;
- The individual received a healthcare service from the professional in an emergency situation or in circumstances where the service is minor in nature; and
- The professional has taken reasonable steps to transfer the care of the individual to another professional or there is no reasonable opportunity to transfer care to another member.

SPECIFIED OFFENCES TRIGGERING MANDATORY REVOCATION

Additional changes to regulations that are now in effect have also specified the sexual offences under the *Criminal Code* which will trigger mandatory revocation of a regulated health professional's certificate of registration.

- 151 - Sexual interference
- 152 - Invitation to sexual touching
- 153 - Sexual exploitation
- 153.1 - Sexual exploitation of a person with disability
- 160 (3) - Bestiality in the presence of or by a child
- 162 - Voyeurism
- 162.1 - Publication, etc., of an intimate image without consent
- 163.1 - Child pornography
- 170 - Parent or guardian procuring sexual activity
- 171.1 - Making sexually explicit material available to a child
- 172.1 - Luring a child
- 172.2 - Agreement or arrangement - sexual offence against a child
- 271 - Sexual assault
- 272 - Sexual assault with a weapon, threats to a third party or causing bodily harm, and
- 273 - Aggravated sexual assault.

REQUIREMENTS TO POST ON THE PUBLIC REGISTER

Colleges are now required to report certain information about a regulated health professional on the public register, including:

- If there has been a finding of guilt against a professional under the *Criminal Code* or the *Controlled Drugs and Substances Act* and certain information related to it;
- Any currently existing conditions of release following a charge for an offence under the *Criminal Code* or *Controlled Drugs and Substances Act*;
- If a professional has been charged with an offence under the *Criminal Code* or the *Controlled Drugs and Substances Act* and the charge is outstanding;
- If a member has been the subject of a disciplinary finding by another regulatory or licensing authority in any jurisdiction; and
- If a member is currently licensed or registered to practice another profession in Ontario or a profession in another jurisdiction.

FUNDING FOR THERAPY SERVICES EXPANDED


The proclamation of *Protecting Patients Act* regulations on May 1, 2018 also has made it easier for patients who have been sexually abused by a regulated health professional to be able to access funding for therapy and counselling services. Instead of waiting for a finding by a panel of the Discipline Committee, a patient can now request funding through the College's Patient Relations Program to help pay for therapy or counselling services immediately after the College has been made

aware of a complaint or a report of sexual abuse by a pharmacist or pharmacy technician.

Should a patient wish to access this funding, there is little more required than to complete a simple form now available on our website along with information we need from the patient's therapist or counsellor. The College then pays the therapist directly for services provided to the patient. The communication between patients and the College to help them access these funds is discreet, confidential and respectful of a patient's right to choose whether to participate in the program.

This is an important part of our regulatory responsibility and commitment to protect the public. The College is fully supportive of the move to make access to funding for therapy services easier for victims of sexual abuse. For more information about the Patient Relations Program or about the funding available for patients through this program, [please visit our website](#).

WHAT'S NEXT

These important regulatory changes will further strengthen our collective commitment to zero tolerance for sexual abuse of patients by regulated health professionals and will also result in greater consistency between the *Drug and Pharmacies Regulation Act* and the *Regulated Health Professions Act* with respect to interim suspensions. The College remains committed to working closely with government as additional regulations – including those related to the composition of panels and committees and functions of the Patient Relations Committee – are developed. 



Preparing for **ONTARIO'S MEDICATION SAFETY PROGRAM**

Patient safety and protecting patients from the harm associated with medication incidents is a priority that patients, pharmacy professionals and the College share. Recognizing that we can always do more to protect patients, College Council approved a mandatory medication safety program for all of Ontario's community pharmacies in 2017.



THE MEDICATION SAFETY PROGRAM

There has always been an expectation that pharmacies are engaging in continuous quality improvement, illustrated in the NAPRA Model Standards of Practice (see [Safety and Quality Standards](#)), the College's pharmacy assessment process and policies for pharmacy professionals and designated managers (see DM Policy - [Professional Supervision of Pharmacy Personnel](#)). Moving forward with Ontario's new medication safety program will lead to more standardized, accurate and complete tracking of this information across the province and help provide a better understanding of medication incidents in pharmacies and how they can be prevented. It also clarifies the College's expectations of how pharmacies engage in continuous quality improvement.

While the anonymous recording of incidents to a third party (Pharmapod, the College's chosen vendor) via an online reporting platform may be the biggest change for pharmacy professionals under this program, the other elements of the program are equally as important to ensure that all pharmacy professionals in the pharmacy learn from incidents and review and enhance their policies and procedures to reduce the risk of recurrence. Additionally, the program addresses both incidents that reach the patient and those that are detected before reaching the patient (near misses) in order to maximize the learning opportunities.

PREPARING FOR IMPLEMENTATION

It is the College's expectation that community pharmacies are currently preparing for implementation

INCIDENTS

Any preventable event that may cause or lead to inappropriate medication use or patient harm. Medication incidents may be related to professional practice, drug products, procedures, or systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

NEAR MISSES

An event that could have led to inappropriate medication use or patient harm but did not reach the patient. Near misses provide valuable insight into areas of risk and may indicate where systems can be improved to prevent harm.

of the program by **familiarizing themselves with the program requirements (see next page) and educating staff about the program, including how it will help to improve patient safety and outcomes.**

Recognizing that many aspects of the Document, Analyze and Share Learnings components of the program (as described on the next page) are already occurring in accordance with the Standards of Practice, the College expects pharmacies and pharmacy professionals to focus on putting these elements in place ahead of getting access to the Pharmapod incident recording platform.

PHARMACIES MUST ACHIEVE ALL OF THE FOLLOWING FOUR ELEMENTS AS PART OF THE PROGRAM:



REPORT

Anonymous reporting of medication incidents by pharmacy professionals to Pharmapod, via an online platform, in order to populate an aggregate incident database to identify issues and trends to support patient safety improvements.

.....



DOCUMENT

Pharmacy professionals document appropriate details of medication incidents and near misses in a timely manner to support accurateness. Continuous quality improvement (CQI) plans and outcomes of staff communications and quality improvements implemented are also documented.

.....



ANALYZE

When a medication incident occurs, pharmacy professionals analyze the error in a timely manner for causal factors and commit to taking appropriate steps to minimize the likelihood of recurrence of the incident. Pharmacies must complete a Pharmacy Safety Self-Assessment (PSSA), which will be available as part of the Pharmapod reporting platform to facilitate use, within the first year of the implementation of the program, then at least once every two to three years, but it may be done more frequently depending on any significant changes in the pharmacy. Pharmacy management should also take the opportunity to analyze aggregate pharmacy data regularly to help inform the development of quality improvement initiatives.

.....



SHARE LEARNINGS

There should be prompt communication of appropriate details of a medication incident, including causal factors and actions taken as a result, to all staff. The development and monitoring of CQI plans and outcomes should be supported. Pharmacies should have regular CQI communication with pharmacy staff to educate all pharmacy team members on medication safety, encourage open dialogue on medication incidents, complete a PSSA, and develop and monitor quality improvement plans.

Onboarding to the online Pharmapod platform will commence in late December 2018, using a phased approach through to mid-2019. Pharmacies will be contacted directly by Pharmapod to organize access to the platform.

The participation and cooperation of pharmacies and pharmacy professionals is integral to the success of the program. In the coming months, both the

College and Pharmapod may contact pharmacies regarding necessary training or other activities – it is an expectation of the College that pharmacies will respond promptly to these communications.

The College has posted [Frequently Asked Question on the Medication Safety Program](#) to assist pharmacy professionals in understanding and preparing for the program.

KNOWLEDGE IS POWER

The medication safety program is built upon the principles of a just culture, very similar to what exists in other parts of the health system. A just culture recognizes that mistakes will be made, but that they must be harnessed to improve the system as a whole. It helps promote open recording of incidents, leading to opportunities to learn from them and to share those learnings with others to help prevent similar incidents from occurring across the system. It also encourages pharmacy professionals to come forward and share opportunities for learning without fear of punishment for admitting a mistake. The focus is not on individual blame, but on system opportunities.

While the medication safety program requires the anonymous recording of medication incidents, including near misses, in a third party platform, the program is much more than this; it promotes continuous quality improvement within individual pharmacies and sets stronger expectations related

to prevention and learning. Additionally, the program requires shared accountability between pharmacies, for the systems they design and how they support and respond to staff behaviour, and pharmacy professionals, for the quality of their choices and for recording incidents and identifying possible system vulnerabilities.

It is important to note that any incident and pharmacy level data that is recorded in the platform **will not be accessible** by the College and will not be used in any complaint, discipline or other College process. All data that the College receives will be in an aggregate, non-identifiable format and will be used to identify general areas of risk and provide appropriate guidance for all pharmacy professionals.

The fundamental purpose of the program is to help protect patients and improve the care that they receive – a goal that the College, pharmacies and pharmacy professionals all share. 📌



AN UPDATE ON THE AMBASSADOR SITES

Late last year, the College identified 100 community pharmacy ambassador sites to be the first to participate in the medication safety program, providing beneficial feedback to inform the development of the program before it is fully rolled out across the province. These sites have been working with Pharmapod to train staff and onboard them to the reporting platform. As of

the beginning of May, more than 127 individuals are using the system and have logged over 160 incidents and near misses.

Throughout the summer, the ambassador sites will participate in a formal evaluation, providing the College with qualitative feedback and data to support province-wide roll-out and change management.

STAY INFORMED ON **RECALLS,** **SHORTAGES** AND **ADVERSE** **REACTIONS**



Pharmacy professionals have an obligation to stay informed on issues that may affect patient safety. These issues could include recalls, shortages, adverse reactions or other safety notices.

In many cases, patients may have questions regarding their drug therapy that may have arisen as a result of a media story, a conversation with another healthcare professional or their own research.

