

THE OFFICIAL PUBLICATION OF THE ONTARIO COLLEGE OF PHARMACISTS



# AN EXPANDING SCOPE OF PRACTICE FOR PHARMACY:

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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.

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- Fitness to Practise
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- Patient Relations
- Quality Assurance
- Registration

#### Standing Committees

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



## (2019-2021) OCP STRATEGIC FRAMEWORK

VISION

A trusted, collaborative leader that protects the public and drives quality and safe pharmacy care and improved patient outcomes.



MISSION

The Ontario College of Pharmacists regulates pharmacy practice to serve the interests, health and wellbeing of the public.



**VALUES** 

**ACCOUNTABILITY** 

INTEGRITY

**TRANSPARENCY** 



STRATEGIC PRIORITIES

Enhance system and patient outcomes through collaboration and optimization of current scope of practice

Strengthen trust and confidence in the College's role and value as a patients-first regulator Enhance the College's capacity to address emerging opportunities and advance quality and safe pharmacy practice and regulatory excellence



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 registrants with other allied health care professionals; and to communicate our role to registrants 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 feedback 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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## PHARMACONNECTION

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Nancy Lum-Wilson, R.Ph., B.Sc.Phm., MBA CEO and Registrar

Dear Colleagues,

Pharmacy professionals play an important role in the lives of patients, who rely on their skills and expertise to manage their health. Whether it's instructing a parent on how to administer an antibiotic to treat their child's ear infection. or helping an elderly patient with multiple chronic conditions manage their medications, pharmacists

and pharmacy technicians are part of the continuum of care, using their clinical knowledge to help improve the health outcomes of our patients.

The role of pharmacy professionals will be growing. The provincial government announced in May that it would expand scope of practice for a number of regulated health professions, including pharmacists. The College has been asked to assist in this process by developing regulatory amendments that would enable these changes while protecting patient safety.

As a regulator, the College has a singular mandate to serve and protect the public, and plays a critical role in enabling and promoting quality, safe and ethical pharmacy care. The College also recognizes that pharmacy professionals, and other healthcare professionals, have a critical role to play in the work that they do to ensure that patients always come first; patients must receive the care they need and feel that they are heard and considered. As such, we will continue to consult broadly with the profession, the public and key stakeholders in this process, gathering feedback that is crucial to developing regulatory amendments that won't compromise patient safety.

As the needs of patients continue to evolve and pharmacists take on a greater role in their healthcare, the responsibility to improve quality and safety as well as understand the impact of their work becomes even more important. The responsibility to provide quality, safe and ethical care is shared by pharmacy professionals, managers and pharmacy owners and operators. It is the foundation of the public's trust and confidence in our profession.

Many pharmacy professionals have already demonstrated their commitment to enhancing patient safety by embracing the Assurance and Improvement in Medication Safety (AIMS) Program and anonymously reporting all medication incidents and near-misses through an independent, third-party platform. The aggregate data collected through the program will be analyzed by an independent team of experts to identify trends, determine key findings and provide guidance to the pharmacy sector on how to improve patient safety. Their first set of recommendations will be shared with both pharmacy professionals and the public in the very near future an important step in our collective efforts to prevent medication errors

Quality indicators for pharmacy is another key component to improving patient care. Other areas of the health system, such as primary care, have a strong focus on indicators to measure quality and support quality improvement efforts. With the launch of the first set of quality indicators for pharmacy in June – developed by the College in partnership with Health Quality Ontario – we are on a path to better understanding the influence of pharmacy care on quality and health outcomes for our patients. The College is currently engaging patients, pharmacy professionals, academics and others on how these indicators can be implemented, and what tools and resources will be needed to support registrants in their work to improve quality of care.

Every day, patients across Ontario place their trust in the hands of pharmacy professionals. As we enter this new chapter in expanding scope of practice, we must all renew our commitment to improve patient safety and quality of care and demonstrate to the public that they can continue to have confidence in pharmacy as it takes on a greater role in managing their health.

Sincerely,

Nancy Lum-Wilson

**CEO** and Registrar

Ontario College of Pharmacists

## JUNE 2019 COUNCIL MEETING

As recorded and published following Council's regularly scheduled meeting held on June 17th, 2019.

#### COUNCIL ELECTION 2019 UPDATE

Council elections are underway in districts T, TH, K and L. Dr. Wayne Hindmarsh and Ms. Deanna Williams were appointed as scrutineers for these elections which close on Wednesday, August 7th.

#### RESPONSE TO COLLEGE NAME CHANGE REQUEST

In December 2018, the Council passed a motion to formally request that the Ministry of Health and Long-Term Care consider a recommendation to change the College's name from Ontario College of Pharmacists to Ontario College of Pharmacy, which would require changes to legislation. The Minister has subsequently responded that any discussions to change the name would require evidence and support that patients would be better served. The College will consider moving this request forward if and when it pursues other proposed legislative changes with government in the future.

# COUNCIL DEBATES AND APPROVES THE NEXT LEVEL INTENTIONS FOR GOVERNANCE REFORM

Following the approval of four governance renewal principles in December 2018, the Council participated in a facilitated discussion reviewing the next steps involved in governance reform. The governance framework is grounded

in adopting best practices and in building greater public trust in the role of the Council and the mandate of the College.

#### Separation of Council and statutory committees

True separation cannot be achieved until the governing legislation is amended; however in order to move closer to this intention, Council agreed to appoint all elected professional members to the Discipline Committee only and to appoint two public members to each statutory committee for which public members are mandatory as per the legislation. The College, along with its Advisory Group for Regulatory Excellence (AGRE) partners, will continue to advocate for changes to the legislation to achieve complete separation of Council from statutory committees.

#### Competency-based selection

To further the College's public protection mandate, Council agreed to shift from the current geographical districts for the election of Council members to having positions on Council that reflect various patient populations, such as acute, urban, rural, northern, and Indigenous. Candidates who wish to run for election will need to have demonstrated experience in serving the patient populations listed. Council also approved the development of a more robust and transparent selection process for future Council members. In the absence of legislative change to separate Council from statutory committees, there is a requirement that elected professional members serve on the Discipline Committee. Therefore, prospective candidates will be encouraged to have had prior service on College committees, such as having served as a non-Council committee member (NCCM).

## Reduction in Council size and equal number of public and professional members

Council approved the reduction in the number of elected members from 17 currently to the minimum of nine (of which two must be technicians) as legislated in the *Pharmacy Act*. A plan will be developed to ensure Council retains knowledge and experience during the transition to a smaller governing body. As well the bylaws will ensure that parity between publicly appointed members and elected members of Council is maintained.

#### Other governance modernization and best practice changes

Changes were approved to the titles of people and groups who register with the College and govern the College to make their roles and responsibilities clearer to the public. For example, Council will be called the Board of Directors and the President and Vice President will be known as Chair and Vice Chair. 'Members'

of the College will be officially referred to as 'registrants' to better reflect their fundamental relationship with the College. Also, the terms of office for elected Council members will be reduced to a maximum of two consecutive three-year terms to ensure that new perspectives are regularly brought to the Board, while appropriate transition and succession planning is maintained.

A decision regarding the Council's intentions was necessary in order for the College to move forward with drafting the bylaw changes required to operationalize the governance framework, which will become effective at the start of the 2020/21 Council year. Council will continue to be consulted as the processes are developed and will be responsible for approving the draft bylaws over the coming year.

#### **COUNCIL APPROVES THE** SUBMISSION OF A NEW DRAFT OF THE QUALITY **ASSURANCE REGULATIONS**

In December 2017, further to broad open consultation, Council approved changes to the General Regulation 202/94 to make changes to the classes of registration (to remove pharmacy students and add pharmacy technician interns) as well as to update the Quality Assurance regulation to reflect the new program model and add the requirement for pharmacy technicians to participate in the Quality Assurance program, including practice assessments. The College submitted these regulatory amendments in March 2018. but partially as a result of a change in government, they have not moved through the approval process.

During recent discussions with government, the College expressed the desire to move the

regulatory changes needed to include pharmacy technicians in the Quality Assurance program forward, in order to align with the College's implementation of pharmacy technician practice assessments earlier this year. In order to support this request, the Ministry recommended the College re-submit the proposed changes to General Regulation 202/94, previously approved by Council, in two separate phases, first with the Quality Assurance program changes followed by the registration amendments. Council approved the submission of a new draft of Regulation 202/94 with the amendments to Part VIII (Quality Assurance) and a subsequent resubmission of the Regulation to include the proposed amendments for Parts I through VII (Registration). The intent of the proposed changes remains the same

#### **COUNCIL APPROVES THE** PROPOSED CHANGES TO THE JURISPRUDENCE **EXAM BLUEPRINT**

A working group was tasked with reviewing and updating the exam blueprint for the Jurisprudence, Ethics and Professionalism assessment which was last updated in 2012. The exam blueprint was updated with a greater focus on scope, ethics and professionalism. The exam question format will be changed to include case-based multiple choice questions to allow for scenario-type questions better suited to assess ethics and professionalism. As well the exam timing will be changed such that the exam will only be offered postgraduation for all applicants, to allow for assessment of critical thinking and application of jurisprudence and ethics to case-based questions. A transition plan, including timelines for implementation of the changes is in development and will be communicated with stakeholders.

#### HOMEOPATHY IN PHARMACY

Council reviewed a briefing note regarding the provision of homeopathic products in pharmacies, following receipt of a change.org petition. Currently, no province or territory in Canada has regulations or guidelines in place to prohibit the sale of homeopathic products in pharmacies or to prevent pharmacists from recommending them. The College will monitor the outcome of the recent consultation activity of the College of Pharmacists of British Columbia and will continue to monitor the environment with regard to public comments, petitions and voiced concerns on the topic of homeopathy. In the meantime, the College does and will continue to expect pharmacy professionals to follow the Code of Ethics and all relevant laws, regulations and standards. This includes having the knowledge and competency to be able to provide safe, evidence-based advice to patients.

#### **SCOPE OF PRACTICE**

On May 30, 2019, the College received a letter from the Minister of Health and Long-Term Care asking Council to make regulations that would enable pharmacists to:

- Administer the flu vaccine to children as young as two years
- Renew prescriptions in quantities of up to a year's supply;
- Administer certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration: and
- Prescribe drugs for certain minor ailments.



In addition, the Minister has asked the College to work with the Ministry to provide pharmacists with the authority to perform certain point of care tests for certain chronic conditions.

An internal working group has been established to create a detailed work plan that will include policy development, broad stakeholder, public and registrant consultation and regulatory drafting. Regulatory amendments for the first three activities are to be submitted by November 30, 2019, thereby requiring two special Council meetings to meet the timeline. The first meeting will be held in August for approval of open consultation on the draft amendments and the subsequent meeting for approval of the final regulatory amendments to be submitted to government will be held in November. Regulatory amendments to permit prescribing for certain minor ailments are to be submitted by June 30, 2020.

The College has committed to providing updates as this work moves forward, including details related to planned consultation and engagement activities once confirmed. Watch for updates on the College's website, in e-Connect and in Pharmacy Connection.

## ASSURANCE AND IMPROVEMENT IN MEDICATION SAFETY (AIMS)

As part of the Registrar's report the Council was given an update

on the implementation of the College's mandatory Assurance and Improvement in Medication Safety (AIMS) Program which continues to gain momentum across the province. Approximately 80 per cent of Ontario's community pharmacies now have access to the medication incident reporting platform with the remaining pharmacies expected to gain access by mid-2019. The aggregate, de-identified data will be analyzed by a Response Team of pharmacy professionals and patient safety experts to develop recommendations on how pharmacies can reduce the risk of patient harm and support continuous quality improvement. The recommendations will be shared with pharmacy professionals and other healthcare stakeholders to help reduce medication errors and improve patient safety, with the first report expected in summer 2019.

#### QUALITY INDICATORS SYMPOSIUM UPDATE AND PRESENTATION

Council was provided with a summary of the Quality Indicators Symposium held on June 6, 2019 in Toronto. Those in attendance at the symposium, including representatives from the legislature and the Ministry of Health and Long-Term Care, offered overwhelming support of the initiative.

The Quality Indicators for Pharmacy were developed in collaboration

with HQO, the provincial advisor on healthcare quality, and selected by an Expert Panel that included patients, practicing pharmacists, academics and other health system stakeholders. The quality indicators, which focus first on community pharmacy given the work already done to establish indicators within hospital practice, will enable both pharmacy professionals and the College – which is responsible for promoting quality improvement within the pharmacy profession - to gain a clearer picture of the quality of pharmacy care and make evidence-based decisions to support quality improvement.

The College will continue to engage patients, frontline pharmacy professionals, corporate pharmacy sector leaders, academics and health system data experts as it moves forward with implementation, including developing an understanding of what tools and resources pharmacy professionals will need to support quality improvement.

#### **NEXT COUNCIL MEETING**

The next scheduled meetings will be held Monday, September 16 and Tuesday, September 17, 2019. Two special meetings of Council will be held to facilitate approval of regulations related to expanded scope of practice. The first will be held on August 22, 2019 and the second will be held on November 21, 2019

Council meetings are open to the public and are held in the Council Chambers of the College at 483 Huron Street, Toronto, ON M5R 2R4. If you plan to attend, or for more information, please contact Ms. Sarah MacDougall, Council and Committee Liaison at <a href="mailto:council@ocpinfo.com">council@ocpinfo.com</a>. You can also follow along via Twitter during Council meetings.

# 2019 COUNCIL ELECTION RESULTS



Council elections were completed on August 7, 2019. The results are as follows:

#### **DISTRICT K**



Tracey Phillips (acclaimed)



Mark Scanlon (acclaimed)

H Hospital

T Pharmacy Technician

TH Hospital Pharmacy Technician



**DISTRICT L** 



Billy Cheung



James Morrison



Siva Sivapalan

**DISTRICT T** 



Connie Beck

**DISTRICT TH** 



Goran Petrovic

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# Expanded Scope of Practice: CONSULTATION ON DRAFT REGULATIONS NOW OPEN

In May, the provincial government announced its intention to <u>expand scope of</u> <u>practice</u> for Ontario pharmacy professionals to help improve access to care and enhance the patient experience.

Specifically, the government asked the College to draft regulations that would enable pharmacists to:

- administer the flu vaccine to children as young as two years old;
- renew prescriptions in quantities of up to a 12-month supply;
- administer certain substances by injection and/ or inhalation for purposes that are in addition to patient education and demonstration; and
- prescribe drugs for certain minor ailments.

The government also requested that the College work with Ministry staff to enable pharmacists to perform certain point of care tests to support their role in medication management and the treatment of patients.

The College is to submit draft regulations pertaining to the first three activities and point of care testing to the government by November 30, 2019. A second set of regulatory amendments that would facilitate the prescribing of drugs for certain minor ailments is to be submitted by June 30, 2020.

The College has worked closely with the Ministry of Health on policy development and has also completed stakeholder consultation. We are committed to meeting the Ministry's deadlines while fulfilling our mandate to serve and protect the public.

#### DEVELOPMENT OF THE FIRST SET OF PROPOSED REGULATIONS

The College consulted with a broad group of stakeholders to develop the first set of proposed regulations. These stakeholders included pharmacy

associations, provincial pharmacy regulators and subject matter experts in pharmacy, medicine and public health. The College has also drawn on lessons learned from other jurisdictions where pharmacists have acquired similar scopes of practice. Pharmacy professionals provided preliminary feedback on the first three scope-related activities during an eight-day online survey (linked from e-Connect).

These efforts have helped the College define the appropriate parameters to maximize the knowledge and skills of pharmacy professionals while also ensuring the delivery of safe, high quality patient care.

#### **CONSULTATION ACTIVITIES**

In our efforts to meet the timeline for the first three activities, the College held a special Council meeting on August 22 seeking approval to post the draft regulatory amendments for a 60-day open public consultation.

Council approval was granted and these proposed regulatory changes are now posted on the College website for comment through October 26. The Ministry will also post them concurrently on the

government of Ontario's public registry for a 45-day consultation period.

Pharmacy professionals wishing to provide feedback on the draft regulations are invited to participate in the public consultation. There will also be the opportunity to provide input in the near future as the College moves forward to draft regulatory amendments to enable prescribing of drugs for certain minor ailments.

#### FINALIZING REGULATORY AMENDMENTS

A second special Council meeting will be held November 21 to request approval of the final regulatory amendments before they are submitted to the Ministry for consideration.

Our highest priority in finalizing these amendments will continue to be the best interest of patients. Further information will be provided to registrants as this work moves forward, including details about planned consultation and engagement activities. Watch for updates on the College's website, in e-Connect and in future issues of Pharmacy Connection.

#### **CURRENT SCOPE OF PRACTICE FOR ONTARIO PHARMACY PROFESSIONALS**

Pharmacists, interns and pharmacy students who have injection training are currently permitted to administer certain vaccines to eligible patients five years of age or older. These include the flu shot and 13 other vaccines for preventable diseases (list of vaccines).

Pharmacists, interns and registered pharmacy students under the supervision of a pharmacist have the authority to renew prescriptions for the purpose of continuity of care (with the exception of narcotics and other controlled substances and monitored drugs). The prescribed quantity of a renewal cannot exceed the total quantity (including refills) that was authorized by the original prescriber, or a six-month supply whichever is less. Additional information can be found on the OCP website.

Currently, pharmacists, interns and registered pharmacy students under the supervision of a pharmacist are able to administer a substance by injection or inhalation for the purposes of education and demonstration as outlined in the legislation. The expanded scope would enable these pharmacy professionals to administer substances beyond the purposes of education and demonstration, to therapeutic purposes as well.

Currently, pharmacists, interns, registered pharmacy students and pharmacy technicians under the supervision of a pharmacist are able to pierce the dermis to obtain blood for the purpose of patient education and demonstration. The expanded scope would enable them and pharmacy technicians to perform this act for purposes beyond that of patient education and demonstration. Point of care testing will also require the Ministry of Health to make amendments to the Laboratory and Specimen Collection Centre Licensing Act regulations.

# Shared Learning, Shared Accountability

A Ssurance and Improvement in Medication Safety

A PATIENT SAFETY AND QUALITY IMPROVEMENT PROGRAM OF THE ONTARIO COLLEGE OF PHARMACISTS

Most of the province's 4,400+ pharmacies have been onboarded to the <u>Assurance and Improvement in</u> <u>Medication Safety (AIMS) Program.</u>

The remaining pharmacies will gain access to the medication incident recording platform by fall 2019, marking the culmination of the largest medication safety program for pharmacies of its kind in Canada.



## SHARED LEARNING: AN INTEGRAL COMPONENT AT THE PHARMACY

The **sharing of learnings** resulting from the analysis of medication incidents is one

of the four mandatory AIMS Program requirements, along with **report**, **document** and **analyze**. As more pharmacists, pharmacy technicians and pharmacy assistants have onboarded to the AIMS program and have gained access to the incident recording platform over the last year, there has been a strong focus on recording medication incidents and near misses into the platform. While recording events is a fundamental

part of the program, it is not the only effort that needs to take place following a medication incident or near miss; recording should lead to analysis and key learnings, which should then lead to quality improvement actions, as appropriate.

To enable and promote effective shared learning within the pharmacy team resulting from a medication incident or near miss, there should be.

- prompt communication of appropriate details of a medication incident or near miss, including causal factors and actions taken as a result, to staff and colleagues;
- regular scheduling of continuous quality improvement communication with pharmacy staff to educate all pharmacy team members on medication safety;
- encouragement of open dialogue on medication incidents:
- completion and discussion of a Pharmacy Safety Self-Assessment (PSSA), once available on the platform; and,
- development and ongoing monitoring of quality improvement plans.

#### SHARED ACCOUNTABILITY BETWEEN **PROFESSIONALS AND PHARMACIES**

Designated Managers (DMs), owners and directors play a pivotal role in facilitating the adoption and implementation of the <u>AIMS Program</u> within individual pharmacies. It is part of the expectations of the program and is expressed in the supplemental Standard of Practice and Standards of Operation. The responsibilities of owners/operators, directors and DMs to ensure an effective and appropriate environment for pharmacies and professionals to satisfy operational and professional obligations are also spelled out in the Standards of Operation.

They must ensure that pharmacy professionals have access to the incident recording platform and associated tools and resources, including confirming that the mandatory AIMS Program web-based training has been completed. The DM must also ensure the pharmacy's operations are conducive to the principles of the AIMS Program and a safety culture, as well as satisfy all of the elements outlined in the associated standards.

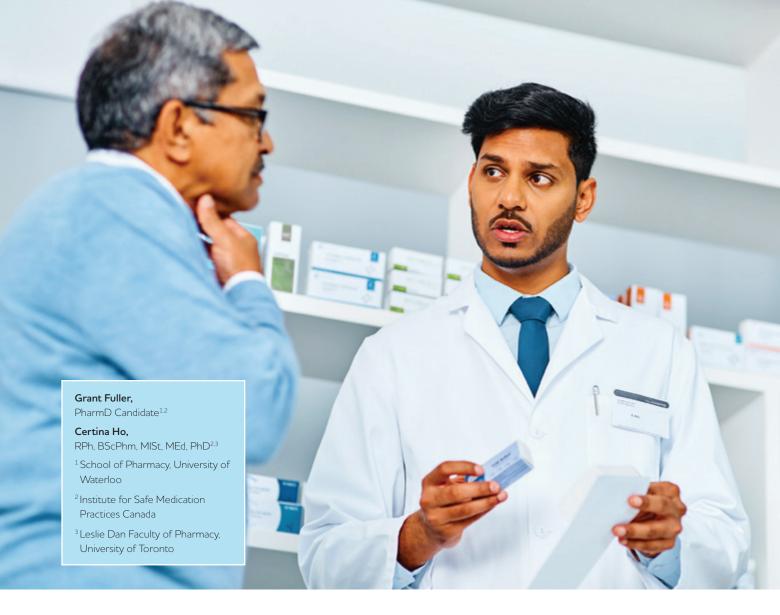
A safety culture enables staff to engage in open, honest discussions about medication incidents and near misses. It also permits staff to identify the causal factors of incidents and share lessons learned with an emphasis on preventing errors from recurring. This is a foundation for supporting meaningful and sustainable change at the pharmacy level and, eventually, across the health system. It's clear that the adoption of a safety culture in other parts of the health system has helped to improve patient safety and the intent of the AIMS Program is to help foster a similar culture within pharmacy.

Patient safety requires that all participants are engaged and focused on the same goal: preventing harm and enhancing care. By participating and supporting the identification, analysis and sharing of medication incidents, pharmacy professionals, DMs, owners and directors share the responsibility for the successful implementation of the AIMS Program at the pharmacy.