Consider the following:


- A patient heard a media story about a recall of their medication due to an error in a manufacturing process. They want to know whether they are affected and what they should do with their medication.
- A patient has been advised by another healthcare professional that the drug they are taking has been found to have potentially serious side effects that were not previously identified in the information provided with their drug. They want to know if the pharmacist is aware of this side effect and their advice on what to do.
- A patient has been taking a medication for years. They have heard that there is currently a shortage and are worried about their future supply. They want to know whether they will still have access to their medication when they need it.

All of these are situations that pharmacy professionals should be prepared to discuss with the patient and/or their caregiver. Even if the pharmacy professional is unaware of the specific issue when the patient asks, they should know where to find the information

needed. Additionally, there may be times when pharmacy professionals need to be proactive in their communications to patients.

Pharmacy professionals can stay informed through:

- Notices from drug manufacturers and suppliers
- Internal communications (e.g. company intranet, memos)
- [Notices from Health Canada](#) such as
 - [MedEffect e-Notice](#)
 - [Health Product InfoWatch](#)
 - [Canada Vigilance Adverse Reaction Online Database](#)
- [Drug Shortages Canada](#)

Ultimately, under the College's [Designated Manager – Medication Procurement and Inventory Management Policy](#), the Designated Manager of the pharmacy must ensure that there is a method for identifying products that are outdated, deteriorated, recalled, obsolete, or hazardous. Additionally, the Designated Manager will support safe medication practices within the pharmacy through the development of policies and procedures to ensure that clinically relevant information that impacts patient care is immediately available to appropriate staff members, including drug recalls, advisories, and warnings (see the [Designated Manager – Professional Supervision of Pharmacy Personnel](#) policy). 

OPIOID RESOURCES FOR PATIENTS

Pharmacy professionals have an obligation to ensure patients are informed of the potential risks and benefits of their therapy. This is particularly important when it comes to opioid use, especially considering the ongoing opioid crisis and the potential for misuse, addiction and overdose.

While patient counselling is obviously an integral component of education for patients and/or their caregivers, they may be overwhelmed, in pain or otherwise distracted during the conversation with the pharmacist, or a previous conversation with their prescriber, to recall all that was discussed. It may be helpful for pharmacy professionals to make patients aware of the resources that are available to them.

Many of these resources can and should also be posted in the pharmacy to enable maximum awareness.

MINISTRY OF HEALTH AND LONG-TERM CARE POSTER AND BROCHURE - PRESCRIPTION PAIN MEDICATION: KNOW THE POTENTIAL RISKS OF OPIOID USE

These have been developed by the Ministry to help educate patients about prescription opioid use. They cover information on what an opioid is, what they are used for, signs of opioid addiction and opioid overdose and brief

information on naloxone. The Ministry has requested that the poster and/or the brochures are available in pharmacies. [Learn more and order copies.](#)

HEALTH QUALITY ONTARIO: PATIENT REFERENCE GUIDES ON OPIOID STANDARDS



Health Quality Ontario has created quality standards that outline for clinicians and patients what quality care looks like for opioid prescribing for acute pain, opioid prescribing for chronic pain and opioid use disorder. To accompany these standards, they have created patient guides so that patients, families and caregivers know what to discuss about their care with healthcare professionals. Access the [Patient Guide on Opioid Prescribing for Acute Pain](#), the [Patient Guide on Opioid Prescribing for Chronic Pain](#), and the [Patient Guide on Opioid Use Disorder](#).



HEALTH CANADA: AWARENESS RESOURCES FOR OPIOIDS

Health Canada makes a variety of resources – videos, posters, wallet cards – available on their website. These include resources on Opioids 101 as well as preventing overdose and addiction. It also includes handy resources on what to do when you suspect someone has overdosed on opioids. [View and download the resources from Health Canada.](#)



INSTITUTE FOR SAFE MEDICATION PRACTICES (ISMP): RESOURCES FOR PATIENTS

ISMP makes available three easy to understand handouts for patients. One focuses on the general risks and side effects of opioids and clearly lays out the potential signs of an overdose. An additional handout focuses on preventing medication accidents with opioids, with three clear steps to follow. Recently, ISMP and other groups produced a handout on Opioids for Pain After Surgery that highlights five questions that patients may have when taking an opioids following surgery. View the resources at OpioidStewardship.ca.



Opioids:
When you need them - and when you don't.

Choosing Wisely Canada

If you just had surgery or are experiencing a health problem, pain is a natural and expected part of the process. Pain medicines may help you function better and cope with the amount of pain you are experiencing, but will not eliminate it entirely.

Opioids are common pain medicines. They can help if you have bad short-term pain — like pain after surgery for a broken bone. They can also help you manage pain if you have an illness like cancer.

But opioids are strong drugs. And usually they are not the best way to treat long-term pain, such as arthritis, low back pain, or frequent headaches. This kind of pain is called “chronic” pain. Before getting opioids for these problems, you should discuss other options with your health care provider. Here’s why:

Opioids are prescribed too often.

Chronic pain is one of the most common reasons people see their health care provider. However, for most types of chronic pain, opioids should only be used as a last resort.

Common opioids include:

- Hydromorphone (Dilaudid®)
- Morphine (Kadian®, M-Eslon®, MS-Contin®, Staxel®)
- Codeine (Tylenol No. 3®)
- Oxycodone (OxyNes®, Percocet®)
- Tramadol (Rialvis®, Tridural®, Zyltram®)

Short-term use of these medicines may help. But there is no proof that they work well over time.



Opioids have serious side effects and risks.


Over time, the body gets used to opioids and they stop working as well. To get the same relief, you need to take more and more. This is called “tolerance.” Higher doses can cause serious side effects:

- Nausea
- Vomiting
- Itching
- Constipation
- Not being able to urinate (empty your bladder)
- Slowed breathing, which can be deadly
- Confusion and mental disturbance

Opioids can be addictive. Long-term use of opioids can lead to “physical dependence” — if you stop using them abruptly, you will experience withdrawal symptoms, such as strong cravings, sweating, muscle aches and insomnia. People who take opioids long-term can become addicted, sometimes with dangerous results. In 2017, 4000 Canadians died from an opioid overdose.



CHOOSING WISELY: OPIOIDS: WHEN YOU NEED THEM – AND WHEN YOU DON’T

Choosing Wisely Canada, a national campaign to help clinicians and patients engage in conversations about unnecessary tests and treatments, has created a fact sheet for patients on opioid use, including potential serious side effects and risks. The handout explores whether opioids might be appropriate for three common situations and provides a list of other pain treatments that patients may want to try in place of opioids. Access the handout at the [Choosing Wisely Canada website](http://ChoosingWiselyCanada.com). 



RESOURCES FOR PHARMACY PROFESSIONALS

Looking for opioid-related resources to improve your own knowledge and practice? Be sure to check the College’s [Opioid Practice Tool](#) as we add new resources regularly. Additionally, the College maintains a list of [continuing education opportunities](#) for pharmacy professionals, including a category specifically related to opioids.



Health Canada Introduces New Rules for **Pharmacies that Compound APIs for Veterinary Use**

Do you provide pharmacy services for veterinarians or pet owners? If so, please note the following important information regarding federal regulation changes that may apply to you or your practice.

Regulatory changes to federal [Food and Drug Regulations](#), meant to ensure the responsible use of antimicrobials in animals, may affect you if:

- You import active pharmaceutical ingredients (APIs) that are set out on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#); and/or
- You are a pharmacy professional who compounds antimicrobial drugs using APIs on List A for animal use.

The increased oversight on APIs for veterinary use require:

- Manufacturing according to good manufacturing practices (GMPs)
- Persons who fabricate, import, package, label and test active pharmaceutical ingredients (APIs) for veterinary use to hold a drug establishment license (DEL)
- Pharmacists, veterinarians or those compounding a drug under the supervision of a licensed veterinarian to hold a drug establishment license (DEL) when importing medically important antimicrobials that are on List A.

Therefore, as of May 17, 2018, you may need to:

- Be inspected by Health Canada.
- Comply with GMP and/or
- Obtain a DEL (see below regarding transition period)

Health Canada has established a 14 month transition period to obtain a DEL. If you were already performing activities with respect to API for veterinary use before May 17, 2018, then you must submit a complete DEL application by July 17, 2019. If you were not already undertaking these activities before May 17, 2018, then you cannot conduct licensable activities until you obtain an appropriate DEL. There is no transition period for meeting GMP requirements – they must be met by May 17, 2018.

If you are a manufacturer, importer, or compounder of antimicrobial drugs for veterinary use that contain an active pharmaceutical ingredient on List A, you will need to report annual sales data to Health Canada. This means you will need to collect data throughout 2018 and report by March 31, 2019.

Please [visit the College website](#) to access resources provided by Health Canada regarding these changes. 



AN UPDATE ON CANNABIS

The Ontario College of Pharmacists recognizes that the issue of use of cannabis for medical purposes and its distribution is of growing interest to Ontarians including patients and pharmacy professionals. At its June 2017 meeting, the Council of the Ontario College of Pharmacists endorsed the [position](#) of the National Association of Pharmacy Regulatory Authorities (NAPRA) regarding cannabis for medical and non-medical purposes and the role of pharmacy practitioners. The College's support of that position remains unchanged.


At its September 2017 meeting, Council agreed to establish a task force to develop a cannabis strategy for pharmacy in Ontario that is grounded in our public-protection mandate. Through robust discussions amongst a wide variety of stakeholders

involved, the task force is drafting a multi-pronged strategy that will be expected to simultaneously address relevant areas of practice and prepare the College and pharmacy professionals to address evolving cannabis-related issues, while considering how to best serve patients and Ontarians who may be using cannabis for recreational or medical use.

The Strategy, which remains under development, will be presented to Council on June 11, 2018. Along with the Strategy, the College also intends to present to Council a formal position statement on the distribution of cannabis within pharmacy.

As shared in the last Council Report from the March 2018 meeting, Council discussed and unanimously supported the


recommendation that the College require all Part A pharmacists to complete cannabis education in preparation for anticipated practice changes associated with increased use of and demand for recreational cannabis and cannabis used by patients for medical purposes. College staff will work towards establishing a process for implementation of the requirement and collaborate with continuing education providers to assure appropriate courses are accessible to pharmacists to meet this mandatory education requirement.