#### **PROVINCE-WIDE LEARNINGS**

An important benefit of the AIMS Program is that the data collected through the anonymous recording platform will help the College - together with its health system partners – to identify trends and develop solutions and recommendations that will assist pharmacy professionals in reducing the risk of patient harm caused by medication incidents. A team of pharmacy professionals and patient safety experts is assisting the College by analyzing the de-identified, aggregate data and developing recommendations for the pharmacy sector aimed at reducing the risk of medication incidents and near misses, as well as identifying strategies for continuous quality improvement.

The first set of recommendations will be shared with pharmacy professionals in the very near future – an important step in our collective efforts to prevent medication errors. The College also plans to share aggregate provincial data publicly on our website and make it available directly to pharmacies and health system stakeholders.



# Disclosure of Medication Incidents: A SUGGESTED FRAMEWORK

#### **CASE EXAMPLE**

Mr. Jones, a patient of your pharmacy, states that he has been feeling nauseated and has had a few episodes of diarrhea ever since he picked up his new prescription two days ago. Upon examining his pharmacy profile and the medication vial he has brought in, it becomes apparent that he has received another patient's metformin prescription by accident, instead of his intended medication, atorvastatin.

#### INTRODUCTION

Every patient has the right to be informed about their healthcare. This includes the right to be promptly notified when an incident associated with medication

therapy has occurred. In fulfilling this commitment to their patients, as well as meeting their ethical and organizational obligations, practitioners need to understand when disclosure is appropriate or necessary and how to properly disclose medication incidents.

In addition to disclosure, there can be other challenges in responding to medication incidents. The Assurance and Improvement in Medication Safety (AIMS) Program relies on practitioners to share details of medication incidents when they are discovered. However, this requires an environment in which staff feel comfortable reporting medication incidents without undue consequences to their self-image, status, or career.¹ (For further information, refer to

a previous article published in the Summer 2018 edition of Pharmacy Connection: Safe Pharmacies Need Psychological Safety.)

Very often, practitioners involved in medication incidents experience psychological and physical consequences which include extreme sadness, difficulty sleeping, and intrusive memories.<sup>2</sup> Recognizing these responses and the need to support practitioners are often overlooked in the aftermath of a medication incident. (For further information, refer to a previous article published in the Spring 2019 edition of Pharmacy Connection: Aftermath of a Medication Incident: Caring for the Patient, the Family, but also the Healthcare Professional.)

To support practitioners, we have provided a framework for medication incident disclosure and applied it to the case example above. This framework has been adapted from the Canadian Patient Safety Institute (CPSI) Canadian Disclosure Guidelines and a previouslypublished continuing education lesson for pharmacy technicians on How to Handle a Medication Error<sup>3,4</sup> We also consulted the Canadian Medical Protective Association (CMPA) article, Disclosing harm from healthcare delivery: Open and honest communication with patients. 5 We would like to refer readers to these original resources for further information.

#### SUGGESTED DISCLOSURE FRAMEWORK

#### Immediate Actions<sup>3,4</sup>

After a medication incident is discovered, there are immediate actions that must be taken before beginning the disclosure process:

- Attend to the affected patient(s); ensure their care needs are met.
- Take immediate measures to prevent similar safety risks from harming other patients or staff.

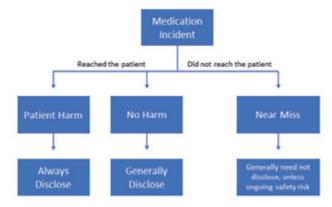
#### Is Disclosure of the Medication Incident Needed?3,4

After any immediate safety concerns are addressed, practitioners must decide whether disclosing the medication incident to the patient is appropriate or necessary.

• Consider the degree of harm the patient experienced or could have reasonably experienced as a result of the incident (Figure 1)

- o "Harm" refers to incidents that reached the patient and resulted in temporary or permanent impairment (including mental, physical, sensory functions and pain) in body functions or structures<sup>6</sup>
- o "No Harm" refers to incidents that reached the patient but resulted in no injury<sup>6</sup>
- o "Near Miss" refers to events that could have resulted in patient harm but did not reach the patient<sup>6</sup>
- When in doubt about disclosing a medication incident, consider whether a person would reasonably want to know about the incident.

Figure 1 - Circumstances When Disclosure is Appropriate or Necessary<sup>3</sup>



Source: Canadian Patient Safety Institute. <u>Canadian disclosure</u> guidelines: being open and honest with patients and families; November 2011.

#### Apologies<sup>3,4</sup>

Apologies are crucial to the disclosure process and should be offered as they make patients feel validated and respected. Legislation exists in several provinces, including Ontario, to protect practitioners from legal liability due to apologizing.<sup>7</sup> Features of an effective approach are presented below:

- Communicate genuine sincerity about the medication incident.
- Use a personal tone including terms such as "I" or "We."
- Use appropriate non-verbal gestures (body) language, tone of voice, facial expressions).
- Assure that harm did not result from anything the patient or family did or did not do.

#### Preparing the Disclosure<sup>3,4</sup>

After it has been determined that a disclosure is needed, consider the following when preparing for the initial meeting:

- Schedule an in-person disclosure meeting at the earliest practical opportunity. Select a time that is convenient for the patient and family and a place that is private and free of interruptions. Allow adequate time for a complete discussion about the incident
- The most responsible healthcare provider who
  is involved should facilitate the disclosure. All
  others who played a role in the incident should
  be prepared to discuss relevant events with the
  patient and family.
- Anticipate emotions; both the patient and practitioners should have supports available at the disclosure meeting if needed.
- Assign a staff member as the primary contact for the patient and family throughout this process.

#### Disclosure<sup>3,4</sup>

The initial disclosure is a crucial step as it provides an opportunity for the patient and family to understand what the medication incident was and why/how it might have happened.

- Focus on the events that led to the medication incident, using clear and understandable terminology. Avoid speculation and assigning blame.
- Encourage the patient and family to discuss the incident from their point of view.
- Discuss any changes to the ongoing care of the patient in consultation with the patient's primary healthcare provider.
- Keep a record of the discussion. Allow the patient and family to review the documentation to ensure everyone agrees on the facts.

#### Continued Feedback<sup>3,4</sup>

The disclosure process requires continued dialogue with the patient and family rather than a single discussion. After the initial disclosure meeting and when the medication incident has been fully reviewed and analyzed:

- Communicate new findings about the incident to the patient and family members.
- Reinforce, update, or correct information provided in previous meetings.
- Discuss any improvements or changes made to prevent similar events from occurring.
- Provide continued practical and emotional support to the patient and family.

#### **CASE EXAMPLE – APPLICATION**

#### Immediate Actions<sup>3,4</sup>

Ensure that Mr. Jones is not experiencing any symptoms of potentially dangerous hypoglycemia (e.g. confusion, dizziness, vision changes) due to the inadvertent administration of metformin. Follow up on the management of his nausea and diarrhea in consultation with his primary healthcare provider. Secure the metformin prescription and provide Mr. Jones with his correct medication, atorvastatin. Ensure a new metformin prescription was prepared for the intended patient.

#### Is Disclosure of the Medication Incident Needed?<sup>3,4</sup>

Mr. Jones has experienced "harm" in the form of nausea and a few episodes of diarrhea due to this incident. Disclosure is necessary as it helps Mr. Jones understand that a medication incident occurred and what circumstances might have contributed to this event.

#### Apologies<sup>3,4</sup>

A suggested initial apology can be: "I am very sorry about this, Mr. Jones. It appears you received the wrong medication. I want to emphasize that none of this is your fault and we will work with you to figure out why/how this happened."

#### Preparing the Disclosure<sup>3,4</sup>

The pharmacy should make every effort to schedule an in-person disclosure meeting with Mr. Jones as soon as possible. The Designated Manager (DM) or pharmacy manager will facilitate communication with Mr. Jones and oversee the disclosure process as the DM is the most responsible healthcare provider involved in the patient's care in this case. The staff member who gave the medication to Mr. Jones at

pick-up should also be prepared to discuss the incident with him.

A possible arrangement would be: The disclosure meeting is scheduled next Sunday when the pharmacy is closed to allow for privacy and the time needed for a thorough discussion. Mr. Jones is advised that he may bring his family for support if desired.

#### Disclosure<sup>3,4</sup>

Here is a potential disclosure: "Mr. Jones, I want to take some time to discuss the events that have led up to you receiving the wrong medication. When you picked up the prescription, we neglected to ask you for an additional patient identifier or information besides your name, such as your address or date of birth. You share a very similar name to one of our other patients. These factors contributed

to you receiving the wrong prescription. I have contacted your family physician who agrees that no changes to your current care are needed. Again, we are very sorry about what happened. Would you like to share your thoughts on this incident with us?"

#### Continued Feedback<sup>3,4</sup>

While reviewing and analyzing the medication incident, the pharmacy team discovered that Mr. Jones had refused counselling when he picked up his medication as he was in a rush. As a result of this incident, the pharmacy has changed its processes related to prescription pick-up. All staff will request secondary patient identifiers upon prescription pick-up and counselling will be given for all prescriptions (new prescriptions and refills). These process improvements

and workflow changes will be shared with Mr. Jones along with any new findings the pharmacy discovers.

#### CONCLUSION

When a medication incident occurs, the ensuing process from reporting and disclosure to the point where eventual system improvements are implemented can be complicated. Having both a framework and the knowledge to appropriately disclose medication incidents are important, however, they represent just one step in addressing the challenges of medication incident reporting and learning. Improving how we deal with medication incidents will take continued effort on the part of organizations, teams and individual practitioners.

#### REFERENCES

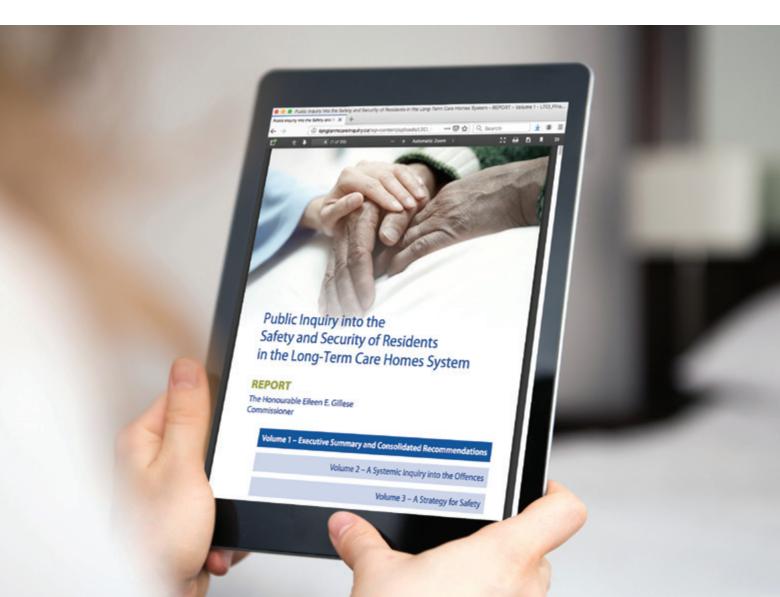
- 1. Edmondson AC, Lei Z. Psychological safety: The history, renaissance, and future of an interpersonal construct. Annu Rev Organ Psychol Organ Behav 2014; 1: 23-43.
- 2. Burlison JD, Quillivan RR, Scott SD, Johnson S, Hoffman JM. The Effects of the Second Victim Phenomenon on Work-Related Outcomes: Connecting Self-Reported Caregiver Distress to Turnover Intentions and Absenteeism. Journal of Patient Safety 2016 Nov. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC5413437/pdf/nihms-788857.pdf
- 3. Disclosure Working Group. Canadian disclosure guidelines: being open and honest with patients and families. Edmonton, AB: Canadian Patient Safety Institute; 2011. Available from: https://www.patientsafetyinstitute.ca/en/ toolsResources/disclosure/Pages/default.aspx
- 4. Ho C, Kawano A. How to handle a medication error. TECH talk CE 2013; May: 4-10. Available from: http://www. canadianhealthcarenetwork.ca/files/2013/05/TechTalkMay-2013.pdf
- 5. Canadian Medical Protective Association. Disclosing harm from healthcare delivery: Open and honest communication with patients. 2017. Available from: https://www.cmpa-acpm.ca/en/advice-publications/browsearticles/2015/disclosing-harm-from-healthcare-delivery-open-and-honest-communication-with-patients
- 6. ISMP Canada. Definitions of Terms. Available from: https://www.ismp-canada.org/definitions.htm
- 7. Government of Ontario. Apology Act. 2009. Available from: https://www.ontario.ca/laws/statute/09a03



# MANDATORY REPORTING TO PREVENT PATIENT HARM

Learning from Ontario's Long-Term Care Homes Public Inquiry

In July 2019, the Long-Term Care Homes Public Inquiry released its <u>final report and recommendations</u>. The inquiry was established to examine the events which led to the offences committed by Elizabeth Wettlaufer while working as a registered nurse in long-term care homes within Ontario.



The report outlined a total of 91 recommendations, including system-wide opportunities involving regulators, government and other stakeholders to improve the safety and quality of long-term care in the province.

The report also encouraged an increased role for pharmacists and pharmacy technicians in longterm care to help deter harm to residents through strengthened medication management systems. As government moves forward in responding to the report's recommendations, the College welcomes any opportunity to work with the government and other stakeholders in our shared goal to protect the public and looks forward to the opportunities presented to us to contribute within our mandate to a safer long-term care system.

#### **UNDERSTANDING** REPORTING OBLIGATIONS

A major theme of the recommendations is that healthcare professionals should be educated on the possibility that healthcare providers may intentionally harm those in their care, especially vulnerable patients. The inquiry encouraged the adjustment of institutional (including regulators, education providers and healthcare facilities) training, investigative processes and policies to reflect this possibility. The recommendations also noted that healthcare professionals, their employers and healthcare facility operators should be better educated on when and how they must file mandatory reports regarding a healthcare professional's conduct or capacity.

Recognizing that the reporting of specific concerns regarding a healthcare professional's conduct, capacity or competence could help prevent harm to a patient, the College is reminding pharmacy professionals of our expectations regarding mandatory reporting.

#### WHEN TO MAKE A MANDATORY REPORT

As regulated healthcare professionals, and under the Regulated Health Professions Act and Health Professions Procedural Code, pharmacists, pharmacy technicians, employers and facility operators have obligations to report certain information to the College. These obligations are in place to protect patients and contribute to safe and effective pharmacy care.

- Employers (e.g. pharmacy owner, DM) must file a report with the College if a registrant's employment is terminated, they are suspended or other privileges are revoked for reasons of professional misconduct, incompetence or incapacity. This obligation remains even if the registrant resigned or relinquished any privileges prior to the employer having done so. Reporting is not required for employmentrelated reasons (e.g. issues such as lateness or personal incompatibility that don't compromise patient safety or contravene standards of practice).
- Facility operators must file a report with the College if they suspect a registrant has sexually abused a patient or if they suspect the registrant is incompetent or incapacitated.
- All pharmacists and pharmacy technicians must file a report with the College if they suspect another registrant has sexually abused a patient.

Under the Code of Ethics, pharmacists and pharmacy technicians are expected to report professional incompetence or unethical behaviour by colleagues or other healthcare professionals to the appropriate regulatory body.

Note that the requirement to report to the appropriate regulatory college also applies to other healthcare professionals (e.g. physicians, nurses).

Pharmacists, pharmacy technicians, employers and facility operators may also report other concerns to the College that fall outside of mandatory reporting.

#### **HOW TO MAKE A MANDATORY REPORT**

Please visit the College's webpage on Mandatory Reporting.

Employers, facility operators, pharmacists and pharmacy technicians should use the Mandatory Reporting Form available on the College website. The form can be emailed, faxed or mailed. Please provide as much information as possible.

The College cannot assist employers, facility operators, or registrants in determining their legal obligation to make a mandatory report. If you are in doubt about whether a mandatory report is required, you may wish to submit one and allow the College to assess the information contained within the report to determine if further action is required. 🖭

# QUALITY INDICATORS FOR PHARMACY: Next Steps

The College, in partnership with Health Quality Ontario (HQO), has launched the <u>first set of quality indicators for community pharmacy in Canada</u> to help pharmacy professionals, health system stakeholders and the public gain a better understanding of pharmacy's impact on patient outcomes and to drive quality improvement. The indicators were launched at the Quality Indicators for Pharmacy Symposium in June 2019. <u>Watch a video summary of the symposium</u>.

The indicators were developed by an <u>expert panel</u> that included patients, practicing pharmacists, academics and other health system stakeholders. Their work is reflected in an <u>Expert Panel Report on Quality Indicators for Pharmacy</u>. In addition, the College has developed a <u>Quality Indicators for Pharmacy leaflet</u> that provides a short summary of the indicators as well as their importance and relevance to pharmacy.

Quality indicators already existed in other areas of the health system, such as primary care and longterm care, and a great deal of work has been done to establish indicators in hospital pharmacy. However, it is relatively new territory for community pharmacy in Ontario.

#### WHAT ARE THE SELECTED INDICATORS MEASURING?

Patient/Caregiver
Experience and Outcomes

Appropriateness of Dispensed Medications

Medication-related Hospital Visits

**Transitions of Care** 

Read the <u>Quality Indicators for Pharmacy leaflet</u> for more information.

#### **PROVIDER EXPERIENCE**

One of the measurement areas selected is provider experience and engagement. There is a well-established link between provider experience and engagement and patient outcomes. However, there are currently no pharmacy-specific measures available in the literature. This measurement area will be prioritized for future development and the College will be reaching out to various stakeholders, including

frontline pharmacy professionals, to collaborate on further development and refinement of this indicator.

#### **NEXT STEPS**

The College is moving forward in developing a plan to implement these quality indicators. We are currently consulting with key stakeholders including patients, pharmacy professionals, corporate pharmacy sector leaders, academics and health system data experts. Pharmacy professionals who would like to provide feedback on next steps for quality indicators can complete the Quality Indicators for Pharmacy Next Steps survey.

Initially, the College will look to use the indicator data for public reporting at an aggregate provincial and regional level to provide transparency to the public, pharmacy professionals, patients and stakeholders on the impact of pharmacy care on patient and system outcomes. We anticipate that we will later be able to make data available for quality improvement use by pharmacies and pharmacy professionals.

Indicator-based information can help pharmacists and pharmacy technicians make evidence-based decisions in their continued efforts to enhance quality of care. Future planning will, in part, focus on developing an understanding of the tools and resources required by pharmacy professionals to support quality improvement, incorporating the data that will be available from the indicators. Starting this fall, a working group comprising health care providers, data and analytics experts, measurement experts, policy makers and system representatives will be developing processes for collecting the data required to report on each of these indicators.

# Non-Sterile Compounding FAQS

Commonly asked questions regarding the implementation of the NAPRA Standards for Pharmacy Compounding of Non-Sterile Preparations

Note: OCP would like to thank the Alberta College of Pharmacists and the New Brunswick College of Pharmacists for allowing us to adapt their Frequently Asked Questions (FAQs).



Council approved a three-phased approach for implementation. Implementation priorities and timelines for completion of each phase are:

- **Phase 1:** January 1, 2020 Assessing Risks and Gaps
- Phase 2: July 1, 2020 Personnel Training and Quality Assurance
- **Phase 3:** January 1, 2021 Facilities and Equipment

Learn more about each phase on the <u>Non-Sterile</u> <u>Compounding Standards and Implementation</u> page of the OCP website.

## WHAT IS THE DIFFERENCE BETWEEN THE STANDARDS AND GUIDANCE DOCUMENTS?

The standards are now the **minimum requirements** for all registrants involved in non-sterile compounding.

Standards establish requirements, using the language of "must." It is mandatory that the people and places involved in non-sterile compounding be compliant with the standards.

The <u>Guidance Document for Pharmacy Compounding of Non-Sterile Preparations</u> was developed by NAPRA as a supplemental resource and provides direction on and assistance with implementing the new standards. The guidance uses the language of "should" and establishes the professionally-accepted means by which pharmacies can achieve compliance with the standards. Pharmacies and pharmacy professionals may choose to meet the required standard using another process than one suggested in the guidance document; this is acceptable as long as the process meets or exceeds the requirements in the standard.

## CAN YOU EXPLAIN WHAT IS REQUIRED OF ME AND MY TEAM DURING PHASE 1 OF THE IMPLEMENTATION TIMELINE?

During "Phase 1," the College expects pharmacies involved in non-sterile compounding to evaluate their current practices and determine what areas require

work to be compliant with the standards ("Assessing Risks and Gaps"). Learn more in the Winter 2019 Pharmacy Connection article <u>Timelines Announced for Non-Sterile Compounding Standards</u>.

Since Phases 2 and 3 of the implementation plan contain a greater workload than Phase 1, all pharmacies involved in non-sterile compounding are encouraged to commence work on those sections of the implementation timeline ahead of the required deadlines.

#### HOW DO I PREPARE A GAP ANALYSIS/ SELF ASSESSMENT? IS THERE A FORM OR CHECKLIST I CAN USE?

The <u>Self-Assessment Criteria for Non-Sterile</u>
<u>Compounding Standards</u> can be found on the OCP
website. This document is intended to be used by
pharmacy professionals to assess the gaps between
current processes/practices at the pharmacy and the
requirements of the NAPRA Model Standards for
Pharmacy Compounding of Non-Sterile Preparations.

The document lays out each standard and the accompanying section in the NAPRA Guidance Document for Pharmacy Compounding of Non-Sterile Preparations to illustrate specific insights or activities required to ensure adherence to the standard. Pharmacy professionals can "check off" each standard as it is met and track their progress at meeting the standards. However, this document is not meant to replace the standards. Pharmacies should not send this document to the College.

#### CAN YOU PROVIDE EXAMPLES OF LEVEL A, B AND C COMPOUNDS?

As a self-regulated health professional, you are expected to use your knowledge, skills and judgment to perform a risk assessment of each preparation compounded in your pharmacy. Consider all the factors outlined in the standards, utilizing all necessary resources and references, then assign the risk level and document your decision with rationale in the master formulation record. Examples of how a risk assessment may be conducted have been provided by other regulatory bodies in Canada, however, the individual factors in your practice setting may result in a different risk assessment for the same formulation than another practice site. If there is uncertainty regarding the risk level to assign, the compounding supervisor, in collaboration with the manager, may

choose to adhere to the higher standard in the interest of safety.

# AS PART OF OUR RISK ASSESSMENT, WHICH IS MORE IMPORTANT, THE WHMIS LIST OR THE NIOSH LIST? I DON'T UNDERSTAND THE DIFFERENCE BETWEEN THE TWO.

While both resources may be used as part of a risk assessment process in the pharmacy, each provides a different perspective to ingredient classification.

- WHMIS refers to products used in various workplaces, not just pharmacies, as outlined in Health Canada's Workplace Hazardous Materials Information System. WHMIS encompasses a far wider group of chemicals used in workplaces than NIOSH.
- NIOSH is an American reference from the U.S.
   Department of Health and Human Services,
   Centers for Disease Control and Prevention,
   National Institute for Occupational Safety and
   Health (NIOSH), and refers to a list of ingredients
   more specific to health care materials: NIOSH List
   of Antineoplastic and Other Hazardous Drugs in
   Health care Settings 2016

Practitioners may be familiar with the WHMIS Material Safety Data Sheets with regard to products used in the pharmacy for such things as cleaning supplies. The NIOSH list may be more useful for medications used during compounding.