More information on the requirement, including implementation timeline, will be communicated as details are confirmed over the coming months. No implementation date for this requirement has been set. 

REMINDER: NEW HEALTH CANADA GUIDANCE ON REPORTING NARCOTIC LOSSES



Health Canada has released a new [Guidance Document – Report of Loss or Theft of Controlled Substances and Precursors](#). This document provides guidance on the scope of what should be reported to Health Canada when a loss or theft is detected.

Any theft, loss or forgery related to controlled substances and precursor chemicals must be reported to police immediately, and to the Office of Controlled Substances no later than 10 days after its discovery. 



New Model Standards **APPLY TO ALL PHARMACIES** Performing **NON-STERILE COMPOUNDING**

The National Association of Pharmacy Regulatory Authorities (NAPRA) has released new standards on non-sterile compounding. College Council adopted the [Model Standards for Pharmacy Compounding of Non-Sterile Preparations](#) at their meeting in December 2017. The Model standards are accompanied by a [Guidance Document for Pharmacy Compounding of Non-Sterile Preparations](#).

WHY ARE THESE STANDARDS IMPORTANT?

These standards are an important way of protecting patients and increasing patient safety.

The aim of the standards is to provide pharmacists and pharmacy technicians who compound non-sterile preparations with the standards necessary to evaluate their practice, develop service-related procedures and implement appropriate quality controls for both patients and compounding personnel.

Model standards represent the minimum requirements that must be met regardless of practice site and against which performance can be measured. The College gave pharmacy professionals the opportunity to weigh in on the draft standards

through a consultation in late 2016. NAPRA also incorporated input from pharmacy regulatory bodies and experts across the country. It is the intention of the College that, whenever possible, national standards will be adopted.

WHO DO THESE STANDARDS APPLY TO?

The standards apply to **ALL pharmacies that perform any type of non-sterile compounding in any quantity** (whether once in a while or every day). Not sure if you are compounding? Read the recent *Pharmacy Connection* article [Compounding: Are You Doing It?](#)

WHAT DO THESE STANDARDS REPLACE?

These standards effectively replace the College's 2006 *Guideline for Compounding Preparations* and NAPRA's *Guidelines for Pharmacy Compounding (2006)*.

WHAT IS THE DEADLINE FOR THE IMPLEMENTATION OF THE STANDARDS?

The College is currently working towards establishing an appropriate implementation deadline. However, **pharmacies are expected to begin implementation of the standards now.**

HOW CAN YOU BEGIN IMPLEMENTATION?

Pharmacy professionals should be proactive:

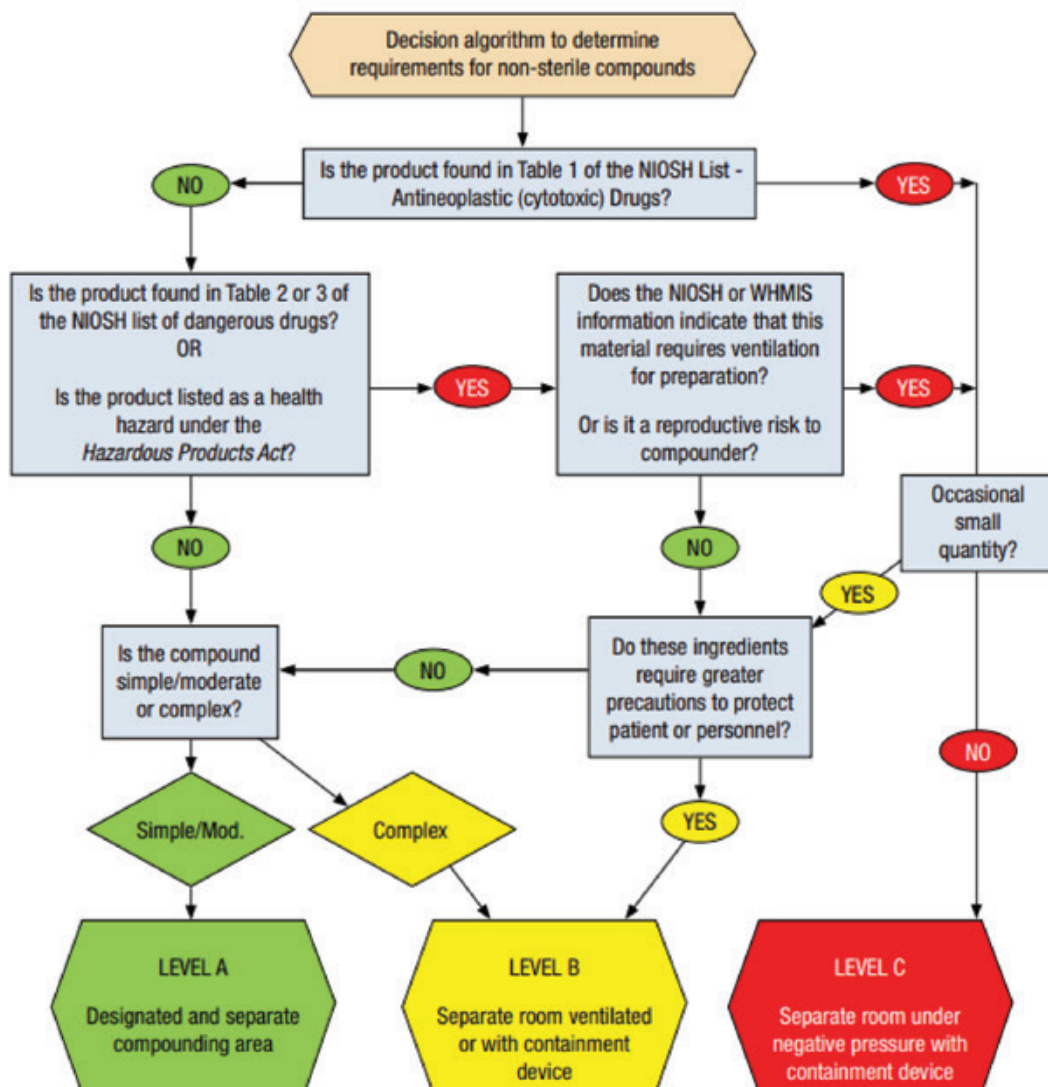
- Review and become familiar with the standards and guidance.
- Undertake a risk assessment to identify the appropriate level of requirements to minimize contamination of each compounding product and to provide adequate protection for personnel. Use *Diagram 1: Decision algorithm for risk assessment* found in the guidance document (and below).
- Conduct an assessment to identify gaps between the standards required in the pharmacy and your current practice, processes and compounding environment.

The guidance document can then provide more details on how the standards can be achieved.

- Start work to close those gaps. For example, pharmacies can begin by reviewing current policies and procedures, master formulations and Safety Data Sheets. Pharmacies and pharmacy professionals can start looking for resources (e.g. education) that are relevant to any gaps in their knowledge or processes.

It is the expectation of the College that this work should begin now; there is no need to wait until the implementation deadline is announced. **Pe**

Diagram 1: Decision algorithm for risk assessment from the [Model Standards for Pharmacy Compounding of Non-Sterile Preparations Guidance Document](#).





IDENTIFYING COUNTERFEIT OR TAMPERED FENTANYL PATCHES

The College asked **Detective Constable Chris Auger of the OPP Drug Enforcement Unit – Prescription Drug Diversion** to provide some tips on what pharmacists can quickly look for when determining whether a returned fentanyl patch has been altered or counterfeited.

On October 1, 2016, the [Safeguarding Our Communities Act \(Fentanyl Patch for Patch Return Policy\)](#) came into effect. Shortly after the enactment of the Patch for Patch program, pharmacies and policing communities started seeing counterfeit patches being returned. The reasons for this diversion might have been legitimately lost patches and attempting to replace them, deliberate misuse or trafficking. The types of counterfeit returns are diverse. Some of the original counterfeit

returns were easy to spot, a clear material, such as packing tape, placed on the patch return sheet to mimic a returned patch.

As the program has been established, pharmacists and law enforcement officers have gotten better at recognizing the counterfeits. However, there is still a need to assist one another in regards to these investigations. The regulation section that directly involves law enforcement is found in [section 4\(3\) of the regulation](#).

The section is as follows:

3. *The dispenser may contact a law enforcement agency in Canada if he or she has reasonable grounds to believe that the missing patches or the suspected counterfeiting, misuse or tampering relate to a contravention of the laws of Ontario or Canada and may disclose to the agency,*

i. the name of the patient and, if applicable, the name of any authorized representative who attended the pharmacy on behalf of the patient,

ii. the fact that some used fentanyl patches are missing or the dispenser's belief that the fentanyl patches returned to the pharmacy are counterfeit, have been misused or have been tampered with, as the case may be, and

iii. any other information that the dispenser reasonably believes will aid in an ongoing investigation by the agency or that will enable the agency to determine whether to conduct an investigation for the purpose of a law enforcement proceeding or from which a law enforcement proceeding is likely to result.

(2) A dispenser who notifies a prescriber in accordance with subsection (1) shall document the notification in the dispenser's record of the patient.

The police will investigate under fraud or uttering a forged document, based under sections 380 and 368(1) the *Criminal Code of Canada* and, after securing the suspected counterfeit patches, may use judicial authorizations (i.e. production order or search warrant) in order to secure additional supporting documentation (prescription history, medical records etc.)

IDENTIFYING COUNTERFEIT PATCHES

When officers perform searches they might come across patches that appear to be valid and used – the main characteristic is that you can see what is likely hair or skin detail.

Counterfeit fentanyl patches often do not possess any hair or skin detail along the edges that a worn or used patch would possess. They appear to be clean and fresh. They are often created using a metal template to accurately size them to the specifications of the various patch sizes. The ink is placed on by way of a printer. A common mistake is that the patches have an incorrect marking.

A good rule to remember is the Locards exchange principle of forensic science which states that a perpetrator will always bring something into a crime scene and leave with something from it. In the case of counterfeit patches, they should have some detail that they were present on a person's skin. And although the person exchanging patches may say that they washed the patches, there would still be presence of some detail of usage on the adhesive.