Ultimately, the standards reference both documents and, as such, both should be used while performing risk assessments of various ingredients used in making compounds.

HOW DO I DETERMINE IF A
PRODUCT IS LISTED AS A HEALTH
HAZARD UNDER THE HAZARDOUS
PRODUCTS ACT? HOW DO I USE
THE PRODUCT SAFETY DATA SHEET
(SDS) TO DETERMINE THE HAZARDS
IDENTIFIED WITH THAT PRODUCT?

See schedule 2 under the *Hazardous Products Act* for a <u>listing of health hazard classes</u>.



Refer to the SDS for the active pharmaceutical ingredient (API) to determine any associated health hazard classes. Canada has aligned the Workplace Hazardous Materials Information System (WHMIS) with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). On each SDS, refer to Section 2 - Hazards Identification. A health hazard can be identified with a pictogram (see above). Refer to the Canadian Centre for Occupational Health and Safety to learn more.

The compounding supervisor should make risk assessments for APIs available to all staff involved in compounding to make sure that they are aware of all possible risks.

#### **WHAT ARE THE MINIMUM DIMENSIONS OF A DESIGNATED COMPOUNDING AREA?**

There is no minimum size requirement. The compounding area must be large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner in clean and secure surroundings. Also, the area should be designed and arranged to prevent cross-contamination between products, and it should be located away from parts of the pharmacy where there is a considerable amount of traffic (e.g., aisles, entrance and exit).

#### **WHAT IS A SMALL QUANTITY?**

Small quantity depends on the risk assessment for each API which should include an assessment of frequency of compounding with these ingredients. As per the guidance document Section 4.1, some factors to consider in the risk assessment include the:

- complexity of compounding the preparation;
- need for verification and uninterrupted workflow;
- frequency of compounding high-risk or low-risk preparations;
- risk of cross-contamination with other products (e.g., allergens);
- concentration of ingredients in the preparation;
- quantity of ingredients being handled;
- physical characteristics of ingredients (e.g., liquid vs. solid vs. powders, or water-soluble vs. lipidsoluble):
- education and competency of compounding personnel;
- availability of appropriate facilities and equipment;
- classification of ingredients if identified by WHMIS

as presenting a health hazard, or a drug classified by NIOSH as hazardous (see reference to NIOSH in section 4.3);

- type of hazardous drug (e.g., anti-neoplastic, non-antineoplastic, reproductive risk only);
- exposure to compounding personnel for each preparation and accumulation of exposure over time: and
- risk of microbial contamination (liquids, creams, and ointments may be particularly susceptible to microbial and other contamination).

The risk assessment must be reviewed on a continuum to identify and mitigate risk, thereby providing quality assurance.

A decision algorithm to assist in determining requirements for non-sterile compounding can be found in section 4.2

Note: Occasional small quantities of materials must not be considered in isolation. If several different highrisk or low-risk preparations are being compounded, the cumulative risk must be considered even if they are compounded on different days. This must be documented in the risk assessment. Registrants must make available an environment and equipment that ensures the safety of pharmacy personnel when evaluating level of risk. If there is uncertainty as to the level of risk, then the registrant shall defer to the higher standard.

#### **WHAT DOES "MITIGATING RISK" MEAN EXACTLY. IN RELATION TO LEVEL B RISK COMPOUNDS?**

The table on page 5 of the standards document contains an outline regarding what to look for when seeking to mitigate risk, particularly to compounding personnel. Key points to consider in your decision making are:

- the level of risk the ingredient(s) may present;
- the volume/frequency of that ingredient's use; and
- the **combined** exposure to all higher risk ingredients.

If there is uncertainty as to the level of risk, then personnel shall defer to the higher standard.



# Implementing the Non-Sterile Compounding Standards:

### A CLOSER LOOK AT PERSONAL PROTECTIVE EQUIPMENT (PPE)

Pharmacies engaged in non-sterile compounding must undertake a risk assessment to identify the appropriate level (A, B or C) of precautions required to provide adequate protection for personnel and to minimize the risk of contaminating the preparation. This article focuses on the protection of personnel and the use of personal protective equipment (PPE) as described in the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and accompanying Guidance Document.

The standards define PPE as "all garb and accessories, such as mask, gloves, gown and safety goggles, that protect the non-sterile preparation and the worker. PPE enables compliance with the expected specifications of a controlled environment and protects the worker from exposure to physical or chemical risks."

For all levels of compounding, personnel must be trained in the pharmacy's policies and procedures for conduct, which must include wearing a clean laboratory coat that is reserved for compounding (or a disposable gown) and powder-free gloves. The Master Formulation Record for a particular preparation must indicate the PPE required for compounding and indicate if it is being used as a risk mitigation measure for compounding small, occasional quantities of a potentially hazardous ingredient. This documentation should specify the potential risks to personnel and the extra steps that must be taken to mitigate the risks along with supporting references.

As explained in Section 9 of the guidance document, the compounding of products classified as hazardous by NIOSH+, or as irritating to the respiratory tract, skin and mucous membranes by WHMIS‡, requires additional safety measures to protect personnel from chemical exposure.

NIOSH† created a "hierarchy of controls" diagram depicting the various levels of controls that can be implemented to protect personnel by controlling exposure to occupational hazards. It is important to understand that, as a risk mitigation measure, PPE is the least effective compared to other measures, such Hazardous products can penetrate the body through (needle-stick injury) or by inhalation



Absorption through the skin occurs by direct contact with ontaminated surfaces or objects. According to some studies this is the primary known route of penetration.



ngestion occurs by eating foods that have been contaminated



Inhalation of vaporized drugs can also be a source of contamination.

as engineering controls like ventilated containment devices or closed-off, ventilated rooms. Therefore, personnel must be trained in the proper use of PPE and their work routinely observed and assessed to ensure compliance with PPE procedures. This applies to compounding personnel as well as individuals involved in routine cleaning of the compounding area and/or dealing with spills.

Like any other equipment used in compounding, PPE must be maintained and inspected for integrity before and after each use. Equipment that is damaged or worn must be repaired or replaced to ensure its effectiveness. Section 9.2.3 of the guidance document describes PPE in detail, including gloves, gowns, respiratory protection and more

Risk mitigation is a key element of implementing the standards and information related to PPE can be found throughout the guidance document. It is important to read and use these documents in their entirety for comprehensiveness and to achieve full implementation.

#### **NON-HAZARDOUS**

#### **HAZARDOUS**

Note: This is a brief summary only. Please refer to the standards and guidance and the references provided for the detailed information necessary for full PPE compliance.

ALWAYS: Powder-free gloves

Two pairs chemotherapy gloves (ATSM International Standard D6978)

ALWAYS: Clean lab coat or disposable gown (preferred)

Disposable, impermeable gown made of polyethylene-coated polypropylene

IF NEEDED: Mask

Respiratory protection (N95 or N100 mask)

IF NEEDED: Head/hair covers (e.g. cap, beard guard)

Head/hair, shoe covers (2 pairs) and sleeve covers

IF NEEDED: Eye protection

Safety goggles or face shield (Glasses with side shields do not provide adequate protection from splashes)

GLOVES

Nitrile or neoprene gloves are preferred over polyurethane or latex.

- Vinyl gloves are not recommended as they are more permeable
- Gloves may be sterile or non-sterile

MASKS

N95/100 masks will protect against airborne particles but **not** against vapours or gases and only slightly against liquid splashes.

 For protection from vapours and liquids, a full-face chemical cartridge respirator or powered air-purifying respirator (PAPR) should be worn

GOWNS

Surgical scrubs or cloth isolation gowns are absorbent and not as protective as outerwear.

- Should close in the back (no open front) and have long sleeves with fitted cuffs at the wrist
- Laminate materials offer better protection than uncoated materials

#### **ADDITIONAL REFERENCES**

- Article Timelines Announced For Non-Sterile Compounding Standards; Pharmacy Connection (Winter 2019) (https://pharmacyconnection.ca/non-sterilecompounding-winter-2019/)
- OSH Answers Fact Sheets; Canadian Centre for Occupational Health and Safety (CCOHS) (<a href="https://www.ccohs.ca/oshanswers/about.html">https://www.ccohs.ca/oshanswers/about.html</a>)
- Safe Handling of Hazardous Drugs in Healthcare, 2013; Public Services Health & Safety Association™ (https://www.pshsa.ca/wp-content/uploads/2013/11/ PSHSA-Whitepaper-Safe-Handling-of-Hazardous-Drugs-in-Healthcare.pdf)
- Table 5 in List of antineoplastic and other hazardous drugs in healthcare settings, 2016; National Institute

- for Occupational Safety and Health. (https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugslist\_2016-161.pdf)
- Prevention guide—safe handling of hazardous drugs, 2008: Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTSAS). (https://asstsas.qc.ca/sites/default/files/publications/documents/ Guides Broch Depl/GP65A hazardous drugs.pdf)
- †National Institute for Occupational Safety and Health; Centers for Disease Control and Prevention
- ‡Workplace Hazardous Materials Information System

# Implementing the Non-Sterile Compounding Standards:

# THE COMMUNITY PHARMACY EXPERIENCE

Bronwyn Tolmie,

RPh, BScPhm, ACPR
Owner – Designated Manager,
Elora Apothecary Pharmasave

As owner and designated manager of a community pharmacy and a practicing hospital pharmacist, Bronwyn Tolmie was recently involved in the implementation of the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations in both community and hospital settings.

The Ontario College of Pharmacists requires all pharmacies engaging in non-sterile compounding activities to comply with the standards, using the following phased approach:

Phase 1: Assessing Risks and Gaps - January 1, 2020

Phase 2: Personnel Training and Quality Assurance - July 1, 2020

#### Phase 3: Facilities and Equipment - January 1, 2021

In fulfilling Phase 1 of the standards, Bronwyn did a full review of compounding practices at her existing community pharmacy location, applying the knowledge she acquired from her involvement in the hospital experience. She also applied lessons learned to ensure appropriate facilities were set in place to accommodate non-sterile compounding facilities and procedures at a future pharmacy location.

In this article, Bronwyn describes

the steps she took to assess risks and gaps in order to meet the initial January 1, 2020 timeline.

#### DESIGNATE A NON-STERILE COMPOUNDING SUPERVISOR

When preparing for the implementation of the new NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations an important first step is to designate a regulated pharmacy practitioner to be the non-sterile compounding (NSC) supervisor. With hospital experience and training in sterile compounding and an interest in expanding my knowledge of non-sterile compounding, it was determined that I would assume this role. The NSC supervisor is responsible for developing, organizing and overseeing all activities related to non-sterile compounding; therefore, it is imperative that individuals in this role review and understand the standards and accompanying guidance document.<sup>1,2</sup> The standards are based on General Chapter USP < 795 > (2016) and refer to hazardous drugs classified by National Institute for Occupational Safety and Health (NIOSH) as Table / Group 1 and hazardous materials classified by Workplace Hazardous Materials Information System (WHMIS).3.4 As

NSC supervisor, I wanted to ensure I had a strong understanding of these resources – including the ability to interpret the content and apply the standards to my practice site. Reviewing the standards is a critical first step in performing a gap analysis when one evaluates their current pharmacy compounding procedures and plans the changes required to successfully implement the new standards.