The colour and abbreviation used for labelling on the returned patches can be observed for

Under Ontario's Patch for Patch program, patients who receive a prescription for fentanyl must return their used patches to a pharmacy before receiving new ones. The legislation places certain obligations upon pharmacists to ensure that only patients with legitimate prescriptions are receiving fentanyl patches and that these patients are receiving the intended benefit of the therapy. Pharmacists are expected to examine returned patches for signs of counterfeiting, tampering or diversion. The College's [Patch for Patch Fentanyl Return Program Fact Sheet](#) provides additional details.

inconsistencies. As well a printer error might indicate counterfeiting, such as where a laser printer coloured the bottom left hand corner of the patch with two small lines. The colour and placement of the abbreviation should match that of the original product.

Another common form of diversion with fentanyl patches is the cutting of edges so that a portion of the patch can be misused but a majority is placed back on the return sheet. Take time to know the measurements of the patches made by each company. Fentanyl patches are made to be very durable and do not reduce in size even when exposed to body temperature.

The police in your community want to help prevent the diversion of prescription narcotics and want to see prescription medication only used therapeutically for any of your patients. We understand that by working together we can give the support needed to assist with any diversion related incidents and reduce the amounts of diverted prescription narcotics in our communities.

Any questions about a possible diverted patch or diverted medication or fraud please contact me at chris.auger@opp.ca or (519)494-1043. 📧

Key Questions ON STERILE COMPOUNDING

The **January 1, 2019 deadline** for the implementation of the [Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations](#) and the [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations](#) is quickly approaching. The College has prepared a [Sterile Compounding Key Initiative](#) page to provide guidance to pharmacies and pharmacy professionals as they work to implement the standards. Here are a few of the common questions that the College has received so far.

WHAT DO I NEED TO DO BY JANUARY 1, 2019? WHAT IF I CAN'T MEET ALL OF THE STANDARDS BY THAT DATE?

As communicated, the College expects full compliance on all elements of the standards by January 1, 2019. If a pharmacy needs additional time to meet compliance, then the expectation is that:

A. All critical elements of the standards, as specified in the [assessment document](#) are fully met by January 1, 2019:

B. Pharmacies that require additional time to achieve full compliance on all elements of the standards, including facility or equipment upgrades, will have an **action plan towards full compliance – including timelines and risk mitigation strategies satisfactory to the College – in place and submitted to us within 30 days of their 2018 assessment. College Practice Advisors will work collaboratively with pharmacies to review and**

finalize action plans and remain available to assist towards compliance with the standards.


Please refer to [information on Sterile Compounding Standards and Implementation](#) on the OCP website, under Key Initiatives.

IF I NEED TO DO AN ACTION PLAN, WHAT SHOULD IT INCLUDE?

If a pharmacy has an action plan after their assessment, it is the expectation of the College that they will submit a detailed explanation of the corrective actions that have been put in place or a risk mitigation strategy that has been implemented until the long term corrective changes are addressed. The action plan must address the issues identified in enough detail that it clearly outlines the steps taken to mitigate risk, optimize outcomes and sufficiently rectify the issue. If there is not sufficient detail provided, the Practice Advisor will communicate back to the pharmacy to request further information. It is the responsibility

of the pharmacy to continue to review their active action items and status on an ongoing basis until the issues are appropriately addressed. While the action plan is required 30 days from the date of the assessment, an ongoing collaborative dialogue may occur as the Practice Advisor assists the organization towards full compliance.

WHAT TRAINING AND CERTIFICATION PROGRAMS ARE RECOMMENDED IN ORDER TO MEET THE STANDARDS?

The College does not recommend or endorse any particular training or certification programs. The pharmacy manager and/or compounding supervisor is responsible for ensuring that any training or certification programs meet the needs of the specific practice of the pharmacy/pharmacy professionals. Pharmacies are encouraged to collaborate with other hospitals or pharmacies in their LHIN to share best practices and operational advice. 



2017 ANNUAL REPORT PUTTING PATIENTS FIRST

The College recently published its 2017 Annual Report. The report, with the theme of **Putting Patients First**, features highlights and trends from the calendar year, including:

- Messages from the Registrar and President;
- Achievements under the College's three strategic priorities;
- Plans for 2018;
- Data and trends on pharmacists, pharmacy technicians and pharmacies;
- Audited financial statements; and
- Special features on medication safety, partnerships, data, the opioid crisis, compounding, the *Protecting Patients Act* and integrating the patient voice in our work.



SEE THE (MOBILE AND TABLET FRIENDLY!) HIGHLIGHTS AT
ocpannualreport2017.ca

For the full version, including financials, download the [2017 Annual Report \(pdf\)](#) on the College's website.

THE IMPORTANCE OF PATIENT ASSESSMENT

In this four part series, the College will focus on the four domains of the pharmacist practice assessment, highlighting trends that we are seeing in practice. Part 1 focuses on the patient assessment domain.

PATIENT ASSESSMENTS ARE CRITICAL FOR PATIENT HEALTH

For every prescription that is dispensed, pharmacists must ask whether the prescription is therapeutically appropriate. This includes gathering relevant information through dialogue with the patient, and creating, adjusting or reviewing the patient profile. Note that patient profiles need to be maintained; a patient's health is not static and their profile should be reviewed on a regular basis.

Relevant information can include, but is not limited to:

- Allergies.
- Medical conditions.
- Lifestyle factors (e.g. smoking, nicotine use, cannabis use, caffeine, diet, alcohol, exercise).
- Other prescription medications, over the counter medication and natural health products.
- Changes to patient's health status, and
- Indication for medication.

Utilizing this information allows for the pharmacist to ensure the appropriateness of the prescription for the patient and identify any drug therapy problems or issues that have the potential to affect

the optimization of health outcomes, while also considering patient specific needs.

Every prescription – new and refill – regardless of how they are packaged – must have both the therapeutic check (for appropriateness) and technical check (for accuracy) completed prior to release to the patient.

REFILL PRESCRIPTIONS

In the course of conducting pharmacist practice assessments, College practice advisors have identified that many pharmacists are not conducting appropriate therapeutic checks on refill prescriptions. In many cases, the pharmacist's perception was that because a patient had a medication before or they haven't asked to speak with the pharmacist, that there are no problems with the therapy. However, it is ultimately the pharmacist's responsibility to determine appropriateness before dispensing, without relying on assumptions. A complete therapeutic check process for refill prescriptions is also an opportunity to address medication management and monitoring (see the example patient scenario below).

Some of the activities that a pharmacist may undertake to determine ongoing appropriateness of a medication and/or identify any drug therapy problems or issues that may affect the optimization of health outcomes could include:



- Reviewing the patient profile to identify any issues of adherence or overuse,
- Reviewing the patient profile to identify any drug interactions between the medication being filled and other medications on file,
- Reviewing the patient profile to identify other issues related to the medication being filled (e.g. duplication, contraindications, newer therapy on file, no longer indicated),
- Considering the indication for the refill and the ongoing need,
- Speaking with the patient to determine if any changes have occurred that may not be captured in the patient profile review, and
- Speaking with the patient to gather further information regarding issues identified/flagged through patient profile review.

The best practice for refill prescriptions is to have a process in place to communicate with every refill patient to determine if there are any changes or issues (e.g. effectiveness, adverse effects, new medical conditions/allergies, new medications, medications

from other sources). Having a pharmacy staff member ask the patient if they have any questions as a courtesy might be considered good customer service, however it is not a substitute for a patient assessment. Pharmacy staff could, however, assist the pharmacist by asking appropriate questions, such as whether there have been any changes to the patient's health, and alerting the pharmacist as appropriate.

Additionally, if the dispenser is changing a brand upon a refill (i.e. switching from the original brand to a generic, or from one generic brand to another), it is good practice to address the change with the patient prior to dispensing. This can help prevent any confusion for the patient on why the name of their medication has been changed or appears different (colour, shape, different markings).

AN EXAMPLE PATIENT SCENARIO

The patient is a 59 year old male who has filled his prescriptions at the pharmacy for about 1 year. His patient profile shows that he has Type 2 Diabetes, dyslipidemia, osteoarthritis and is a smoker. He fills his medications mostly on time, doesn't say much when picking up his medications and you haven't noticed any changes on his prescriptions profile. He is currently on:

- Atorvastatin 10mg once daily
- Metformin 1000mg twice daily
- Gliclazide MR 30mg daily
- Venlafaxine 150mg once daily

The prescriptions were written six months ago, with a one year supply. There is nothing on file that indicates whether he is on any over the counter medications or natural health products. It is not likely that he will have any kind of follow-up until his refills run out.

AN OPPORTUNITY FOR EVALUATION AND INTERVENTION

Use the [Chat, Check, Chart method](#) to identify potential drug therapy problems and evaluate the appropriateness of therapy for this patient:

- **I: Is the therapy indicated?** Understand the indication and if it is still valid (for example, has anything changed with his health status? Was the medication meant for short term use?)
- **E: Is the therapy effective?** Understand if the goals of the therapy are being met (for example, are the medications supporting changes in blood sugar?)
- **S: Is the therapy safe?** Understand if there are changes in medications or conditions, if monitoring is needed (e.g. blood work), if there are potentially other untreated conditions or if additional therapies could be instituted.
- **U: Is the patient willing to use/adhere to the therapy?** Understand the patient's compliance with the drug regimen and schedule.

The most effective way of ensuring you have all of the information is to have a quick check in with the patient. It doesn't need to be long – just a basic check on how the medication has been working for them and any changes in their health status or medication use. Try some of the following conversation prompts:

- Can we take a minute to update your patient information since your last visit?
- What has changed regarding your medical conditions since you were last here?
- Are there any new allergies or medical conditions that we should be aware of?
- Are there any new prescription medications you are taking that I should add to your record?
- Are you taking any new non-prescription medications including herbals or vitamins that I should have on your profile?
- What are you taking this medication for?

- How is the medication working for you?
- Are you experiencing any side effects?
- How do you take your medication?