## DETERMINE RISK OF COMPOUNDS AND LEVEL OF REQUIREMENTS

The facility requirements for non-sterile compounding are based on the complexity and risks associated with preparing each compound. After reviewing the standards, the NSC supervisor should understand how to assess and determine the level of risk and complexity of the compounds one is making or planning to make at their pharmacy. I found this exercise to be an excellent opportunity to evaluate the compounding services my pharmacy currently provides and to facilitate decision making in terms of the level of compounding I was equipped to offer moving forward.

The NSC supervisor should identify all compounding ingredients currently being used at the pharmacy and determine for

each the risk to the compounding personnel handling these chemicals. Identification of ingredients classified as hazardous drugs can be determined by reviewing the NIOSH List of Hazardous Drugs.<sup>3</sup> One should also identify any ingredients that WHMIS deems as a potential health hazard by reviewing the safety data sheets provided by the supplier or manufacturer of the ingredient.<sup>5</sup> With knowledge as to the ingredient's classification as hazardous or not, the NSC supervisor is able to evaluate a compound being prepared and determine if it is classified as simple, moderate, or complex as defined by USP General Chapter <795> (2016), and summarized in Section 8 of the guidance document.<sup>2,4</sup>

Once the risk and complexity of the compounds being prepared have been established, the Decision Algorithm for Risk Assessment in the guidance document can be used to determine if your pharmacy compounding space will be required to meet Level A, B, or C requirements.<sup>2</sup> Both the standards and guidance document outline what is required for a Level A, B, or C compounding space and can be used to decide if any facility modifications are needed within one's current place of practice. 1.2

#### TRAINING AND SKILLS **ASSESSMENT**

After determining what level of compounding you will be performing at your pharmacy, it is important to decide if there is a need for additional training. As the NSC supervisor is responsible for training and performing skills assessments for all compounding personnel practicing at the pharmacy, I determined that attending a non-sterile compounding training course would enhance my skills and ability to oversee the assessment program. The course provided training on foundational compounding techniques, as well as education on developing master formulations and implementing standard operating procedures. The training was key to instilling confidence in my ability to properly ensure all compounding personnel at my pharmacy have the required knowledge, skills, and resources to competently perform non-sterile compounding procedures within the scope of our facility.

#### **DEVELOP MASTER FORMULATIONS**

Each non-sterile compound requires a master formulation, which includes all necessary information to compound the

preparation, as well as safety data sheets for each chemical used. The guidance document (Section 6), provides an outline of the information to be included in each master formulation, as well as a template.<sup>2</sup> The master formulation should be developed by pharmacy personnel with adequate experience and broad knowledge of non-sterile compounding - for example, the pharmacy's NSC supervisor. Any references used in the development of the master formulation should be clearly documented and easily retrievable.

#### MY FINAL THOUGHTS

There are many steps to take when implementing the new standards at one's practice site, as well as decisions to make regarding the level of compounding you feel confident in continuing to provide. Acknowledging some initial intimidation, my experience in this process taught me that a strong understanding of the standards, coupled with additional training, provided me with the confidence to enhance our compounding practices at our current and future pharmacy locations.

#### **REFERENCES:**

- 1. National Association of Pharmacy Regulatory Authorities (NAPRA). Model standards for pharmacy compounding of non-sterile preparations: Companion to the Model standards for pharmacy compounding of non-sterile preparations. Ottawa, ON: NAPRA; 2018 Mar.
- 2. National Association of Pharmacy Regulatory Authorities (NAPRA). Guidance document for pharmacy compounding of non-sterile preparations. Ottawa, ON: NAPRA; 2018 Mar.
- 3. NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings. Cincinatti, OH: U.S. Department of Health and Human Services, Centres for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161.
- 4. United States Pharmacopeial Convention (USP). General chapter <795>: pharmaceutical compounding nonsterile preparations. In: USP compounding compendium. Rockville, MD: USP; 2016.
- 5. Health Canada. Workplace Hazardous Materials Information System (WHMIS). Ottawa, ON: Health Canada; 2016.

# TIPS FOR EFFECTIVE COMMUNICATION

Between Pharmacists and Prescribers



Framing written information in a clear and concise way when communicating to prescribers is essential to the delivery of effective patient care. This responsibility falls under the "communication and education" domain observed during community practice assessments and is outlined in the NAPRA Standards of Practice for pharmacists.

Effective and efficient messages are an extension of the critical role played by pharmacists within the circle of care. In addition to conveying information relevant to patient care, they support continuity of treatment for the patient.

Instead of writing your communication by hand, consider typing it so that it is easy to read. Messages should be kept factual and brief, as prescribers may receive many messages each day.

#### IS THE COMMUNICATION REQUIRED?

Pause to consider the appropriateness of sending a message prior to preparing it. Consider the following questions:

- Can I adapt/renew this prescription on my own authority?
- Have I outlined the relevant details and provided all the information for the prescriber to make an informed decision?
- How will this message be perceived by the prescriber?
- Will the prescriber accept my input and inquiry or will he/she ask why the pharmacist isn't helping the patient?

A decision to adapt, initiate or renew a prescription can be made after conducting a therapeutic assessment if patient or agent consent is granted. A pharmacist must notify the prescriber within a reasonable time after initiating such an action. For more information, visit the Guideline: Initiating, Adapting and Renewing Prescriptions on the College website.

Pharmacists are periodically required to contact prescribers to manage drug interactions or suggest changes to therapy that could help ensure best possible patient outcomes. In such situations, describe the issue succinctly and accurately. Most prescribers deal with a high volume of patients and need to be apprised of the individual scenario when approached with drug-related inquiries. Don't assume they will recall the patient, their health information and prescribed therapy.

#### **PROVIDE OPTIONS**

Manage a drug-related problem by providing your therapeutic recommendations to the prescriber, including how to manage the situation. Present concrete solutions based on patient assessment and your professional judgment. For example, if a proposed antibiotic is not covered by insurance, suggest a therapeutic alternative based on the indication. Providing specific options in the initial communication reduces the chances of receiving responses that do not address the situation or are misunderstood, requiring additional time and effort to respond further.

Always endeavor to include a reference to the evidence that supports your recommendation(s). This can increase the prescriber's comfort level with this and future recommendations

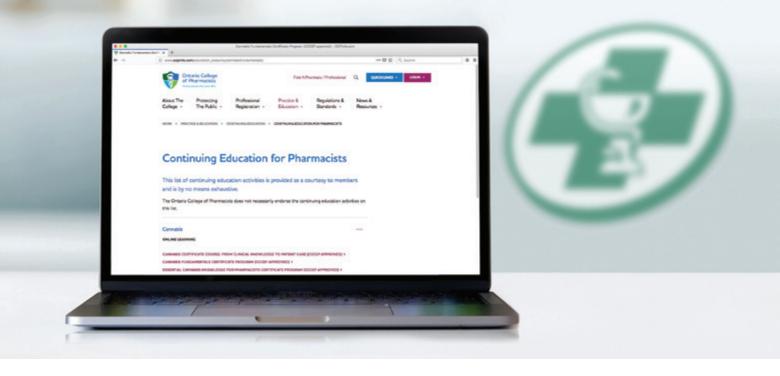
#### STREAMLINED APPROACHES

Some pharmacists have developed templates for prescriber memos to facilitate consistent and effective communication. This can foster positive, inter-professional team approaches to patient care.

There are now a number of e-prescribing solutions available to Ontario pharmacies. Their functionality may improve collaboration between pharmacists and prescribers while also eliminating the inefficiencies and paper generated by fax usage.

Take the time to proofread messages prior to sending. Be sure your message is free of spelling and grammatical errors and accurately captures your intention. If possible, have a colleague review the content. Before sending it, remember to include your name as the fax will only identify the pharmacy.

Effective written communication to prescribers is essential to providing appropriate and comprehensive patient care. Reducing the risks associated with unclear messaging promotes patient safety and quality care.



#### ADDITIONAL COLLEGE-APPROVED CANNABIS EDUCATION PROGRAMS FOR PHARMACISTS ARE NOW AVAILABLE

An approved cannabis education program must be completed by March 10, 2020

Additional cannabis education courses that meet the mandatory education requirements set by the College for Part A pharmacists have been approved.

Details of these courses are found on the <u>Continuing</u> <u>Education for Pharmacists</u> page of the College website (under Cannabis).

All programs must be accredited by the Canadian Council on Continuing Education in Pharmacy and meet the required competencies for Cannabis and Patient Care identified by the College's Cannabis Education Advisory Group. Additional cannabis education programs are in development and the College expects them to become available within the next few months.

During the 2020 pharmacist annual renewal process, Part A pharmacists must declare that they have completed a College-approved cannabis course. The deadline to declare is **March 10, 2020** (when annual renewal ends).

The College's <u>Cannabis Strategy for Pharmacy</u> was approved by Council on June 17, 2018. The strategy recognizes that the legalization of recreational

cannabis is an extraordinary public policy shift that has a significant impact on the health and safety of Canadians and increases the potential for more open use among the public and pharmacy patients. As medication experts, pharmacists are in a unique position to support quality and effective patient care for those who are using cannabis, for recreational or medical purposes, along with monitoring other medications that they may be taking. Recognizing the important role pharmacy professionals play in safe medication practices, and in consideration of the legalization of recreational cannabis, Council adopted the College's Cannabis Task Force recommendation in March 2018. It requires all pharmacists to complete cannabis education to support and promote quality and safe patient care for cannabis users.

The College's regulatory approach focuses on patient safety as society adapts to the new realities associated with legal cannabis use. It is not the College's role to advocate for distribution of cannabis for any purpose within pharmacies and OCP continues to remind all pharmacies and pharmacy professionals of the <a href="Legal frameworks">Legal frameworks</a> currently in place related to how cannabis for recreational or for medical purposes can be legally distributed.

# View the College's 2019 Regional Meeting Recording!



This past spring, the College hosted a series of Regional Meetings in communities across the province including one session that was webcast. A recording from the webcast session is now available on the <u>College's YouTube channel</u> for those who were unable to attend.

During the meeting, the College's executive team provided attendees with the latest updates on OCP's transformative approach to using data to inform regulatory programs and sector performance in order to achieve better patient outcomes. They also provided an update on several important key initiatives, including AIMS, Quality Indicators for Pharmacy, OCP's data strategy and more.

View the <u>full 2019 OCP Regional Meeting recording</u> now or view the following excerpts:

- The College's Direction
- The College's Data Strategy
- <u>AIMS Medication Safety Program</u>
- Quality Indicators for Pharmacy

#### **REMINDER:**

PART A PHARMACISTS AND PHARMACY TECHNICIANS:
PLEASE UPDATE YOUR DESIGNATED PRACTICE ASSESSMENT
SITE IF YOUR PRACTICE LOCATION CHANGES

For the purpose of your practice assessment, you are required to identify a place of practice in Ontario where you are providing patient care. Please update your Designated Practice Assessment (DPA) Site in OCP's Member Login Portal in a timely manner whenever this changes.

You are now able to login and change your DPA site at any time (previously you could only change this in the system upon renewal).

It's important to ensure this information is up-to-date as the College and practice advisors depend on the accuracy of this information to facilitate your practice assessment in the location where you provide patient care.



New regulations requiring hospital staff to report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) to Health Canada will take effect in December 2019.

Each event must be reported within 30 days of documentation at the institution where it occurred. The monitoring of therapeutic products plays an important role in public health and patient safety.

Reports of serious ADRs and MDIs help promote the safe use of health products by Canadians and may be the first sign of previously unrecognized rare or serious occurrences. Additionally, they help the Canadian government take action against products that may pose a risk to health and safety.

#### **WHAT TO REPORT**

The <u>mandatory reporting requirements</u> for hospitals apply to the following therapeutic products:

- prescription and non-prescription drugs
- medical devices
- disinfectants
- biologic drugs, such as:
  - o vaccines (except those administered under a routine immunization program of a province or territory)
  - o plasma proteins

- o biotechnology products
- o fractionated blood products
- radiopharmaceutical drugs
- drugs for an urgent public health need.

#### **NOT NECESSARY TO REPORT**

Hospitals are not required to report on:

- semen and ova
- cells, tissues and organs
- blood and blood components
- vaccines administered under a routine immunization program of a province or territory
- natural health products
- drugs and devices used under the <u>Special</u> <u>Access Program</u> for drugs, for clinical trials or <u>investigational testing</u> for medical devices.

When in doubt, Health Canada encourages hospitals to report. Further information on reporting an adverse reaction or medical device problem can be found on the Government of Canada website.



## **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 registrant what course of action to take, provide legal advice or opinions, or make any decisions for a registrant.

#### Does our pharmacy need to notify the College that we are dispensing methadone and/or buprenorphine/naloxone?

A The College's Opioid Policy specifies that pharmacists dispensing methadone for Opioid Agonist Treatment (OAT), also known as methadone maintenance treatment (MMT), must be in compliance with the Fact Sheet: Key Requirements for Methadone Maintenance Treatment (MMT) Dispensing, which states:

"Community pharmacies must inform the College within seven days of starting to dispense MMT and of any changes in this information, using the approved Methadone Dispensing Notification Form."

Notification is required to help the College fulfill its mandate to protect the public. All 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. A community pharmacy dispensing methadone will be evaluated according to the <u>operational assessment</u> <u>criteria</u> more often than a pharmacy which does not.

Pharmacies dispensing methadone as an opioid analgesic for pain or buprenorphine/naloxone are not required to notify the College.

• We have a patient who has been prescribed methadone for pain management. What do we need to have in place before we can dispense this prescription?

A The College's <u>Opioid Policy</u> sets out expectations for pharmacists dispensing all opioids, which includes methadone for pain or analgesia.

Pharmacists should adhere to the most recent clinical practice guidelines and the appropriate standards of practice to ensure best patient outcomes for individuals on opioid therapy. The Opioid Practice Tool provides easy access to numerous resources to support pharmacy professionals in safe opioid dispensing, including the 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain.

#### I have received a prescription for buprenorphine/naloxone. Can I dispense it, or do I need to have specific training first?

A Guidance from the College with respect to buprenorphine/naloxone dispensing for Opioid Agonist Treatment (OAT) can be found in the Opioid Policy. This includes practicing in accordance with <u>CAMH's</u> Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorder.

Additional resources are available in the Methadone and Buprenorphine Practice Tool and practitioners can access the CRISM National Guideline for the Clinical Management of Opioid Use Disorder via the Opioid Practice Tool.

Although the Opioid Policy does not mandate formal training as a prerequisite for dispensing buprenorphine/naloxone, the College lists Continuing Education opportunities on the OCP website as a tool to assist with professional development.

As with any medication, pharmacists are relied upon to ensure they have the necessary knowledge, skills and judgment to provide OAT in a safe and effective manner. Re



"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.

#### SUMMARY OF THE INCIDENT

Following a disagreement in the pharmacy about a non-pharmacy matter with a member of the public, the pharmacist locked the pharmacy door and left his pharmacy unattended with the member of the public and her son inside alone. No other staff were in the pharmacy at the time.

#### WHY DID THIS HAPPEN?

A member of the public, accompanied by her son, went to the pharmacy, which had a small postal outlet inside, to pick up a parcel. The pharmacist on duty was the only individual in the pharmacy at the time. The member of the public waited until she thought the pharmacist was free and then asked if the pharmacist could assist her with her parcel.

The pharmacist refused because he was not trained on the postal office's systems. The pharmacist reported that the customer began acting in an angry and rude manner towards him and that, as a result, he left the pharmacy, locking its doors with the customer and her son inside alone.

The pharmacist reported that the reason he left the pharmacy was because he was shaken about the escalating argument with the customer and worried that she would make a false claim against him to the police. Upon leaving, the pharmacist contacted the designated manager to report the incident.

The member of the public responded that "not once" was she told by the pharmacist that he was not trained on the postal office system and that he was unable to help her. The pharmacist disputed this claim.

#### **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

The panel in this case pointed out that, as specified in the Drug and Pharmacies Regulation Act (DPRA s.146), it was the pharmacist's responsibility to supervise the pharmacy at the time and, as such, he should not have left it unattended, particularly with members of the public inside. By leaving the pharmacy and the vast amount of medications inside unattended, he exposed the pharmacy and the public to great potential risk.

The panel observed that the pharmacist did not seem to recognize that his action was highly inappropriate and inconsistent with the expectations imposed on the practice of pharmacy. Further,

the pharmacist did not accept responsibility for his decision to leave the pharmacy or indicate how he would ensure that this would not occur again in the future.

While the panel recognized that the pharmacist was caught in a difficult situation which was escalated by a number of factors and acknowledged that it was not his role to assist with postal outlet matters, the panel felt that the pharmacist must endeavour to effectively manage aggressive people and difficult situations such as this. The panel held the belief that had the pharmacist communicated better at the outset of the incident, it may not have escalated to the degree that it did, and he may not have had to contemplate leaving the pharmacy.

In light of the above reasons, the panel issued the pharmacist Advice/Recommendations and required him to complete specified remediation. The remediation consisted of the requirement to complete the "Managing Conflict When People Are Angry" workshop by a local community agency and the College's Jurisprudence e-Learning modules and Jurisprudence exam.

The pharmacist appealed the panel's decision to the Health Professions Appeal and Review Board (HPARB). While the pharmacist did not take issue with the panel's order to complete

the workshop, he opposed the panel's decision to require him to complete the College's Jurisprudence e-Learning modules and Jurisprudence exam, stating it was unreasonable. HPARB upheld the panel's decision and full remediation, finding the investigation and remediation reasonable and appropriate given the situation.

It's important to emphasize that while the pharmacist had the right to refuse to help the postal customer with her parcel, and explain that he did not work at the outlet and was not trained on the post office's systems, he did not have the right to leave the pharmacy unattended. This, combined with the fact that the pharmacist did not acknowledge and take responsibility for his action, was a major reason for the Advice/Recommendations and remedial training presented by the panel.

#### LEARNINGS FOR PHARMACY **PROFESSIONALS**

The Standards of Practice state that pharmacists must adhere to applicable laws, regulations, and policies relating to pharmacy practice. Leaving the pharmacy unattended with members of the public inside is inconsistent with this standard and professional expectations.

As well, the Standards outline that pharmacists, regardless of the role they are fulfilling, use effective, non-verbal listening and written communication skills and demonstrate sensitivity, respect, and empathy when communicating with diverse groups.

In addition to failing to appreciate the Standards of Practice, the pharmacist in this case also did not follow multiple principles in the Code of Ethics, which describe a

healthcare professional's ethical duty to patients and society and to which all pharmacists and pharmacy technicians subscribe. The Code outlines how a practitioner is expected to fulfill their ethical responsibilities as they practice pharmacy in the province.

Irrespective of the role they find themselves in, the principle of Accountability (Fidelity) states that pharmacists are required to demonstrate professionalism and accept responsibility for their actions and decisions. This principle also outlines that pharmacists must promise to be responsible fiduciaries of the public trust and invariably act in the public's best interests and not their own.

The panel felt that the pharmacist did not understand why his actions, which were not in the best interests of the public, were inappropriate, namely his decision to lock the pharmacy doors with members of the public still inside and leave, and did not take responsibility for that decision, violating the principle of Accountability (Fidelity).

As well, the principle of Non Maleficence refers to pharmacists' obligation to refrain from behaviours which would potentially result in harm and utilize their professional judgment to make every reasonable and conscientious effort to prevent harm to patients and society. By leaving the pharmacy unattended and exposing the pharmacy and public to potential risk, this ethical principle was also not respected.

As a best practice, the College recommends that pharmacy professionals actively seek out ways to improve their communication techniques with patients. There are many resources available to help learn and improve upon effective communication skills, such as the College's Communication and Education Practice Tool. Simple communication and de-escalation techniques can go a long way in helping diffuse and rectify potentially difficult situations and clear up possible misunderstandings.

#### 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

#### ADVICE/ RECOMMENDATIONS

Advice/recommendations allow an opportunity for pharmacy professionals to improve conduct or care.

Advice/recommendations are issued as a remedial measure for matters which are not serious in nature and are considered to pose low risk of harm to the public.

# Have You Checked Out the Latest PHARMACY5IN5 Modules?



<u>Pharmacy 5in5</u> is an interactive learning platform developed by the University of Waterloo School of Pharmacy that helps pharmacy professionals self-audit their knowledge and acquire a deeper understanding of a variety of clinical and professional topics. It also provides valuable educational resources that can be saved, printed out and referenced over time.

We first made you aware of Pharmacy5in5 in the Winter 2018 issue of Pharmacy Connection. Recognizing the time pressures faced by many pharmacy professionals, the platform lets you test your knowledge on a given topic by taking a short quiz and answering just five questions in five minutes.

#### BELOW ARE SOME OF THE LATEST PHARMACY5IN5 MODULES:

#### **NARCOTIC INVENTORY**

Be more proactive about the ways you reconcile controlled substances (narcotics, controlled drugs and targeted substances). Get practical tips for effectively reconciling your inventory and conducting an investigation when things don't add up.

The module includes the video "How Should Pharmacies Protect Their Narcotic Inventory," a handy infographic about narcotic inventories and a variety of other helpful resources.

#### **HYPERTENSION**

Learn how to individualize blood pressure goals according to patient-specific factors. Other topics include: choosing a first line antihypertensive drug, educating patients about home blood pressure monitoring and developing a monitoring plan for a patient taking an antihypertensive drug. Also, learn how to identify appropriate antihypertensive therapy for a patient not meeting their blood pressure goals.

Get access to printable flashcards, infographics and the video "5 Things Healthcare Professionals Should Know About Hypertension." Plus, help a pharmacist choose hypertension medication for a patient and optimize drug therapy.

#### **DRUG INDUCED KIDNEY INJURY**

This module makes it easy for you to test and improve your knowledge with classifying different types of drug-induced kidney injury (DIKI), identifying patient and drug-related risk factors for DIKI, recognizing the signs and symptoms of a DIKI, educating a patient on prevention measures, and more.

You can also watch the video "5 Things Healthcare Professionals Should Know about Drug Induced Kidney Injuries," quiz your knowledge on DIKI basic facts and assist a pharmacist conducting a DIKI medication review.

#### NON-STERILE COMPOUNDING

Review the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations. All pharmacies in Ontario that perform or intend to perform any type of non-sterile compounding must adhere to the College's timelines for implementation of the NAPRA standards. For this reason, the College recommends all pharmacy professionals supplement their learning by completing this Pharmacy5in5 module.

By the end of the module, you should be able to determine when it's appropriate to compound a preparation and verify that a preparation has been compounded correctly. Other topics covered include assessing a prescription for a non-sterile compound to determine its suitability for a specific patient and the responsibilities of the designated compounding supervisor.

View the video "5 Things Pharmacy Professionals Should Know About Non-Sterile Compounding," print out a useful infographic on who can check non-sterile compounds, get a "Should You Compound This Drug?" flowchart, and quiz your proficiency on managing non-sterile compounding, assessing risk, planning for workflow and more.