As a result of this evaluation and intervention, you could potentially identify the following for the patient:

- Issues with blood sugar that are not being managed by the current medication. A recommendation could be made to the prescriber to alter dosage or engage in more proactive monitoring. You could also consider adapting the dose.
- An opportunity to discuss smoking cessation. A conversation could be initiated with the patient to explore options for reducing or eliminating his use of tobacco or a note could be made in the file to follow-up with the patient.
- Side effects from one of the medications that could be managed at the pharmacy or could be brought to the attention of the prescriber.
- Or, no immediate issues with the patient are identified, but you are confident that his therapy is therapeutically appropriate.

Ultimately, every time the patient visits the pharmacy it is an opportunity for a check in, counselling and assessment to ensure that their health outcomes are being optimized and that there are no drug therapy problems that could potentially put their health and well-being in jeopardy. As with any other decision made while providing patient care, a notation of the assessment and any action taken or recommendations made as a result should be made on the patient's profile. **PC**

RESOURCES RELATED TO PATIENT ASSESSMENTS

- [Chat, Check, Chart](#) – The Alberta College of Pharmacists' resources focused on getting patient information, evaluating the appropriateness of therapy and documentation.
- [Optimizing Patient Care Modules](#) – Produced by the University of Toronto, these videos help pharmacists practice to their full scope.
- [Pharmacist Practice Assessment Criteria](#) – Patient Assessment Practice Tool.

New Video Resources

TO INFORM AND ENGAGE THE PUBLIC

The College has developed a number of new videos to help the public better understand important key initiatives from OCP and how we serve and protect their interests.

UNDERSTANDING THE DISCIPLINE PROCESS

The College has procedures in place to address misconduct or incompetence by a pharmacy, pharmacist, or pharmacy technician in Ontario. Many patients and pharmacy professionals alike are unaware of how OCP's Discipline process works. In this video, we clarify the process with a helpful and informative video that focuses on the role of the Discipline Committee.



FIND A PHARMACY OR PHARMACY PROFESSIONAL

The College has been doing a lot of work over the past few years on enhancing its public register, referred to on our website as the "Find a Pharmacy or Pharmacy Professional" tool.

Our enhanced public register gives patients the ability to quickly access important information about a pharmacy, pharmacist, or pharmacy technician anywhere in Ontario. With the tool, patients can find a pharmacy professional who speaks a particular language, view their academic and training history, and any

concerns the College has about them. Patients can also view a pharmacy's assessment results, any concerns the College has about the pharmacy, and more.

5 THINGS YOU SHOULD EXPECT WHEN YOU VISIT YOUR PHARMACY

As Ontario's pharmacy regulator, it's our mission to ensure the public receives quality services and care. In this video we go through five things patients should expect when they visit their pharmacy, all which will help them get the most benefit from their pharmacy experience and support their health goals.



WHAT WOULD YOU DO?



A PATIENT'S REQUEST FOR RENEWAL

In the Spring 2017 edition of *Pharmacy Connection*, the College published [A Framework for Ethical Decision Making](#). The framework provided a process to guide decision making in practice that supports the commitment to serve and protect patients' best interests. This "What Would You Do" explores a specific scenario in practice that presents an ethical issue or dilemma for the pharmacy professional. It does not provide a definitive answer to the dilemma but instead invites pharmacy professionals to make their own professional judgments in practice, while considering all appropriate guidelines and standards.



A patient comes to your pharmacy on a Friday night.

He is not a regular patient of your pharmacy but has his prescription vial and a list of his medications, which he filled at another pharmacy. The prescription vial indicates that he does not have any additional refills from his physician. Both the pharmacy that filled the original prescription and the physician's office are now closed until Monday. You know this physician has a policy of not renewing prescriptions without an appointment. You work with this physician a lot and don't want to undermine her policy or put a strain on your collaborative relationship. However, the patient could potentially experience side effects if they don't have their medication (which is not a controlled substance).

What do you do?

It's helpful to utilize the broad steps of the ethical decision making framework to consider the issue.

IDENTIFY THE ISSUE

You can start by identifying the issues and examining the facts. The issue here is that the pharmacist believes that the physician who originally wrote the prescription would not want it to be renewed without an appointment with the patient. The pharmacist also believes that disregarding the physician's intention could lead to interprofessional conflict with the physician.

However, the patient has expressed that he needs this medication and the pharmacist knows that it could cause uncomfortable side effects to be without for a few days. The medication is not a controlled substance and is unlikely to be used in an illicit manner. The prescription vial appears to be valid.

APPLY GUIDELINES AND STANDARDS

The Code of Ethics, the Standards of Practice, applicable legislation and regulations, College policies, guidelines and other supporting resources can be reviewed and applied when exploring an

ethical dilemma. Examples that could be considered with this scenario include:

- [Code of Ethics](#)
 - **Standard 1.1** Members ensure that their primary focus at all times is the well-being and best interests of the patient.
 - **Standard 1.2** Members utilize their knowledge, skills and judgment to actively make decisions that provide patient-centred care and optimize health outcomes for patients.
 - **Standard 2.5** Members challenge the judgment of their colleagues or other healthcare professionals if they have good reason to believe that their decisions or actions could adversely affect patient care.
 - **Standard 4.8** Members understand that their trust in the care provided by colleagues and other healthcare professionals must be balanced with critical evaluation.
- [Standards of Practice](#) – Expertise in Medications and Medication Use Standards 11 and 12, Collaboration Standard 1
- [Guideline – Initiating, Adapting and Renewing Prescriptions](#)
- [Resources – Optimizing Patient Care Modules](#)
 - A Difference of Opinion – Managing Issues Due to Expanded Scope
 - What Will the Doctor Think? Managing Relationships with Physicians

EVALUATE POSSIBLE RESOLUTIONS

As a pharmacist, you must use your professional judgment to make decisions. It's important to note that each situation and patient is unique. Evaluate the various factors to make the best decision for this

particular scenario. Here are some things to consider when doing so:

- What are your ethical obligations as a healthcare professional?
- How could the patient benefit or be harmed through your decision? What is in the best interest of the patient?
- What do you know about the condition and drug therapy in question? What was the original amount of the prescription?
- Has the patient made an appointment with the physician?
- What does your patient assessment tell you? For example, what is the indication for use? How has the patient been using the medication? How long? What has their experience with the therapy been? What other medications are they taking?
- What would you advise your fellow pharmacist colleague to do in this situation if they asked you?
- What could be the reasoning behind the physician's decision making?
- What is ultimately influencing your decision making – the patient's need, the physician's reaction and/or something else?

The actions you take should: put your patient first, bear public scrutiny, be considered acceptable as a precedent for future behaviour, and support the commitment to serve and protect the best interests of patients.

DOCUMENT YOUR DECISION MAKING

Once you have made your decision, you should document that decision, your rationale for it, what the expected result is and how it

supports the patient. If you have communicated with the patient, the prescriber or any other healthcare professional, ensure you've made a notation to that effect. Having this information on hand will help you address any questions that may arise at a later date as well as support future patient care.

In this case, you may want to communicate the decision to the other pharmacy so that they are aware of any notes that should be made in their patient record.

You will need to notify the prescriber if you have renewed the prescription.

Remember: *doing nothing is also a decision.*

REVIEW AND REFLECT

Following the decision, you have an opportunity to review and reflect. What did you learn? How can you be more prepared for these types of situations in the future?

Good relationships with the other healthcare professionals on a patient's care team are important and both pharmacists and physicians have critical and complementary roles in patient care. Regardless of the decision made in this particular scenario, you may identify that there is an opportunity to connect with the physician to discuss with her what you, as a pharmacist, can do to help your mutual patients. A conversation could help identify why the physician feels there is a need for a policy that requires appointments for renewals and whether there are any collaborative solutions to those issues. 📌



5 THINGS YOU SHOULD KNOW ABOUT CLOZAPINE

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Clozapine is a unique atypical antipsychotic, heralded for its effectiveness in treatment-resistant schizophrenia (TRS).¹ An estimated 25% to 30% of those living with schizophrenia meet the criteria for TRS, which is defined as non-responsiveness to, or intolerance of, two or more adequate trials of non-clozapine antipsychotic medications.¹

In studies, clozapine consistently demonstrates superior efficacy compared to other antipsychotics, but its use has been restricted because of rare side effects such as agranulocytosis, seizures, myocarditis, and severe (sometimes fatal) cases of constipation. Due to its risk of agranulocytosis, clozapine also comes with stringent monitoring requirements such that patients are required to register with a clozapine monitoring system run by the manufacturer. Pharmacists have a key role to play in the safe use of this medication. Below are five essential components of working with clozapine, particularly for pharmacists working in outpatient or community pharmacy settings.

1. Before receiving clozapine, the patient must be enrolled in a brand-specific clozapine registry and have completed required baseline blood work.

In contrast to most medications, the prescribing physician, dispensing pharmacy, and patient **must** be registered in a manufacturer-specific distribution system to ensure the safe dispensing of clozapine.² By enrolling in a distribution system registry, the manufacturer aids in tracking clozapine usage and monitoring patient health. There are presently three manufacturers of clozapine, each with their own registry (see Table 1).^{3,4,5}

A patient must not be switched from one brand of clozapine to another by a pharmacist unless he/she obtains a new, registry-

specific patient registration form completed by the prescribing physician.² Regular complete blood count results are recorded in patient registries to make sure that clozapine is not given to a patient with a history of clozapine-induced agranulocytosis or myocarditis.³

Before starting therapy, baseline white blood cell (WBC) and differential counts are required.³ Sometimes prescribers will issue a prescription before the patient has been cleared by the registry to start clozapine. *Pharmacists should not dispense the first clozapine prescription until confirmation has been received from the registry that it is safe to start clozapine.* The same recommendation applies to patients re-starting clozapine after a period of being off the medication.

Prior to dispensing subsequent clozapine prescriptions, the pharmacist should verify that the patient has completed their WBC and differential tests by checking with the registry online or by telephone. *If the blood work has not been done within the required time frame, pharmacists should not dispense clozapine (i.e., "No blood, no drug").* Since clozapine adherence is important for effectiveness and safety, pharmacists are encouraged to contact the registry for guidance if blood work is delayed. Pharmacists should refer to the product monograph for guidance on interpreting hematological values. If hematological values are abnormal, contact the prescriber to collaborate on next steps. *Additionally, pharmacists should not renew or adapt prescriptions for clozapine.*

2. Clozapine coverage is usually different from most drugs, and this has implications on ensuring seamless care.

In order for clozapine to be covered for a patient, they must either:

- 1) have coverage through third-party insurance or
- 2) more commonly, qualify for Ontario's Special Drugs Program. To qualify for the Special Drugs Program clozapine must be: prescribed by a hospital staff physician; recommended by a provincial psychiatric hospital regional coordinator; and prescribed to a patient with TRS.⁶

If a patient is obtaining their clozapine through the Special Drugs Program, they will need to fill the prescription at a designated hospital.⁷ Community pharmacies cannot be reimbursed for clozapine through this program. However, they may enter into an agreement with a hospital that can provide the pharmacy with a free supply of clozapine, to be used for mutual patients of the hospital and community pharmacy while patients are seen in an outpatient setting. This arrangement is encouraged if it means that the patient will get all of their medications dispensed from a single pharmacy (which helps with adherence and detection of drug interactions). If a patient continues to get their clozapine from a hospital pharmacy, both the community pharmacy and hospital pharmacy should keep the patient's medication list up-to-date.

For hospital pharmacists or those with access to provincial drug databases, it's important to ask specifically about clozapine when collecting a list of current and/or prior medications. Clozapine can get missed during medication reviews because it does not appear in the Ontario Drug Benefit (ODB) Drug Profile Viewer nor ConnectingOntario even though it is covered under the Special Drugs Program.

3. If a patient misses clozapine for more than 48 hours, contact the prescribing physician for an appropriate re-titration regimen.

It is important to tell patients to contact their pharmacist or prescriber if they have missed more than two days of clozapine because the dose might need to be decreased and re-titrated.³ Risks of continuing at the same dose after a period of missed doses include seizures, orthostatic hypotension, and excessive sedation. Also, if more than three days are missed, more frequent monitoring of WBC and differential counts could be required for a certain period of time.³ More information is available in the product monograph.

4. Encourage patients to report any side effect they experience, no matter how minor they think it may be.

Due to clozapine's nonspecific and extensive receptor binding profile, several side effects must be discussed with the patient. The most common side effects are sedation, dizziness, hypersalivation, tachycardia, and constipation.³

Clozapine-induced constipation can lead to fatal complications so it is important for the pharmacist to ask about this side effect at every visit.

Evidence suggests that regularly scheduled osmotic laxatives, such as lactulose (15-30 mL once or twice daily) or polyethylene glycol (17 g once or twice daily) effectively prevent and treat clozapine-induced constipation.⁸ Bulk-forming agents, such as psyllium, are to be avoided as they can worsen the risk of fecal impaction.⁸

Less common, but serious side effects of clozapine should be communicated as well, including seizures, agranulocytosis, and myocarditis.³ Agranulocytosis, as a result of clozapine, can lead to a significant decrease in white blood cells, which can predispose the body to infections.³ Patients should promptly report any flu-like symptoms (fever, chills, sore throat), mouth sores, weakness or lethargy.³

In addition, with the increased risk of myocarditis, pharmacists should be vigilant of persistent tachycardia at rest when coupled with other signs and symptoms of heart failure (e.g. chest pain, shortness of breath), fatigue, flu-like symptoms, hypotension, or unexplained fever.³ This is especially important during the first month of clozapine treatment.³ In some institutions, patients receive troponin and C-reactive protein (CRP) tests before starting the drug, followed by four more weekly tests as the risk of myocarditis is highest early in therapy. Pharmacists should encourage prescribers to get these tests done at the time of initiation because symptoms of myocarditis tend to be non-specific. These lab values can be used in conjunction with a physical assessment for the physician to make a diagnosis of myocarditis.

Given clozapine's high propensity for weight gain and metabolic disturbances, pharmacists should

also recommend that patients get baseline metabolic tests done (weight, waist circumference, blood pressure, lipid profile, fasting blood glucose). These tests should be repeated periodically during therapy with clozapine and monitored by both prescriber and pharmacist.³

5. Monitor for changes in other medications and smoking status.

Clozapine is largely metabolized by CYP1A2 and CYP3A4, and pharmacists should be cautious when clozapine is combined with strong inducers or inhibitors of either enzyme.³ Drugs to consider include antibiotics, like ciprofloxacin, and erythromycin, as well as fluvoxamine, carbamazepine, phenytoin, and cimetidine.³ Tobacco smoking (and cannabis smoking) can also induce CYP1A2 through polycyclic aromatic hydrocarbons found in the smoke.⁹ Sudden smoking cessation (e.g., during a hospital admission) may increase the clozapine plasma level and potentiate side effects.³ Re-starting smoking (e.g., upon hospital discharge) can decrease clozapine plasma levels which can lead to a relapse in symptoms of schizophrenia. When developing a smoking cessation plan, the pharmacist should work closely with the patient to minimize drug-smoke interactions via close monitoring. Since the smoke from cigarettes affect clozapine metabolism, nicotine replacement therapies do not interfere with clozapine plasma levels.⁹ However, certain smoking cessation medications, like bupropion, can further lower seizure thresholds, and should be prescribed with caution.⁹

Pharmacodynamic interactions can also be important. Drugs with CNS depressant effects can potentiate

sedation caused by clozapine.³ Concurrent use of anticholinergic drugs can potentiate the risk of constipation, and other drugs that are also associated with neutropenia and agranulocytosis (e.g. carbamazepine) should be avoided.³ If they must be used, closer monitoring of WBC and differential counts should occur. 

TABLE 1

Contact the designated clozapine registry for further questions or concerns.

For further questions on complete blood count monitoring, patient-registry status, or technical assistance, contact the designated clozapine registry, and a representative may be able to assist you.^{3,4,5}

- CSAN (HLS Therapeutics)¹⁰
1-800-267-2726
- AASPIRE Patient Care Network (AA Pharma)
1-877-276-2569
- GENCan (Mylan Pharmaceuticals)
1-866-501-3338

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FREQUENTLY ASKED QUESTIONS

from Pharmacy Practice

Note that these answers were current at date of publication and are meant as guidance for pharmacy professionals. The College cannot tell a member what course of action to take, provide legal advice or opinions, or make any decisions for a member.

MEDICAL DIRECTIVES

Q When processing a prescription written by someone who has been given a medical directive, is the physician listed as the prescriber or would it be the healthcare practitioner who has been designated?

A The prescriber should indicate who is ultimately responsible for the prescription. The College's Policy – [Medical Directives and the Delegation of Controlled Acts](#) explains that "When delegating an act or procedure, the authorizer is responsible for ensuring that the act is performed competently...Accountability for the delegated act remains with the authorizer..."

The Federation of Health Regulatory Colleges of Ontario (FHRCO) has developed an [Interprofessional Guide on the Use of Orders, Directives and Delegation for Regulated Health Professionals in Ontario](#) which contains a template for a *Recommended Format for a Prescription or Requisition Completed Pursuant to a Directive*. The *Pharmacy Connection* article [Physician Assistants \(Fall 2014\)](#) may also be of interest.

INJECTIONS

Q I have been contacted by a doctor's office to inject [specified vaccine] into one of their patients. Are we allowed to inject it without a medical directive?

A Please refer to the Guideline on [Administering a Substance by Injection or Inhalation](#).

Since October 2012, pharmacists have been authorized to administer the influenza vaccine through the Ministry's UIIP, and to administer a substance specified in the regulation to a patient who has been prescribed a self-administered injection for the purpose of education and demonstration. (Refer to **Schedule 1**



in [O. Reg 202/94](#) to the *Pharmacy Act* for a list of these substances). In December 2016, the regulations were amended to allow for the administration of additional vaccines, found in **Schedule 3** of [O. Reg 202/94](#).

Situations outside of the pharmacist's scope of practice as defined in the legislation (i.e. substances not listed in the regulations, or not for the purposes of education and demonstration) would require delegation of authority, such as a medical directive.

Pharmacists who have completed the appropriate training and feel they have sufficient skills and knowledge to perform other injections may wish to explore collaboration with other health care providers to do so. Please refer to the Policy on [Medical Directives and the Delegation of Controlled Acts](#).

Q We had a patient come into the pharmacy and ask the pharmacist to “prescribe” a vaccine. If the patient has a drug plan that pays for the vaccine can the pharmacist write the prescription and administer the vaccine? We were wondering if this would be similar to how we bill publicly-funded flu shots.

A Billing a prescription to a third party payer does not have any bearing on the scope of practice of pharmacy defined by the [Pharmacy Act](#) and [Ontario Regulation 202/94 – General](#). Vaccines (listed in Schedule 3 of the regulation) may be administered under independent authority in accordance with the [Guideline - Administering a Substance by Injection or Inhalation](#). Vaccines listed in Schedule I of the NAPRA Drug Schedules require a valid prescription in order to be dispensed prior to administration.

To receive reimbursement for influenza, which is a Schedule II vaccine, a claim is submitted to ODB via the Health Network System. This requires the pharmacist to enter information similar to that of a prescription, with the pharmacist's identification in the 'prescriber' field (refer to the Ministry of Health and Long- Term Care's Executive Officer communications). As this is a billing mechanism (which also creates documentation for the patient) it should not be interpreted as prescribing the vaccine, as pharmacists do not have the independent authority to do so.

STERILE COMPOUNDING

Q What are the specific requirements for the accreditation and operation of a compounding pharmacy that makes sterile preparations? Is there a list of required courses and equipment approved by the College?