VISIT PHARMACY5IN5 TODAY!

# PRACTICE TOOLS UPDATE FORGERY AND FRAUDULENT PRESCRIPTION FACT SHEETS

<u>Fact sheets</u> are resources that are found on the College's website and are intended to remind pharmacy professionals of certain aspects of practice, such as obligations under provincial and federal legislation. Two OCP fact sheets have been updated to support pharmacy professionals in identifying, managing and reporting the diversion of controlled substances through forgery.

The fact sheets have been revised to reflect that the information therein applies to all controlled substances, which are drugs listed in Schedules in the federal <u>Controlled Drugs and Substances Act</u>, and includes narcotics, controlled drugs, benzodiazepines and other targeted substances.

The Fact Sheet — Narcotic Reporting of Forgeries and Losses is now the Fact Sheet — Forgery:

Management and Reporting of Fraudulent

Prescriptions. It contains information to assist pharmacists and pharmacy technicians in complying with legislative requirements and summarizes the steps to take in the event of a forgery.

The information related to reporting of losses (such as theft) of controlled substances can be found in the Fact Sheet — Narcotic Reconciliation and Security and in the Health Canada Guidance Document:

Reporting of loss or theft of controlled substances, precursors and cannabis.

The Fact Sheet — Identifying Forgeries and Fraudulent Prescriptions is now the <u>Fact Sheet</u> — Forgery: Tips for Identifying Fraudulent

Prescriptions. The suggestions and best practices have been reviewed and updated where appropriate, and are intended to assist pharmacy professionals with detecting fraudulent prescriptions by assessing the patient and the prescription. The section on steps to take if a forgery has been identified can now be found in the <u>Fact Sheet</u> — <u>Management and Reporting of Fraudulent Prescriptions</u>.

These fact sheets, along with other helpful resources, can be found in the <u>Narcotics Practice Tool</u> on the OCP website.

As a reminder, all pharmacies in Ontario receive Prescription Forgery Alert emails from the Ministry of Health's Drug Programs Delivery branch via the Health Network System's ONE® Mail email service. Please be sure to look out for these notices and check them on a regular basis to stay informed.

#### LEGISLATION GOVERNING CONTROLLED SUBSTANCES: A VISUAL OVERVIEW

Federal Legislation for Controlled Substances **Controlled Drugs** Food and Drugs and Substances Act (FDA) Act (CDSA) Food and Benzodiaze-Narcotic Drug pines & other Regulations. Control Targeted Regulations Part G: Substances (NCR) Controlled Regulations Drugs

For complete information, including specific drug schedules, please refer to the legislation itself.

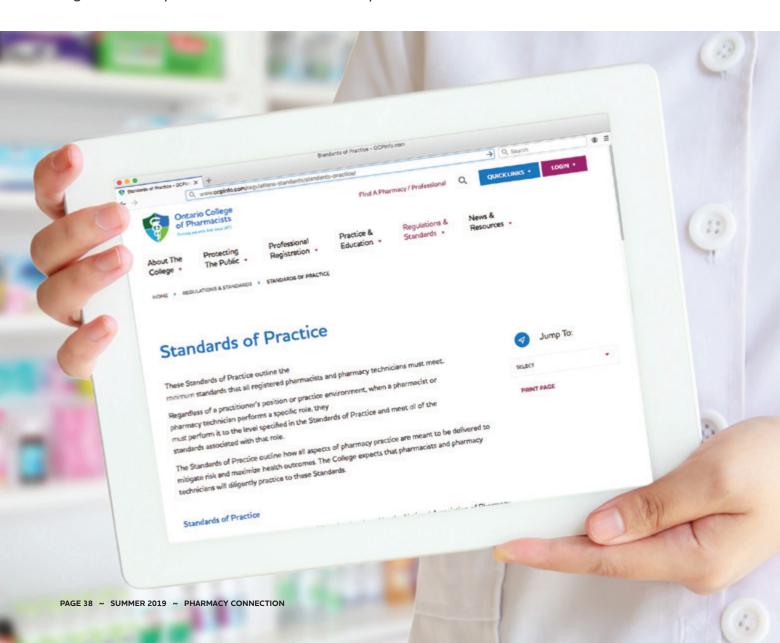
#### **ADDITIONAL RESOURCES:**

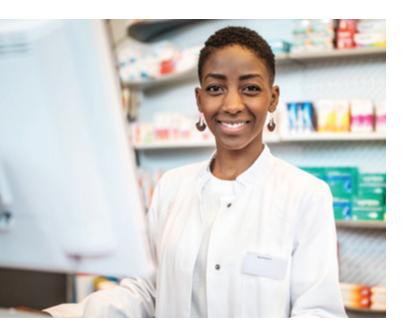
- Prescription Regulation Summary Chart (Summary of Laws)
- •Controlled Drugs and Substances Act (CDSA) and Narcotics Safety and Awareness Act (NSAA) Module

## WHERE DO I GO FOR

## Information Regarding Pharmacy Accreditation and Registrant Certifications?

The Ontario College of Pharmacists regulates both pharmacies and registrants. There are <u>provincial and federal</u> pieces of legislation, accompanying acts, regulations and <u>College By-Laws</u> along with the <u>Standards of Operations</u> and <u>Standards of Practice</u> that affect the issuance and renewal of certificates of accreditation for pharmacies and certificates of registration for registrants. The College ensures only those applicants who have met the registration requirements are authorized to practice in Ontario.





The College website is the primary resource for information surrounding the responsibilities of issuing and maintaining certificates of accreditation and registration. College staff in Pharmacy Applications & Renewals (PAR) and Member Applications & Renewals (MAR) are available to assist if necessary.

The following FAQs outline what to expect when consulting these resources:

#### PHARMACY APPLICATIONS & RENEWALS (PAR)

#### **CAN YOU EXPLAIN WHAT PAR DOES?**

PAR provides front-line customer service to pharmacy applicants, operators and third party providers. It assesses applications to determine eligibility/suitability, and creates and maintains records (dispensing fees, hours of operation and personnel) for community and hospital pharmacies as well as pharmacy Health Profession Corporations. It also responds to gueries about pharmacy accreditation and annual renewals.

#### WHERE CAN I GET INFORMATION **ABOUT PHARMACY TRANSACTIONS?**

Information on Health Profession Corporations as well as community and hospital pharmacies is found on the College website under Practice & Education. Each section contains specific information about fees, forms, processes, timelines and relevant legislation, regulations and bylaws. It is important to familiarize yourself with the College website content and formulate specific questions before contacting PAR.

Representatives are available to help clarify information about processes; however, they will not provide legal interpretations. Independent counsel should be used for all legal advice.

#### WHAT IS THE BEST WAY TO REACH A PAR REPRESENTATIVE?

For PAR representatives, email pharmacyapplications@ ocpinfo.com at any time or call the College at 416-962-4861 ext. 3600 during regular business hours.

#### **MEMBER APPLICATIONS** & RENEWALS (MAR)

#### **CAN YOU EXPLAIN WHAT MAR DOES?**

MAR provides support and information regarding requirements and processes for obtaining and maintaining a certificate of registration.

#### WHERE CAN I FIND THE MOST **UP-TO-DATE INFORMATION** PERTAINING TO MY CERTIFICATE OF REGISTRATION APPLICATION?

To access current information on the status of your application for a certificate of registration, including all validated requirements and outstanding requirements, log on to the online services portal. Registrants and applicants should refer to the College website for further information, including details on requirements, fees and timelines, and supporting documentation.

#### WHAT IS THE BEST WAY TO REACH A MAR REPRESENTATIVE?

To reach a MAR representative, email memberapplications@ocpinfo.com at any time or call the College at 416-962-4861 ext. 3400 during regular business hours.

Phone calls and emails are answered in the order they are received regardless of the communication method. However, communicating by email facilitates the ability to receive links to helpful resources. Our representatives strive for a high level of service with the goal of providing timely responses to all inquiries. Please allow up to three business days for a reply before following up. Multiple points of contact are discouraged as this creates inefficiencies and prolongs response times to inquiries.



# FOCUS ON ERROR PREVENTION

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

Pharmacists and pharmacy technicians are often under pressure to process prescriptions and dispense medications quickly and efficiently.

The use of technology is one strategy employed to achieve these operational efficiencies. Many pharmacy computer software products permit the autopopulation of fields during computer entry in an effort to save time. For example, upon entering the name of a drug into the computer, the system auto-populates the common directions for its use.

Since the directions for use of a drug can vary by patient and indication, the auto-populated usage instructions are often incorrect. It is therefore critical that all pharmacy staff carefully review all auto-populated fields during computer entry before accepting it as correct.

#### CASE:

Rx: Metformin 500mg tablets Sig: One tablet twice daily Mitte: Three months A 60-year-old patient was given this prescription which was taken to a local community pharmacy for processing. A member of the pharmacy team took the prescription from the patient and began to enter the necessary information into the computer.

Upon entering the name of the drug (metformin) into the computer, the system auto-populated the directions for use as "two tablets twice daily." Both the staff member who entered the prescription and the dispensing pharmacist who checked the entry missed the computer entry error. The incorrect quantity of metformin tablets with the incorrect directions for use was therefore prepared and dispensed to the patient.

After arriving home, the patient read the directions on the prescription label and thought that it was different to what her physician had stated. She contacted the pharmacy for clarification. Upon investigation, the error was discovered.

#### **POSSIBLE CONTRIBUTING FACTORS:**

- The auto-population of key information (especially directions for use) by many computer software systems.
- The directions to take two metformin 500mg tablets twice daily is often seen in pharmacy practice. Hence, both the pharmacy staff member and dispensing pharmacist "saw" what they knew and not what was actually written on the prescription. An example of "confirmation bias."
- Patient counselling did not take place. The staff member who gave the medication to the patient likely assumed that the medication had been taken previously.

#### **RECOMMENDATIONS:**

- Be aware of the potential for error due to the auto-population of key information by the computer software. All pharmacy staff must be made aware of this issue.
- Be aware that the potential for error also exists when information is copied from one prescription to the next for a specific drug. Key prescribed changes including changes in drug strength and directions for use can be missed.

- The patient's medication history should always be consulted to identify previous drug use and to assist in the identification of potential errors.
- Before a specific drug is dispensed, consider all aspects of the prescription for appropriateness.
   Factors to be considered include the patient parameters, medication history, indication for use, the dose, dosing interval, duration of therapy, etc. In the above case, the patient had never previously taken metformin. Consider whether 1000mg metformin twice daily is an appropriate starting dose.
- New drug therapy should always be flagged to ensure the patient receives appropriate counselling. In these instances, the patient should never be asked if they would like to speak to the pharmacist. Instead, the patient should be informed that the pharmacist needs to discuss aspects of the drug therapy with him/her. This is a key and often last opportunity to detect potential errors.

Please continue to send reports of medication errors in confidence to lan Stewart at: <a href="mailto:ian.stewart2@rogers.com">ian.stewart2@rogers.com</a>. Please ensure that all identifying information (e.g. patient name, pharmacy name, healthcare provider name) are removed before submitting.













# Niagara Apothecary

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### The College has moved Discipline Decisions online to <u>pharmacyconnection.ca</u>.

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 SUMMER 2019 DECISIONS:**

Shohreh Torabi (OCP #204608)

Rita Jurkuvenas (OCP #52086)

Sameh Sadek (OCP #610938)

Yale Pan (OCP #201472)

Ashit Shihora (OCP #109452)

Diep Nguyen (OCP #98949)

The full text of these decisions is available at <a href="www.canlii.org">www.canlii.org</a>.
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