A The College does not issue a separate certificate accreditation for pharmacies compounding sterile preparations. All community pharmacies, regardless of the specific services provided, must meet the minimum standards for accreditation as set out in the *Drugs and Pharmacies Regulation Act* and in the College's [Accreditation and Operation of a Pharmacy - Guidance for Pharmacy Professionals](#). Pharmacy professionals engaging in sterile compounding have additional standards to meet, namely the [Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations \(NAPRA\)](#) and the [Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations \(NAPRA\)](#) adopted by Council for implementation by January 1, 2019.

The College does not approve or endorse training programs, equipment, vendors, etc. or maintain a list of companies that offer products for sterile compounding. It is the responsibility of the Designated Manager to source the appropriate resources to meet the standards.

If changes will be made to the accredited area of an existing pharmacy, please follow the instructions for [Pharmacy Renovations](#) available on the OCP website. For new pharmacies, there is a section on the application to indicate which specialty services the pharmacy plans to offer. This information does not appear on the public register, however it is necessary to determine the frequency of [pharmacy assessments](#). All community pharmacies undergo routine assessments every one to four years, depending on the activities performed at the pharmacy and the risk of harm those activities pose to the public. Therefore, to help the College fulfill its mandate to protect the public, a pharmacy engaged in sterile compounding will be assessed more often than a pharmacy that does not. 📄



“Close-Up on Complaints” explores incidents reported to the College that have occurred in the provision of patient care and which present learning opportunities. Ideally, pharmacists and pharmacy technicians will be able to identify areas of potential concern within their own practice, and plan and implement measures to help avoid similar incidents from occurring in the future.

A FUNDAMENTAL DUTY TO PUT THE PATIENT’S WELLBEING FIRST

SUMMARY OF THE INCIDENT

This incident occurred when a husband attended the pharmacy on a statutory holiday to fill a hydromorphone 2mg prescription for his wife from a Quebec physician. The patient required the prescription to manage the pain of a broken tibial plateau until she was able to see another doctor at their local hospital. The pharmacist indicated to the patient that he could not dispense the prescription because the prescriber did not write down the patient’s health card number on the prescription; he referenced that per Ontario’s Narcotic Monitoring System, prescribers are required to record the patient’s identification number, such as their health card, on any prescription for a monitored drug.

The patient returned to the hospital and, following a five hour wait, received a new prescription which was dispensed the following day.

WHY DID THIS HAPPEN?

This incident illustrates a lack of compassion for the patient, and an adherence to rules over the wellbeing of the patient.

The pharmacist insisted on rigid observance of the rules and regulations. He did not exhibit empathy for the patient nor did he seem to understand how he could use his professional judgment and discretion to make a decision that would have put the patient’s interest first by providing quicker treatment.

COMPLAINT OUTCOME

The College’s Inquiries, Complaints & Reports Committee oversees investigations of each complaint the College receives. A committee panel considers a pharmacy professional’s conduct, competence and capacity by assessing the facts of each case, reviewing submissions from both the complainant and the professional, and evaluating the available records and documents related to the case.

In this case, the panel noted that the patient was required to wait a significant amount of time, until the next day, for pain relief. While pharmacy professionals must adhere to dispensing rules overall, particularly with respect to narcotic prescriptions, there are accommodations that can be made for particular situations. The pharmacist may not have been able to dispense the entirety of the prescription until certain aspects were verified with the prescriber. However, the panel notes that there are more options besides dispensing in full and not dispensing – for example, he could have dispensed a few tablets to provide pain relief while waiting for verification.

The panel emphasized that pharmacists must first and foremost consider the patient and their wellbeing. There was no reason to believe that the prescription was fraudulent and the pharmacist had information to support the authenticity of the prescription, including the availability of the patient who was in a vehicle outside of the pharmacy. The health card number could have been confirmed verbally or by fax with the physician or the clinic. While the prescription was

ORAL CAUTIONS

An oral caution is issued as a remedial measure for serious matters where a referral to the Discipline Committee would not be appropriate. Oral cautions require the pharmacy professional to meet with the ICRC in person for a face-to-face discussion about their practice and the changes they will make that will help avoid a similar incident from occurring in the future.

REMEDIAL TRAINING (SCERPS)

A SCERP is ordered when a serious care or conduct concern requiring a pharmacist or pharmacy technician to upgrade his or her skills has been identified. The ICRC orders SCERPs when they believe that remediation is necessary.

For all complaints filed after April 1, 2015, the College posts a summary of the oral caution and/or SCERP and its date on the "Find a Pharmacy or Pharmacy Professional" tool.

not written exactly as required by Ontario regulations, the pharmacist could have used his judgment and discretion in how the prescription was confirmed and how identifiers were used, recognizing that the physician was from another province.

Furthermore, the panel felt that the pharmacist displayed no compassion for his patient and, in his communication with the patient and response to the investigation, sought only to protect himself.

Due to the seriousness of the incident and the lack of appropriate patient care provided, the panel ordered that the pharmacist appear in person to receive an oral caution, and that he complete remedial training — a specified continuing education or remediation program (SCERP) — related to ethics.

LEARNINGS FOR PHARMACY PROFESSIONALS

The Code of Ethics clearly articulates the ethical principles and standards which guide the practice of pharmacists and pharmacy technicians in fulfilling

the College's mandate to serve and protect the public by putting patients first. The first foundational principle is that pharmacy professionals must actively and positively serve and benefit the patient and society. Specifically, Standard 1.1 states that "members ensure that their primary focus at all times is the well-being and best interests of the patient." This means that pharmacy professionals must maintain the patient's best interests as the core of all activities. They should not place their own interests — or self-preservation — above the patient. Furthermore, pharmacy professionals must be diligent in their efforts to do no harm and, whenever possible, prevent harm, such as unnecessary pain and suffering, from occurring.

Patients seek care because they believe and trust that pharmacy professionals will apply their knowledge, skills and abilities to make them better. Standard 1.2


CODE OF ETHICS MODULES

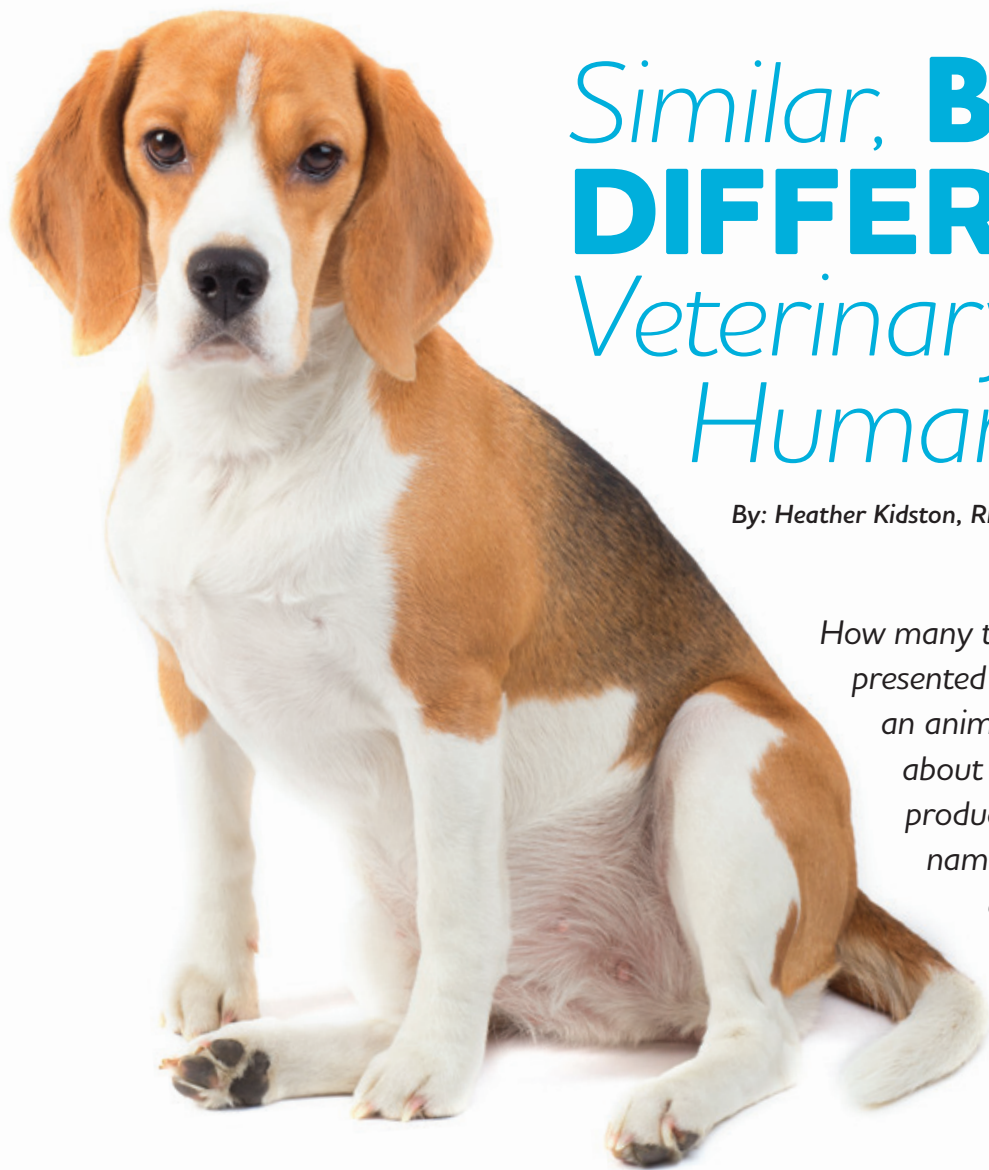
- [Principle of Beneficence](#)
- [Principle of Non-Maleficence](#)

of the Code of Ethics states that "members utilize their knowledge, skills and judgment to actively make decisions that provide patient-centred care and optimize health outcomes for patients." Pharmacists should, when appropriate, look beyond black and white decision making to ensure they are properly assessing and acting on the big picture — incorporating what they know about the patient, the situation, the medication and any other key factors. When making a decision, documentation is critical, including making a note on the rationale for the decision and how it supports the best possible health outcome for the patient.

The Standards of Practice are clear that pharmacists must demonstrate a caring, empathetic and professional attitude. They should seek to understand the patient's perspective and communicate with compassion, recognizing that many individuals seeking healthcare are in pain, frightened or vulnerable. A lack of compassion, and tactful communication, can end up making the situation worse.

CONCLUSION

With Ontario's current opioid crisis, there is a significant focus on narcotics and how pharmacies manage and dispense them. Pharmacy professionals must be diligent in how they assess narcotic prescriptions, manage narcotic inventory and dispense narcotics, including respecting laws and regulations. However, due diligence and caution should not interfere with the fundamental duty that a pharmacist or pharmacy technician has as a healthcare professional to put patients and their wellbeing first and foremost. Pharmacists must use their professional judgment to make appropriate decisions in the best interests of their patients. 



Similar, **BUT DIFFERENT:** *Veterinary and Human Drugs*

By: Heather Kidston, RPh, FSVHP

How many times per week are you presented with a prescription for an animal? Or asked questions about purchasing an OTC product for a pet? Can you name two reliable veterinary drug references?

During my 13 years as a community pharmacist, I was frequently asked questions about drug therapy for clients' pets, and filled many prescriptions for animals. As a veterinary hospital pharmacist, I now recognize how often I incorrectly assumed that I could safely extrapolate my "human" pharmacy knowledge to other species.

As per the *Drug and Pharmacies Regulation Act*, a drug is defined as any substance that is used in the diagnosis, treatment, mitigation or prevention of a disease... **in humans, animals or**

fowl. The intent of this article is to increase awareness of some of the challenges that pharmacists face as a result of animals being included in this definition.

SCENARIO #1

Mrs KL approaches pharmacist MP on his Saturday evening shift. She explains that she has run out of her syringes to administer insulin to her beagle, Beetle. MP has often dispensed prescriptions from the local vet for both insulin and syringes. Based on Beetle's 5 unit BID dose, MP provides Mrs KL with BD 3/10cc syringes.

How could this interaction put Beetle's health at risk?

Pharmacists are accustomed to insulin being 100 U/mL. Many veterinary patients are prescribed human insulin. Others, like Beetle, use veterinary-only Caninsulin (porcine insulin zinc), which is 40 U/mL. Caninsulin syringes are calibrated to 40 U/mL. When Mrs KL draws Caninsulin to the "5 units" mark on the BD syringe, Beetle will receive only 40% of the correct insulin dose.

SCENARIO #2:


Client JD presents a prescription for his dog, Spot, for Clavamox 250mg tablets. He requested a prescription from his veterinarian because he heard that it was less expensive at a community pharmacy. The pharmacist, AB, investigates, and finds that, as the brand name suggests, Clavamox is a veterinary drug containing amoxicillin and clavulanic acid. She informs JD that she doesn't carry the brand that the vet has prescribed, but will substitute the human generic amoxicillin-clavulanic acid 250 mg tablet.

two ingredients in different ratios than human-approved products. Clavamox 250mg contains 200-50 (250mg refers to the total of BOTH compounds), while human generics contain 250-125 (250mg refers to amoxicillin content only). Spot was dispensed 50mg more amoxicillin and 75 mg more clavulanic acid per dose than he was prescribed. Although 50 mg of extra amoxicillin may not be clinically relevant, the higher dose of clavulanic acid places Spot at higher risk of GI side effects.

In addition to veterinary labelled drugs, species-specific

So where does one find veterinary-specific drug information? A great resource to have on hand is [Plumb's Veterinary Drug Handbook](#). Written and reviewed by pharmacists, Plumb's reads just like the CPS. The [Health Canada drug database](#) also provides information on both human and veterinary drugs. For those who wish to learn more, online veterinary pharmacy continuing education courses are offered at some American pharmacy schools.

It is a pharmacist's professional responsibility to acknowledge when he or she lacks sufficient knowledge to provide a service. The challenge is recognizing those knowledge deficits. Failing to properly consider drugs marketed for veterinary use, pharmacokinetic differences and toxicities could result in inadvertent harm to the animal patient.

Pharmacists and veterinarians share a collective duty of care. By working together, we can address these challenges and form an alliance that places animal (patient) safety first. 



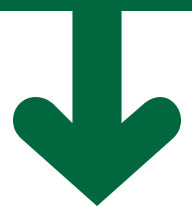
How could this interaction put Spot's health at risk?

Veterinary labelled amoxicillin-clavulanic acid tablets contain the


pharmacokinetics and toxicities complicate the provision of care to animals. These will be discussed in a future edition of *Pharmacy Connection*.

REMINDER:

ALLIED HEALTH PROFESSIONAL DEVELOPMENT FUND



Pharmacists who are registered to practice in Ontario can apply to the [Allied Health Professional Development Fund \(AHPDF\)](#) for education grants for professional development activities that enhance the quality of care and services they provide to Ontarians.

As well, pharmacists are able to create an account on the AHPDF website to access its extensive, practice-focused Electronic Health Library. 



THE *Niagara Apothecary*

EXPERIENCE AN 1869 PHARMACY

The Niagara Apothecary, located in Niagara-on-the-Lake, is a replica of a typical 1869 pharmacy. Visit this beautiful mid-Victorian national historic site and learn about pharmacy practice in the 19th century confederation period. Once there, you'll have the opportunity to speak with retired pharmacists and learn about the building and its artifacts.



Open daily to Labour Day.
Open every weekend to Thanksgiving.

For more information, go to www.niagaraapothecary.ca



DISCIPLINE DECISIONS

Starting this edition, the College has moved Discipline Decisions online to pharmacyconnection.ca.

These easy-to-access decisions facilitate greater accessibility among pharmacy professionals, stakeholders and members of the public and allow us to share decisions more widely via e-connect, our website and social media. As always, pharmacy professionals are encouraged to view these decisions as opportunities to examine and enhance their own practice. Decisions also remain available to view on the public register and CanLii.



LIST OF SPRING 2018 DECISIONS:

Manish Patel (OCP #605365)

Joseph Hanna (OCP #209868)

**Lawrence Varga
(OCP # 608565)**

Susan Janssens (OCP #94811)

Mukesh Khunt (OCP #614354)

**Thomas McNulty (OCP #203604) and T.B. McNulty
Pharmacist Professional
Corporation, as holder of
Certificate of Accreditation
#303416 for Tom's Pharmacy**

Boules Awad (OCP #604940)

Zafar Ahmad (OCP #212220)

Allen Chow (OCP #69841)

Lilian Fam (OCP #608926)

The full text of these decisions is available at www.canlii.org
CanLii is a non-profit organization managed by the Federation of Law Societies of Canada. CanLii's goal is to make Canadian law accessible for free on the Internet.

FOCUS ON ERROR PREVENTION

By Ian Stewart R.Ph, B.Sc.Pharm.



Pharmaceutical manufacturers invest significant resources on designing product packaging and labelling to ensure positive brand identification. The result is often a consistency in product appearance. This similarity in packaging and labelling has been a contributing factor in medication errors reported.

CASE:

Rx:

Derma Smoothe/FS®

Sig: Use as directed

Mitte: One bottle

The above prescription was taken to a local community pharmacy for processing. The pharmacy assistant entered the prescription into the computer as Derma Smoothe/FS® Topical Body Oil.



Upon checking the prescription, the pharmacist did not check with the patient or prescriber to confirm which specific product was needed. Derma Smoothe/FS® Topical Body Oil was therefore dispensed. Patient counselling did not take place as the patient indicated that he was in a hurry and his physician had already told him how to use the product.

Just prior to retiring to bed, the patient opened the packaging to apply the oil to his scalp and noticed that the shower cap was missing.

The following morning, the patient contacted the pharmacy to report the discrepancy.

Following some investigation, the pharmacist learnt that the prescriber intended to prescribe Derma Smoothe/FS® Scalp Oil which contains two shower caps to be used during treatment.

POSSIBLE CONTRIBUTING FACTORS:


- The physician did not specify the product prescribed.
- The pharmacist failed to confirm the indication for use and specific product prescribed.
- Both products are similar in appearance and are usually stored next to each other.
- Their Drug Identification Numbers are identical. (See photo).
- Patient counselling did not take place.

RECOMMENDATIONS:

- To ensure the patient receives the most appropriate drug therapy, always gather the indication for use from the prescriber or patient whenever possible.
- Ensure that the patient receives appropriate patient counselling depending on the drug's indication for

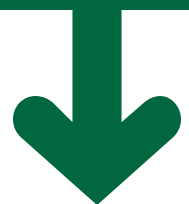
use. Patient counselling not only ensures the patient uses the medication correctly, it is often the last opportunity to detect a dispensing error.

- Derma Smoothe/FS® Topical Body Oil and Derma Smoothe/FS® Scalp Oil each has unique indications for use, directions for use and package content.
 - o Educate all pharmacy team members regarding the potential for error involving these two products.
 - o Meanwhile, consider storing Derma Smoothe/FS® Topical Body Oil and Derma Smoothe/FS® Scalp Oil in separate locations.
- Health Canada should consider assigning unique Drug Identification Numbers to each product to prevent future dispensing errors.

Please continue to send reports of medication errors in confidence to Ian Stewart at: ian.stewart2@rogers.com. Please ensure that all identifying information (e.g. patient name, pharmacy name, healthcare provider name, etc.) are removed before submitting. 

REMINDER:

PHARMACY DOMAIN AVAILABLE FOR INTERNET PHARMACIES



The .Pharmacy Verified Websites Program is a website verification program administered by NAPRA's counterpart in the United States, the National Association of Boards of Pharmacy (NABP), to identify safe and legitimate online pharmacies and online sources of pharmacy information.

NAPRA is a key partner with NABP for the .Pharmacy Verified Websites Program in Canada. Any Canadian pharmacy business or organization seeking to obtain

a .pharmacy domain name can apply through the .Pharmacy Verified Websites Program website.

A .pharmacy domain helps to identify safe and legitimate online pharmacies and online sources of pharmacy information. Any member of the pharmacy community, regardless of location, may apply for a .pharmacy domain. For more information, please see www.safe.pharmacy. 